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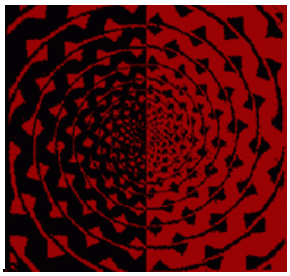

Study for the implementation in Belgium of the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity

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Final report

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LIST OF ABBREVIATIONS

ABS	Access and Benefit-sharing
ABS CH	ABS Clearing-House
ABSWG	Ad Hoc Open-ended Working Group on Access and Benefit-sharing
ANB	Flemish Agency for Nature and Forest
AWEX	Agence wallonne à l'Exportation et aux Investissements étrangers
BAP	EU Biodiversity Action Plan
BCCM	Belgian Co-ordinated Collections of Micro-organisms
BCH	Biosafety Clearing-House
BELSPO	Belgian Federal Science Policy Office
BEW/AEE	Economy and employment administration of the Brussels-Capital Region
BS	Benefit-sharing
BTC	Belgian Technical Cooperation
CAP	Common Agricultural Policy
CBD	Convention on Biological Diversity
CCIEP	Coordinating Committee for International Environment Policy
CFDD	Conseil Fédéral du Développement Durable
CHM	Clearing-House Mechanism to the CBD
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CNA	Competent National Authority
COP	Conference of the Parties
COP/MOP	Conference of the Parties serving as the Meeting of the Parties
DIE-OPRI	Dienst voor Intellectueel Eigendom/Office belge de la Propriété intellectuelle
DG	Directorate-General
DG4	DG Animal, Plant and Food of the FPS Health, Food Chain Safety and Environment
DG5	DG Environment of the FPS Health, Food Chain Safety and Environment
DGARNE	Wallonia's Operational Directorate-General for Agriculture, Natural Resources and the Environment
DGD/DGOS	DG Development Cooperation of the FPS Foreign Affairs, Foreign Trade and Development Co-operation
DGO6	Wallonia's Operational Directorate-General for Economy, Employment and Research
E3	DG Market Regulation and Organization of the FPS Economy, SMEs, Middle Classes and Energy
E4	DG Economic Potential of the FPS Economy, SMEs, Middle Classes and Energy
EC	European Commission
EP	European Parliament
EU	European Union
EWI	Department Economie, Wetenschap en Innovatie of the Flemish government
FLEGT	Forest Law Enforcement Governance and Trade
FIT	Flanders Investment and Trade
FPS	Federal Public Service
GEF	Global Environment Facility
GMO	Genetically Modified Organism
GI	Geographical Indications
GR	Genetic Resources
IA	Impact Assessment
ILCs	Indigenous and Local Communities
ILO	International Labour Organization

INBO	Instituut voor natuur - en bosonderzoek
IPEN	International Plant Exchange Network
IPR	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
ICE	Interministerial Conference on Environment
IUCN	International Union for Conservation of Nature
LNE	Department Leefmilieu, Natuur en Energie of the Flemish government
MAT	Mutually Agreed Terms
MOP	Meeting of the Parties
MOSAICC	Micro-organisms Sustainable Use and Access Regulation International Code of Conduct
MS	Member State
MTA	Material Transfer Agreement
NBGB	National Botanic Garden of Belgium
NFP	National Focal Point
NP	Nagoya Protocol
OECD	Organization for Economic Co-operation and Development
PDO	Protected Designation of Origin
PGI	Protected Geographical Indication
PIC	Prior Informed Consent
PROMETHEE	Preference Ranking Organization Method for Enrichment of Evaluations
R&D	Research and Development
RBINS	Royal Belgian Institute of Natural Sciences
REIO	Regional Economic Integration Organization
RMCA	Royal Museum for Central Africa
SL	Special Law
SMTA	Standard Material Transfer Agreement
TFEU	Treaty on the Functioning of the European Union
TK	Traditional Knowledge
TKaGR	Traditional Knowledge associated with genetic resources
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TSG	Traditional Speciality Guaranteed
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNCLOS	United Nations Convention on the Law of the Sea
UNEP	United Nations Environment Program
VAIS	Vlaams Agentschap voor Internationale Samenwerking
WBI	Wallonie-Bruxelles International
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
WSSD	World Summit on Sustainable Development

EXECUTIVE SUMMARY

General recommendations

- **Both Prior Informed Consent and benefit-sharing should be implemented** as general legal principles in Belgium.
- **A phased approach should be adopted** for the implementation of the Nagoya Protocol, allowing to benefit from the implementation of the basic principles in a timely manner and to deal with more fine-grained choices at a later stage.

Specific recommendations

- Alongside the designation of Competent National Authorities (CNAs), **a centralized input system to the CNAs should be established**.
- With regard to compliance measures, sanctions should be provided for cases of non-compliance with PIC and MAT requirements set out by the provider country. When checking content of MAT, **a provision in the code of international private law should provide for reference to provider country legislation**, with Belgian law as a fallback option.
- At this stage of the implementation, **the monitoring of the utilization of genetic resources and traditional knowledge by a checkpoint should be done on the basis of the PIC available in the ABS Clearing-House**.
- With regard to access to Belgian genetic resources, it is recommended to **refine the existing legislation relevant for protected areas and protected species**, combined with a general **notification requirement for access to other genetic resources**. Later stages of implementation can then include refinement of additional relevant legislation as well as having *ex-situ* collections process the other access requests.
- At this stage of the implementation, and apart from the general obligation to share benefits, **no specific benefit-sharing requirements** should be imposed for the Mutually Agreed Terms. A combination of more specific requirements, including the possibility to use standard agreements, can be considered in a later stage of the implementation.
- **The Royal Belgian Institute of Natural Sciences should be mandated to fulfill the information sharing tasks on Access and Benefit Sharing** under the Nagoya Protocol, through the ABS Clearing-House.

This study aims to contribute to the ratification and the implementation in Belgium of the Nagoya Protocol on Access and Benefit-sharing (ABS), thereby contributing to the conservation of biological diversity and the sustainable use of its components. This is in support of the overall goal to implement the Convention on Biological Diversity (CBD) since the 2010 Nagoya Protocol on Access to

Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is a protocol to the CBD.

The CBD is the main international framework for the protection of biodiversity. It has three objectives: (1) the conservation of biological diversity, (2) the sustainable use of its components and (3) the fair and equitable sharing of benefits arising from the utilization of genetic resources. The Nagoya Protocol therefore delineates the means of implementation of the third objective of the CBD.

ABS potentially encompasses a large range of issues extending far beyond sole environmental matters, including market regulation and access, international trade, agriculture, health, development cooperation, research & development and innovation. As a consequence, the future implementation of the Nagoya Protocol could be relevant to several departments and several levels of competence in Belgium.

Access and Benefit-sharing (ABS) in Belgium

Following successive transfers of competences since 1970, the federated entities have the greatest responsibility in ABS-related issues, including environmental policy, agricultural policy, research and development, and economic and industrial policy. However, within these matters, the Federal Government possesses reserved and residual competences, with relevant examples including, among others, the export, import and transit of non-indigenous plant varieties and animal species, industrial and intellectual property, and scientific research that is necessary to the execution of its own competences. The large range of issues also implies an extended administrative distribution of ABS-related competences within each power level. The implementation of the Nagoya Protocol, as a "double mixed treaty"[1], will thus necessitate competences from both the federal and federate entities and require extensive inter- and intra-departmental coordination.

Access to genetic resources, as understood in the Nagoya Protocol, is not as such yet regulated by Belgian public law measures. Nevertheless, existing public and private law provisions already regulate related matters such as property rights, physical access to (genetic material in) protected areas and protected species, or modification and transformation of natural environments. Several of these existing provisions could be used as a basis for the implementation of the Nagoya Protocol in Belgium.

In order to fully understand the usefulness of these existing measures, four important preliminary remarks need to be made. First, throughout this study, access and utilization of genetic resources and traditional knowledge are analyzed within the framework of the Nagoya Protocol. The Protocol covers genetic resources and traditional knowledge that are provided by Parties from where such resources originate or by Parties that have acquired them in accordance with the Convention on Biological Diversity. Hence, this report covers:

- genetic resources possessed by a country in *in-situ* conditions and on which that country holds sovereign rights ; and

[1] The Nagoya Protocol has been declared a “double mixed treaty" by the Working Group on Mixed Treaties on 22/11/2010. This means that the federal State, the Regions and the Communities need to give their consent in order for Belgium to be able to ratify.

- genetic resources possessed by a country in *ex-situ* collections and which have been acquired after the entry into force of the Nagoya Protocol and / or in accordance with the obligations of the Convention on Biological Diversity.

Second, the CBD distinguishes "genetic material" (*i.e.* any material of plant, animal, microbial or other origin containing functional units of heredity) from "genetic resources" (*i.e.* genetic material of actual or potential value).

Third, a distinction has to be made between the question of legal ownership of genetic resources in their quality of material goods on the one hand, and the regulation of the access and utilization of genetic resources according to the Nagoya Protocol as an exercise of a sovereign right, on the other. The Belgian State holds sovereign rights over its genetic resources and can thus regulate the utilization of these resources by public law measures, as long as these are justified. However, physical access to and use of genetic material are already regulated by property law and the liability and redress options made available under both civil and criminal procedures related to the enforcement of property rights.

Fourth, it is important to remember that while genetic resources can be seen as biophysical entities (*e.g.* a plant specimen, a microbial strain, an animal, etc.), they also include an "informational component" (*i.e.* the genetic code). Access to genetic resources therefore relates both to the physical component and/or the informational component.

Taking the above into account, currently available national provisions relevant for the legal status of genetic resources in Belgium mainly relate to the question of legal ownership over genetic material. Flowing from the central tenets of the right to property found in the civil code, the conditions and rules surrounding the legal ownership of the genetic material, as a biophysical entity, follow from those governing the ownership of the organism this material can be found in. Property over an organism means that the proprietor possesses the rights to use, perceive the benefits and alienate the specimen. Furthermore, any legal measure regulating access to genetic resources could benefit from building upon existing legislation on physical access to and use of genetic material. The rules regulating physical access and use of genetic material depend upon the type of ownership (movable, immovable or *res nullius*), the existence of restrictions to the ownership such as specific protection (protected species, protected areas, forests or marine environments) and the location (all four Authorities apply their own rules) of the genetic material.

As opposed to its physical components, the informational components regarding the genetic resources may constitute a *res communis*: "things owned by no one and subject to use by all". While access to such informational components is not covered by subject-specific legislation, the exercise of some use rights can however be limited through intellectual property rights that have been recognized on portions, functions, or uses of biological material resulting from innovations on these materials. These intellectual property rights can take the form of patents, plant variety rights or geographical indications.

Alongside these principles surrounding the legal status of genetic resources, a number of rules found in civil, criminal and private international law, offer prospects of liability and redress in cases where an illicit acquisition of genetic resources is established. Their application is different with regard to

genetic resources as physical specimens or as informational goods, but also with regard to where the illicit acquisition has taken place.

Finally, there are no contemporary legal provisions in Belgium explicitly governing the concepts of "traditional knowledge", "traditional knowledge associated with genetic resources" and "indigenous and local communities". However, concerns over traditional knowledge and the rights of indigenous and local communities have been addressed in some international instruments to which Belgium is a Party, such as the 1957 International Labor Organization (ILO) Convention No. 107 on Indigenous and Tribal Populations, the ILO Convention No. 169 on Indigenous and Tribal Peoples, and the United Nations Declaration on the Rights of Indigenous Peoples.

Preliminary recommendations for the options for the implementation of the Nagoya Protocol

While the Nagoya Protocol is a recent protocol, it is nonetheless the further implementation of the third objective of the CBD which contains basic principles and ABS related provisions, such as the sovereignty of States over their natural wealth and resources, the fair and equitable sharing of benefits, and the importance of indigenous and local communities and their traditional knowledge. Many Parties to the CBD throughout the world therefore have implemented a series of measures on ABS, which can serve as useful first-hand experience for the implementation of the Nagoya Protocol. Through these experiences, two sets of preliminary recommendations were established in this study, with regard to the available options for the implementation of the Nagoya Protocol in Belgium. The first set of recommendations relates to instruments required for the implementation of the core obligations emanating from the Protocol[2]. The second set of recommendations relates to additional measures which are important elements to be taken into account during the implementation of the obligations, but which go beyond the core obligations.

With regard to the core obligations, the following is recommended:

- **Clarify access conditions**: By holding sovereign rights over its genetic resources, Belgium can choose whether or not to require users to obtain Prior Informed Consent through the competent authority for access to genetic resources under its jurisdictibon.
- **Determine the format of the Mutually Agreed Terms**: Once the Nagoya Protocol enters into force in Belgium, users operating on its territory will be required to share benefits arising from the utilization of genetic resources. Such sharing shall be based upon MAT. However, the Nagoya Protocol does not impose a specific format for MAT, which can be left to the discretion of stakeholders or flow from guidelines and/or mandatory measures imposed by the State.
- **Ensure ABS serves conservation and sustainable use of biodiversity**: It should be made sure that the implementation of the Nagoya Protocol supports the other two objectives of the CBD: conservation of biodiversity and sustainable use of its components. This can be done,

[2] The core obligations are the obligations specified in the terms of reference of this study as requiring special attention: Access to genetic resources and traditional knowledge; Benefit-sharing; the National Competent Authorities and the National Focal Points; Conformity with the national legislation of the provider country and the contractual rules; and compliance and monitoring.

for instance, by linking PIC to mandatory conditions on the sharing of the benefits or by establishing a "benefit-sharing" fund which redirects the benefits towards conservation and sustainable use of biodiversity.

- **Facilitate access for biodiversity-related research:** In order to foster biodiversity-related research and avoiding putting too much burden on non-commercial research utilizing genetic resources, measures could be developed to facilitate access to genetic resources for non-commercial biodiversity-related research.
- **Establish a Competent National Authority:** Each Party has to designate a Competent National Authority that grants access, issues written evidence that access requirements have been met and advises users on applicable procedures and requirements to get access to genetic resources. Given the institutional reality in Belgium, more than one CNA can be established. It should be noted that this task is of the highest priority, as Belgium needs to notify the CBD Secretariat of the contact information of its Competent National Authority/Authorities (and of its national focal point, which is already appointed) no later than the date of entry into force of the Protocol.
- **Give binding effect to the domestic legislation of provider countries regarding PIC and MAT:** As part of the implementation of the Protocol, the basic obligations domestic users have to comply with when utilizing genetic resources in Belgium will have to be laid out. This obligation comes down to giving binding effect to the provider country's PIC and MAT. This could be done by establishing an obligation in the Belgian legislation to comply with the provider country legislation regarding PIC and MAT, or by establishing a self-standing obligation in the Belgian legislation to have PIC and MAT if so required by the provider country.
- **Designate checkpoint(s) for the monitoring of the utilization of genetic resources:** In order to comply with the Nagoya Protocol, at least one institution has to be designated to function as a checkpoint which monitors and enhances transparency about the utilization of GR. This can be a new or existing institution.

With regard to additional measures, the following issues are to be taken under consideration: a) specifying benefit-sharing requirements for the MAT; b) establishing a clear and transparent access procedure; c) clarifying additional rights and duties of the Competent National Authorities; d) establishing a monitoring system; e) creating incentives for users to comply; and f) encouraging the development of model clauses, codes of conducts and guidelines.

Selected options for the implementation of the Nagoya Protocol

In light of the preliminary recommendations for the options for the implementation of the Nagoya Protocol described above, six measures, each including several policy-options, were discussed at the first stakeholder meeting on the 29th of May 2012[3]. Based on the results of that meeting, they were selected by the Steering Committee of this study for an in-depth analysis of environmental, social, economic and procedural impacts.

[3] Report of the stakeholder meeting is available here: http://www.biodiv.be/implementation/cross-cutting-issues/abs/workshop-np-20120529/20120529-nagoya-stakeholder-workshopreport-final.pdf

Prior to implementing these measures, it should be decided whether to establish both Prior Informed Consent and benefit-sharing as general legal principles in Belgium. While the latter is necessary to comply with the Nagoya Protocol, the former flows from the sovereign rights Belgium holds over its genetic resources and is not necessary for compliance. If Prior Informed Consent is established as a general principle, a procedure needs to be established for access to Belgium's own genetic resources (**measure 1**). This can be done by modifying existing legislation, by relying upon qualified *ex-situ* collections, by requiring prior registration or by a combination of these instruments.

Measure 1: operationalizing access to genetic resources

0. **Option 0** – No PIC
   No requirement of Prior Informed Consent for the utilization of genetic resources and traditional knowledge in Belgium;
1. **Option 1** – The bottleneck model
   a. For protected genetic resources: access is made possible through a refinement of existing legislation relevant for protected areas and protected species;
   b. For unprotected genetic resources: access is provided for through the Belgian *ex-situ* collections.
2. **Option 2** – The baseline fishing net model
   a. For protected genetic resources: access is made possible through a refinement of existing legislation relevant for protected areas and protected species;
   b. For unprotected genetic resources: access is accorded upon notification to the competent authority.
3. **Option 3** – Modified fishing net model
   a. For protected genetic resources and genetic resources already covered by specific GR-relevant legislation: access is made possible through a refinement of existing legislation;
   b. For unprotected genetic resources: access is accorded upon notification to the competent authority.

If benefit-sharing is established as a general principle, the conditions for the specific benefit-sharing requirements through the Mutually Agreed Terms, need to be clarified (**measure 2**). The specific benefit sharing requirements can be left to the discretion of users and providers (option 1), or be imposed by the state with more or less standardization (options 2 and 3).

Measure 2: specifying the benefit-sharing requirements for Mutually Agreed Terms

0. **Option 0**: No requirement of benefit-sharing for the utilization of genetic resources and traditional knowledge in Belgium;
1. **Option 1**: No specific benefit-sharing requirements are imposed by the competent authorities for the MAT. Users and providers are free to decide jointly on the content.
2. **Option 2**: Specific benefit-sharing requirements are imposed, including through standard formats for the MAT for certain uses, which are differentiated depending on the finality of access.

3. **Option 3**: Specific benefit-sharing requirements are imposed but without standard formats for the MAT. While taking into account the benefit-sharing requirements, the MAT are tailored on a case-by-case basis by the users and providers. The benefit-sharing requirements are differentiated depending on the finality of access.

In order to comply with the Nagoya Protocol, one or several competent national authorities will need to be established (**measure 3**). Their task is to grant access, to issue written evidence that access requirements have been met and to advise users on applicable procedures and requirements to get access to genetic resources. To fulfill these tasks, the competent national authorities will need to establish entry-points for users of genetic resources. This can be done separately, with each authority having its own entry-point (option 1), or jointly, with a single entry-point for the different authorities (option 2).

Measure 3: establishing one or more competent national authorities

0. **Option 0**: No competent national authority/authorities are established in Belgium;
1. **Option 1**: Competent authorities are established, with a separate entry-point for each authority;
2. **Option 2**: Competent authorities are established, with a single entry-point.

Once the Nagoya Protocol enters into force in Belgium, it will need to set up compliance measures to make sure that genetic resources and traditional knowledge utilized on its territory have been accessed in accordance with the law of the provider country (**measure 4**). This can be achieved by referring back to the legislation of the provider country in question and opening review of the content of MAT in accordance with provider country legislation with Belgian law as a fall-back option (option 1), or by setting-up a self-standing obligation under Belgian law (option 2). In the latter option, Belgian legislation would only refer to the specific obligation of requiring PIC and MAT by the provider country without referring to the actual ABS legislation of the provider country.

Measure 4: setting-up compliance measures

0. **Option 0**: No legal provisions on compliance with the Nagoya Protocol are introduced under Belgian law
1. **Option 1**: A general criminal provision is created that refers back to the legislation regarding PIC and MAT of the provider country. The state enacts a general prohibition to utilize genetic resources and traditional knowledge accessed in violation of the law of the providing country. Review of the content of MAT by judges is subject to provider country legislation, with Belgian law as a fall-back option.
2. **Option 2**: A provision is created containing an obligation to have PIC and MAT from the provider country for the utilization in Belgium of foreign genetic resources, if this is required by the legislation of the provider country.

In order to comply with the Nagoya Protocol, at least one checkpoint needs to be created to monitor the utilization of genetic resources and traditional knowledge in Belgium (**measure 5**). If Belgium

decides to introduce checkpoints, their implementation could take place in several phases. In order to respect the political commitment for a timely ratification of the Nagoya Protocol, the first phase could look at a minimal implementation requiring the establishment of a single checkpoint. Two possible options seem relevant for the first phase, namely monitoring the PIC obtained by users, which is available in the ABS Clearing-House (option 1) and to upgrade the existing patent disclosure obligation (option 2). As options 1 and 2 are not mutually exclusive, a joint implementation could be envisaged.

Measure 5: designating one or more checkpoints

0. **Option 0**: no checkpoints are established in Belgium to monitor the utilization of genetic resources and traditional knowledge
1. **Option 1**: monitoring the PIC obtained by users, which is available in the ABS Clearing-House
2. **Option 2**: the patent authority is used as a checkpoint to monitor the utilization of genetic resources and traditional knowledge

Finally, a Belgian component of/entry-point to the ABS Clearing-House will be created to support exchange of information on specific ABS measures within the framework of the Nagoya Protocol (**measure 6**). Even if the discussions on the exact modalities of the ABS Clearing-House are still on-going internationally, three possible candidates have been identified: the Royal Belgian Institute of Natural Sciences (option 1), the Belgian Federal Science Policy Office (option 2), and the Scientific Institute for Public Health (option 3).

Measure 6: sharing information through the ABS Clearing-House

0. **Option 0**: not creating a Belgian entry point to/component of the Clearing-House
1. **Option 1**: appointing Royal Belgian Institute of Natural Sciences (RBINS) as Clearing-House
2. **Option 2**: appointing Belgian Federal Science Policy Office (BELSPO) as Clearing-House
3. **Option 3**: appointing Scientific Institute for Public Health (ISP/WIV) as Clearing-House

Impact of the selected options for the implementation of the Nagoya Protocol

The evaluation of the possible consequences of the implementation of the above options was conducted through a detailed comparative multi-criteria analysis. This analysis also allowed identifying the possible affected stakeholders.

For the operationalization of access to genetic resources (**measure 1**), the bottleneck option (option 1) and the modified fishing net option (option 3) came out very close. The preference for these options can be explained by the fact they are expected to provide more legal certainty, will have a better environmental impact and correspond better to current practices than the other two options. These two options first require establishing, as a general legal principle, that access to Belgian genetic resources requires Prior Informed Consent.

For the specification of benefit-sharing requirements for Mutually Agreed Terms (**measure 2**) the two options that impose specific benefit-sharing requirements by the Belgian State (options 2 and 3) both ranked better than the option where no specific benefit-sharing requirements are imposed (option 1). This is due to their good economic, environmental and procedural performance (option 2 also has a good social performance). Choosing these options requires adopting benefit-sharing as a general legal principle in Belgium.

Alongside the establishment of the Competent National Authorities, a centralized input system clearly came out as the recommended option (**option 2 of measure 3**). This option scores best on all the criteria and is strictly better on legal certainty and effectiveness for users and providers of genetic resources, at low cost.

For the setting up of compliance measures (**measure 4**), the option to refer back to provider country legislation, with Belgian law as a fallback option, is the recommended option that comes out of this analysis. This can be explained by the closer conformity of this option with existing practices (mainly under the Belgian code of private international law).

For the designation of one or more checkpoints (**measure 5**), the option of monitoring PIC in the ABS Clearing-House stands as the recommended option. It scores at least as well on all criteria and has a better social and procedural performance.

Finally, for the sharing of information through the Clearing-House (**measure 6**), the preference goes to appointing the Royal Belgian Institute of Natural Sciences (RBINS), which has a better performance than other options on most of the analyzed criteria.

Recommendations resulting from the impact assessment

Two general recommendations result from the impact analysis of the study, along with a set of more specific recommendations for each of the measures.

First, the analysis shows that the no policy change baseline (the “0” option for each measure) clearly has the worst performance. This result leads to a first general recommendation, which is to implement both Prior Informed Consent and benefit-sharing as general legal principles in Belgium. Second, the analysis confirmed the validity of a phased approach to the implementation of the Protocol. A phased approach will allow to benefit from the implementation of the basic principles in a timely manner and to deal with more fine grained choices in a later stage. Moreover, the phased approach will be necessary in order to be able to timely ratify the Nagoya Protocol and allow Belgium to participate as a Party to the Nagoya Protocol at the first COP/MOP in October 2014.

Finally, the impact assessment has led to a set of **specific recommendations** on each of the six measures described above:

1. Alongside the designation of Competent National Authorities (CNAs), a centralized input system to the CNAs should be established.
2. With regard to compliance measures, sanctions should be provided for in cases of non-compliance with PIC and MAT requirements set out by the provider country. When checking content of MAT, a provision in the Code of international private law should provide for reference to provider country legislation, with Belgian law as a fallback option.

3. At this stage of the implementation, the monitoring of the utilization of genetic resources and traditional knowledge by a checkpoint should be done on the basis of the PIC available in the ABS Clearing-House.
4. With regard to access to Belgian genetic resources, it is recommended to refine existing legislation relevant for protected areas and protected species, combined with a general notification requirement for access to other genetic resources. Later stages of implementation can then include refinement of additional relevant legislation as well as having *ex-situ* collections process the other access requests.
5. At this stage of the implementation, and apart from the general obligation to share benefits, no specific benefit-sharing requirements should be imposed for the Mutually Agreed Terms. A combination of more specific requirements, including the possibility to use standard agreements, can be considered in a later stage of the implementation.
6. The Royal Belgian Institute of Natural Sciences should be mandated to fulfill the information sharing tasks on Access and Benefit-sharing under the Nagoya Protocol, through the ABS Clearing-House.

Implementation of the recommendations

To implement these recommendations, the phased approach could be organized through a three step process:

1. In the **first step**, a political agreement should be agreed upon by the competent authorities with a clear statement on the general legal principles to be adopted, along with some specification of the actions to be undertaken by the federal and the federated entities to establish these principles and put them into practice. These should include:
    a. Establishment of benefit sharing as a general legal principle in Belgium.
    b. Establishment as a general legal principle that access to Belgian genetic resources requires PIC.
    c. Establishment of the general principle concerning the designation of four Competent National Authorities.
    d. Commitment that legislative measures will be taken to provide that genetic resources utilized within Belgian jurisdiction have been accessed by PIC and MAT, as required by provider country legislation, and to address situations of non-compliance.
    e. Designation of the Belgian CBD Clearing-House Mechanism, managed by the Royal Belgian Institute of Natural Sciences, as the Belgian contribution to the ABS Clearing-House, for dealing with the information exchange on ABS under the Nagoya Protocol.

    The reason for recommending such a political agreement is double. On the one hand, such an agreement provides for a clear political commitment to the core obligations of the Nagoya Protocol, as it specifies the intentions of the competent authorities, within the limits of the decisions already taken at the international and European level at the time of the agreement. On the other hand, it does not prejudge the political decisions to be taken by the different authorities and thus allows for sufficient flexibility to further adjust the implementation process in a later stage. The latter is especially important given the many questions that are still undecided at the present stage, both at the EU and international level, as mentioned and taken into account in this report.

2. In a **second step**, the specified actions should be subsequently implemented, for example through a cooperation agreement and/or by adding provisions in the relevant legislations such as the environmental codes of the federated entities and the federal government, along with other possible requirements.

3. In a **third step**, additional actions can be undertaken once there is more clarity from the negotiations on the EU and the international level.

4.

RÉSUMÉ ANALYTIQUE

Recommandations générales

- **Tant le consentement préalable donné en connaissance de cause (*Prior Informed Consent*, PIC) que le partage des avantages (benefit-sharing) devraient être établis** comme principe général juridique en Belgique
- **Une approche par étapes devrait être adoptée pour la mise en œuvre du Protocole de Nagoya**. Celle-ci permettrait de s'appuyer sur l'instauration, dans les temps requis, de principes juridiques de base et de traiter les options plus précises à un stade ultérieur

Recommandations spécifiques

- La création d'autorités compétentes nationales (Competent National Authorities, CNA) devrait être accompagnée d'**un système d'input centralisé pour les différentes autorités**.
- En ce qui concerne les mesures de conformité, des sanctions devraient être prévues en cas de non-respect des exigences du PIC et des conditions convenues d'un commun accord (Mutually Agreed Terms, MAT) fixées par le pays fournisseur. Pour la vérification du contenu des MAT, **une disposition dans le Code de droit international privé devrait se référer à la législation du pays fournisseur, avec le droit belge comme option de rechange.**
- A ce stade de la mise en œuvre, **la surveillance de l'utilisation des ressources génétiques et du savoir traditionnel par un point de contrôle devrait se faire sur base du PIC disponible dans le Centre d'échanges pour l'APA** (ABS Clearing-House)**.**
- En ce qui concerne l'accès aux ressources génétiques belges, il est recommandé d'une part de **préciser la législation en vigueur pertinente pour les zones et les espèces protégées**, et d'autre part d'instaurer une **obligation générale de notification pour l'accès aux autres ressources génétiques**. Les étapes ultérieures de la mise en œuvre pourront alors introduire des dispositions supplémentaires appropriées et prévoir que le traitement d'autres requêtes d'accès se fasse par les collections *ex-situ*.
- A ce stade de la mise en œuvre, et indépendamment de l'obligation générale de partager les avantages, **aucune disposition spécifique de partage d'avantages ne devrait être imposée pour les conditions convenues d'un commun accord** (Mutually Agreed Terms, MAT). Un ensemble de règles plus standardisées, y compris la possibilité d'utiliser des accords types, peut être envisagée à un stade ultérieur de l'implémentation.
- **l'Institut Royal des Sciences Naturelles de Belgique devrait être mandaté pour remplir les tâches de partage d'information via le Centre d'échange pour l'APA** (ABS Clearing-House), comme imposées par le Protocole de Nagoya.

Cette étude a pour objectif de contribuer à la ratification et à la mise en œuvre en Belgique du Protocole de Nagoya sur l'Accès et le Partage des Avantages (APA), qui à son tour doit contribuer à la conservation de la diversité biologique et à l'utilisation durable de ses éléments. En tant que protocole à la Convention sur la Diversité Biologique (CDB), l'implémentation du Protocole de Nagoya de 2010 sur *« l'Accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation* » participe à l'objectif général de mise en œuvre de la CDB.

La CDB est le principal instrument international pour la protection de la biodiversité. Elle a trois objectifs: (1) la conservation de la diversité biologique, (2) l'utilisation durable de ses éléments et (3) le partage juste et équitable des avantages découlant de l'exploitation des ressources génétiques. Le Protocole de Nagoya dessine les moyens de mise en œuvre du troisième objectif.

L'APA comprend une grande diversité de questions allant bien au-delà des seules matières environnementales, telles que la régulation et l'accès aux marchés, le commerce international, l'agriculture, la santé, le développement et la coopération, la recherche et développement, et l'innovation. Par conséquent, la future mise en œuvre du Protocole de Nagoya pourrait être pertinente pour plusieurs départements et plusieurs niveaux de compétence en Belgique.

L'Accès et le Partage des Avantages (APA) en Belgique

Suite aux transferts successifs de compétences depuis 1970, les entités fédérées ont la responsabilité première pour les questions liées à l'Accès et au Partage des Avantages (APA), parmi lesquelles la politique environnementale, la politique agricole, la recherche et le développement, et la politique économique et industrielle. Cependant, le gouvernement fédéral détient dans ces domaines des compétences réservées et résiduelles, s'appliquant entre autres à l'importation, de l'exportation et du transit des espèces végétales et animales non indigènes, à la propriété industrielle et intellectuelle, et à la recherche scientifique nécessaire à l'exercice de ses propres compétences. La grande diversité des questions traitées nécessite aussi une distribution administrative étendue des compétences relatives à l'APA au sein de chaque niveau de pouvoir. La mise en œuvre du Protocole de Nagoya, en tant que « traité mixte »[4], exigera donc des compétences à la fois de l'Etat fédéral et des entités fédérées, et requerra une coordination inter- et intra-départementale approfondie.

L'accès aux ressources génétiques, tel que défini dans le Protocole de Nagoya, n'est pas encore régis en tant que tel par le droit public belge. Néanmoins, des dispositions existantes en droit public et privé réglementent déjà des cas apparentés, tels que les droits de propriété, l'accès physique aux (matériel génétique dans les) régions protégées et aux espèces protégées, ou encore la modification et la transformation des environnements naturels. Plusieurs de ces dispositions existantes pourraient servir de base pour la mise en œuvre du Protocole de Nagoya en Belgique.

Pour comprendre pleinement l'utilité de ces mesures existantes, il y a lieu de faire quatre remarques préliminaires importantes. Premièrement, tout au long de cette étude, l'accès et l'utilisation des ressources génétiques et du savoir traditionnel sont analysés dans le cadre du Protocole de Nagoya. Le Protocole traite des ressources génétiques et du savoir traditionnel qui sont fournis par les Parties qui sont les pays d'origine de ces ressources ou par les Parties qui les ont acquises conformément à la Convention sur la Diversité Biologique. Par conséquent, ce rapport traite:

- des ressources génétiques qu'un pays possède dans des conditions *in-situ* et sur lesquelles il exerce un droit de souveraineté; et

[4] Le Protocole de Nagoya a été déclaré « traité doublement mixte » par le Groupe de travail Traités Mixtes de la Conférence interministérielle de la Politique étrangère le 22/11/2010. L'Etat fédéral, les Régions et les Communautés doivent donner leur consentement pour que la Belgique puisse ratifier le Protocol.

- des ressources génétiques qu'un pays possède dans des collections *ex-situ* et qui ont été acquises après l'entrée en vigueur du Protocole de Nagoya et/ou en accord avec les obligations de la Convention sur la Diversité Biologique.

Deuxièmement, la Convention sur la Diversité Biologique distingue "matériel génétique" (c.-à-d. tout matériel végétal, animal, microbien ou de tout autre origine contenant des unités fonctionnelles d'hérédité) des "ressources génétiques" (c.-à-d. matériel génétique de valeur réelle ou potentielle).

Troisièmement, il faut distinguer d'une part, la question de la propriété légale de ressources génétiques en leur qualité de biens matériels, et, d'autre part, la réglementation de l'accès et de l'utilisation des ressources génétiques en conformité avec le Protocole de Nagoya en tant qu'exercice d'un droit souverain. L'Etat belge détient des droits souverains sur ses ressources génétiques et peut donc réglementer l'utilisation de ces ressources par des mesures de droit public, pour autant que celles-ci soient justifiées. Cependant, l'accès physique au matériel génétique et leur utilisation sont déjà réglementés par la loi sur la propriété et par les options de responsabilité et de réparation accessibles dans les procédures civiles et pénales relatives au renforcement des droits de propriété.

Quatrièmement, il est important de rappeler que si les ressources génétiques peuvent être considérées comme des entités biophysiques (par exemple, un spécimen végétal, une souche microbienne, un animal, etc.), elles comprennent un "composant informationnel" (c.-à-d. le code génétique). L'accès aux ressources génétiques concerne à la fois le composant physique et/ou le composant informationnel.

Au regard des remarques qui précèdent, les dispositions nationales actuellement disponibles régissant le statut légal des ressources génétiques en Belgique concernent principalement la question de la propriété légale du matériel génétique. Il résulte des principes fondamentaux sur le droit de propriété que l'on trouve dans le code civil, que les conditions et règles relatives à la propriété légale du matériel génétique, en tant qu'entité biophysique, découlent de celles qui régissent la propriété de l'organisme dans lequel ce matériel peut être trouvé. La propriété sur un organisme signifie que le propriétaire possède les droits de l'utiliser, d'en jouir et d'en disposer juridiquement et matériellement. De plus, toute mesure légale qui envisagerait de réglementer l'accès aux ressources génétiques pourrait se baser sur la législation existante sur l'accès physique et sur l'usage de matériel génétique. Les lois réglementant l'accès physique et l'usage du matériel génétique dépendent du type de propriété (mobilière, immobilière, ou *res nullius*), de l'existence de restrictions à la propriété comme une protection spécifique (espèces protégées, zones protégées, forêts ou environnements marins) et de la situation géographique du matériel génétique (les quatre autorités appliquent leurs propres règles).

Contrairement à ses composants physiques, les composants informationnels des ressources génétiques peuvent constituer une *res communis :* "chose qui qui n'appartient à personne mais est sujet à l'usage par tous". Tandis que l'accès à de tels composants informationnels n'est pas couvert par une législation spécifique, l'exercice de certains droits d'utilisation peut cependant être limité par des droits de propriété intellectuelle qui touchent à des parties, des fonctions ou des utilisations de matériel biologique résultant d'innovations faites sur ces matériaux. Ces droits de propriété

intellectuelle peuvent prendre la forme de brevets, de protection des obtentions végétales ou d'indications géographiques.

En parallèle de ces principes directeurs régissant le statut légal des ressources génétiques, le droit civil, pénal, et international privé contiennent des règles et procédures en matière de responsabilité et de réparation relatives à l'acquisition illicite de ressources génétiques. Leur application est différente selon que les ressources génétiques sont des spécimens physiques ou des biens d'information, mais aussi selon l'endroit où l'acquisition illicite a eu lieu.

Enfin, il n'y a pas actuellement de dispositions légales en Belgique qui régissent explicitement les concepts de « connaissances traditionnelles », de « connaissances traditionnelles associées à des ressources génétiques » et de « communautés autochtones et locale ». Toutefois, certaines préoccupations en matière de connaissances traditionnelles et des droits des communautés indigènes et locales ont été traitées dans certains instruments internationaux auxquels la Belgique est partie, telle que la Convention N° 107 de l'Organisation Internationale du Travail (OIT) relative aux populations aborigènes et tribales, la Convention N° 169 de l'OIT relative aux peuples indigènes et tribaux, et la Déclaration des Nations Unies sur les droits des peuples autochtones.

Recommandations préliminaires relatives aux options pour la mise en œuvre du Protocole de Nagoya

Même si le Protocole of Nagoya est récent, il n'en est pas moins l'application du troisième objectif de la CDB, qui contient des principes de base et des dispositions apparentées à l'APA, tels que la souveraineté des Etats sur leurs richesses et ressources naturelles, le partage juste et équitable des avantages, et l'importance des communautés locales, des populations autochtones et de leurs connaissances traditionnelles. Beaucoup de Parties à la Convention à travers le monde ont donc mis en œuvre une série des mesures sur l'APA, qui peuvent servir d'expériences utiles pour l'exécution du Protocole de Nagoya. A l'analyse de ces expériences, deux groupes de recommandations préliminaires ont pu être établies dans cette étude, quant aux options disponibles pour la mise en œuvre du Protocole de Nagoya en Belgique. Le premier groupe de recommandations concerne les instruments nécessaires pour l'exécution des obligations fondamentales résultant du Protocole[5]. Le second groupe de recommandations concerne des mesures supplémentaires à prendre en compte au cours de la mise en œuvre des obligations du Protocole, mais qui vont au-delà des obligations fondamentales.

Recommandations relatives aux obligations fondamentales:

- **Clarifier les conditions d'accès** : Par ses droits souverains sur les ressources génétiques, la Belgique peut choisir si elle exige, ou non, que les utilisateurs obtiennent un consentement préalable donné en connaissance de cause (Prior Informed Consent, PIC) par l'autorité compétente pour accéder aux ressources génétiques dans sa juridiction.

[5] Les obligations fondamentales sont les obligations spécifiées dans les termes de référence de la présente étude comme requérant une attention spéciale : accès aux ressources génétiques et au savoir traditionnel ; partage des avantages ; l'Autorité Nationale Compétente et les correspondants (coordinateurs) nationaux ; conformité avec la législation nationale du pays d'origine (fournisseur) et règles contractuelles ; conformité et monitoring.

- **Déterminer le format des conditions convenues d'un commun accord (Mutually Agreed Terms, MAT)** : Une fois que le Protocole de Nagoya entre en vigueur, les utilisateurs œuvrant sur le territoire belge auront l'obligation de partager les avantages provenant de l'utilisation des ressources génétiques. Un tel partage sera basé des conditions convenues d'un commun accord (Mutually Agreed Terms, MAT). Cependant, le Protocole de Nagoya n'impose pas un format spécifique pour ces MAT qui peuvent être laissés à l'appréciation des parties prenantes ou découler des lignes de directrices et/ou de mesures obligatoires imposées par l'Etat.
- **Assurer que l'APA contribue à la conservation et l'utilisation durable de la biodiversité**: La mise en œuvre du Protocole de Nagoya devra servir les deux autres objectifs de la CDB: la conservation de la biodiversité et utilisation durable de ses composants. Cela peut être réalisé par exemple en soumettant l'obtention du PIC à des conditions obligatoires sur le partage des avantages ou en instaurant un «fonds de partage des avantages » qui redirige les avantages vers la conservation et l'usage durable.
- **Faciliter l'accès pour la recherche relative à la biodiversité** : pour soutenir et promouvoir la recherche relative à la biodiversité et pour réduire la charge de la réglementation pour recherche non commerciale qui utilise des ressources génétiques, des mesures pourraient être mise en place pour faciliter l'accès aux ressources génétiques pour de la recherche non commerciale liée à la biodiversité.
- **Instaurer des autorités compétentes nationales (Competent National Authorities, CNA)**: Chaque partie doit désigner une autorité ou des autorités nationales compétentes qui sont chargées d'accorder l'accès ou, s'il y a lieu, de délivrer une preuve écrite que les conditions d'accès ont été respectées, et de fournir des conseils sur les procédures et les conditions en vigueur pour accéder aux ressources génétiques. Etant donné la réalité institutionnelle en Belgique, plus d'une autorité nationale compétente peut être instaurée. Cette tâche est de la plus haute priorité, puisque la Belgique doit communiquer au Secrétariat de la Convention, au plus tard à la date d'entrée en vigueur du Protocole pour elle, les coordonnées de son correspondant national et de son autorité ou ses autorités nationales compétentes.
- **Accorder force contraignante à la législation des pays fournisseurs concernant le PIC et les MAT**: Parties intégrantes du Protocole, les obligations fondamentales auxquelles les utilisateurs nationaux doivent se conformer lorsqu'ils utilisent des ressources génétiques en Belgique, doivent être énoncées clairement. Cette obligation consiste à accorder force contraignante aux dispositions convenues d'un commun accord (MAT) ou aux consentements préalable donné en connaissance de cause (PIC) du pays fournisseur. Cela pourrait être fait en imposant, dans la législation belge, le respect de la législation du pays fournisseur en ce qui concerne le PIC et les MAT ou en instaurant une règle de police interne dans la législation belge imposant l'obtention d'un consentement préalable et la conclusion de dispositions communes convenues d'un commun accord, si requis par le pays fournisseur.
- **Désigner le(s) point(s) de contrôle pour la surveillance de l'utilisation des ressources génétiques :** Pour se conformer au Protocole de Nagoya, au moins un point de contrôle doit être désigné, qui surveille et garantit la transparence quant à l'utilisation des ressources génétiques en Belgique. Il peut s'agir d'une institution existante ou d'une nouvelle instance.

En ce qui concerne les mesures supplémentaires, les questions suivantes doivent être prises en considération: a) spécifier les conditions pour les conditions convenues d'un commun accord (MAT);

b) instaurer une procédure claire et transparente pour l'accès aux ressources génétiques; c) clarifier les droits et devoirs supplémentaires de(s) l'autorité(s) nationale(s) compétente(s); d) instaurer un système de surveillance (monitoring); e) créer des incitants à se conformer à l'adresse des utilisateurs ; f) encourager le développement de clauses contractuelles types, de codes de conduite et de lignes directrices.

Options sélectionnées pour la mise en œuvre du Protocole de Nagoya

A la lumière des recommandations préliminaires relatives aux options pour la mise en œuvre du Protocole de Nagoya décrites plus haut, six mesures, chacune comprenant plusieurs options politique, ont été discutées à la première réunion des parties prenantes le 29 mai 2012. Sur base des résultats de cette réunion, elles ont été sélectionnées par le Comité de Pilotage de l'étude pour une analyse en profondeur des impacts environnementaux, sociaux, économiques et procéduraux.

Avant de mettre en œuvre ces mesures, il doit être décidé s'il faut inscrire le consentement préalable donné en connaissance de cause (PIC) et le partage des avantages comme principes juridiques généraux en Belgique. Si ce dernier est indispensable pour se conformer au Protocole de Nagoya, le premier (PIC) découle des droits souverains que la Belgique exerce sur ses ressources génétiques et n'est pas indispensable pour la conformité avec le Protocole. Si le consentement préalable en connaissance de cause est effectivement inscrit comme principe général, il faut instaurer une procédure pour l'accès aux ressources génétiques belges (**mesure 1**). Cela peut être fait en modifiant la législation existante, en s'appuyant sur les collections *ex-situ* autorisées, en exigeant une notification préalable ou au travers d'une combinaison de ces dispositifs.

Mesure 1 : opérationnalisation de l'accès aux ressources génétiques

0. **Option 0** – Pas de consentement préalable
   Pas d'exigence de consentement préalable en connaissance de cause (Prior Informed Consent, PIC) pour l'utilisation des ressources génétiques et du savoir traditionnel en Belgique;

1. **Option 1** – Modèle « Bottleneck »
   a. Pour les ressources génétiques protégées : accès possible en affinant la législation existante pertinente pour les zones et les espèces protégées.
   b. Pour les ressources génétiques non protégées : l'accès est autorisé via les collections ex-situ
2. **Option 2** – Modèle « Fishing Net »
   a. Pour les ressources génétiques protégées : accès possible en affinant la législation existante pertinente pour les zones et les espèces protégées.
   b. Pour les ressources génétiques non protégées : accès accordé sur notification préalable auprès de l'autorité compétente
3. **Option 3** – Modèle « Fishing Net » modifié
   a. Pour les ressources génétiques protégées et les ressources génétiques déjà régies par une législation pertinente existante: accès possible en affinant la législation existante.
   b. Pour les ressources génétiques non protégées : accès accordé sur notification préalable auprès de l'autorité compétente

Si le partage des avantages est bien inscrit comme principe général, les dispositions spécifiques de partage des avantages à inclure dans les conditions convenues d'un commun accord (Mutually Agreed Terms, MAT), doivent être spécifiées **(mesure2)**. Ces dispositions spécifiques peuvent être laissées à l'appréciation des utilisateurs (option1), ou être imposées par l'Etat avec plus ou moins de standardisation (options 2 et 3).

Mesure 2 : Spécifier les dispositions pour les conditions convenues d'un commun accord (Mutually Agreed Terms, MAT)

0. **Option 0**: Pas de partage d'avantage pour l'utilisation des ressources génétiques et du savoir traditionnel en Belgique.
1. **Option 1**: Pas de dispositions spécifiques imposées par les autorités compétentes pour les conditions convenues d'un commun accord. Les utilisateurs et les fournisseurs sont libres de décider conjointement de leur contenu.
2. **Option 2**: Imposition de dispositions spécifiques, y compris par des formats standardisés, pour les conditions convenues d'un commun accord pour certains usage, qui seront différenciés selon la finalité de l'accès.
3. **Option 3**: Imposition de dispositions spécifiques mais sans formats standardisés pour les conditions convenues de commun accord. Tout en prenant en compte les conditions exigées de partage d'avantages, les MAT sont définies au cas par cas par les utilisateurs et les fournisseurs. Les dispositions sont différenciées selon la finalité de l'accès.

Pour respecter le Protocole de Nagoya, une ou plusieurs autorités nationales devront être établies **(mesure 3).** Leur tâche sera d'accorder l'accès ou, s'il y a lieu, de délivrer une preuve écrite que les conditions d'accès ont été respectées, et de fournir des conseils sur les procédures et les conditions en vigueur pour accéder aux ressources génétiques. Pour remplir ces tâches les autorités nationales compétentes devront également établir un point d'entrée pour les utilisateurs de ressources génétiques. Cela peut être fait séparément, chaque autorité instaurant son propre point d'entrée (option 1), ou conjointement, un seul point entrée pour les différentes autorités (option 2).

Mesure 3: instaurer une ou plusieurs autorités compétentes

0. **Option 0** : pas d'autorité nationale compétente en Belgique
1. **Option 1** : Instauration d'autorités nationales compétentes, avec un point d'entrée séparé pour chaque autorité.
2. **Option 2** : les autorités nationales compétentes sont instaurées, avec un point d'entrée commun.

Une fois le Protocole de Nagoya entré en vigueur en Belgique, il sera indispensable de mettre en place des mesures de mise en conformité pour s'assurer que les ressources génétiques et le savoir traditionnel utilisés sur le territoire belge ont bien été acquis en accord avec le droit du pays fournisseur (**mesure 4**). Cela peut être réalisé en se référant à la législation du pays fournisseur concerné et en contrôlant le contenu des MAT sur base de cette même législation, avec le droit belge

comme option de rechange (option1), ou en établissant une règle de police interne en droit belge (option 2). Dans cette deuxième option, la législation belge se référerait uniquement aux obligations spécifiques de PIC et de MAT, comme fixées par le pays fournisseur, sans se référer à la législation en vigueur dans le pays fournisseur.

Mesure 4 : instaurer des mesures de mise en conformité

0. **Option 0** : Pas d'introduction de dispositions légales sur la conformité dans le droit belge.
1. **Option 1** : Une disposition pénale générale est créée qui se réfère à la législation du pays fournisseur concernant le PIC et les MAT. L'Etat édicte une interdiction générale d'utiliser les ressources génétiques et le savoir traditionnel obtenus en violation de la loi du pays fournisseur. Le contrôle du contenu des MAT par un juge se fait sur base de la législation du pays fournisseur, avec le droit belge comme option de rechange
2. **Option 2** : Une disposition est créée instaurant l'obligation d'avoir obtenu un PIC et des MAT de la part du pays fournisseur pour l'utilisation en Belgique de ressources génétiques étrangères, s'ils sont requis par la législation du pays fournisseur (d'origine).

Pour se conformer au Protocole de Nagoya, au moins un point de contrôle doit être créé pour surveiller l'utilisation des ressources génétiques et du savoir traditionnel (**mesure 5**). Si la Belgique décide d'introduire des points de contrôle, leur mise en œuvre pourrait être réalisée en plusieurs étapes. Pour respecter l'engagement politique d'une ratification rapide du Protocole, une première étape pourrait consister en une implémentation minimale requérant la création d'un point de contrôle unique. Deux options possibles semblent pertinentes pour cette première étape, à savoir le contrôle du consentement préalable en connaissance de cause (PIC) des utilisateurs, lequel est disponible via le Centre d'échange pour l'APA (ABS Clearing-House) (option 1) et/ou le renforcement de l'obligation de mention de l'origine géographique de la matière biologique dans les brevets d'invention (option2). Comme les options 1 et 2 ne s'excluent pas mutuellement, une mise œuvre combinée pourrait être envisagée.

Mesure 5 : Désigner un ou plusieurs points de contrôle

0. **Option 0**: pas d'instauration de point de contrôle pour surveiller l'utilisation de ressources génétiques et du savoir traditionnel.
1. **Option 1**: contrôler le consentement préalable en connaissance de cause (PIC) de l'utilisateur, lequel est disponible via le Centre d'Echange APA (ABS Clearing-House).
2. **Option 2**: L'autorité des brevets est sollicitée comme point de contrôle pour surveiller l'utilisation des ressources génétiques et du savoir traditionnel.

Enfin, un composant ou un point d'entrée belge au Centre d'échange pour l'APA (ABS Clearing-House) sera créé pour soutenir l'échange d'information sur les mesures spécifiques d'accès et de partage des avantages dans le cadre du Protocole de Nagoya (**mesure 6**). Même si les discussions sur

les modalités exactes du Centre d'échange pour l'APA sont encore en cours au niveau international, trois candidats possibles ont été identifiés : l'Institut Royal de Sciences Naturelles de Belgique (option1), la politique scientifique fédérale (BELSPO) (option 2), et l'Institut Scientifique de Santé Publique (ISP) (option3).

Mesure 6 : Partage d'information via le Centre d'échange pour l'APA (ABS Clearing-House)

0. **Option 0** : Pas de création de point d'entrée /composant belge du Centre d'échange pour l'APA
1. **Option 1** : Nommer l'Institut Royal des Sciences Naturelles de Belgique (IRSNB) comme centre d'échange
2. **Option 2** : Nommer la Politique Scientifique Fédérale (BELSPO) comme centre d'échange
3. **Option 3** : Nommer L'Institut Scientifique de Santé Publique (ISP) comme centre d'échange

Impact des options sélectionnées pour la mise en œuvre du Protocole de Nagoya

L'évaluation des conséquences possibles de l'application des options décrites ci-dessus a été conduite par une analyse comparative détaillée à critères multiples. Cette analyse a également permis d'identifier les parties prenantes qui pourraient être affectées.

Pour l'opérationnalisation de l'accès aux ressources génétiques **(mesure 1)**, le modèle « bottleneck » (option 1) et le modèle « fishing net » modifié (option 3) ont des performances très similaires. La préférence pour ces options peut être expliquée par le fait qu'elles sont supposés apporter une plus grande sécurité juridique, qu'elles auront un meilleur impact environnemental, et qu'elles correspondent mieux aux pratiques actuelles que les deux autres options. Ces deux options requièrent d'abord l'instauration du consentement informé préalable (PIC) pour l'accès aux ressources génétiques belges comme principe juridique général.

En ce qui concerne la spécification des dispositions pour les conditions convenues d'un commun accord (MAT) (**mesure 2),** les deux options qui imposent des dispositions spécifiques par l'Etat belge (options 2 et 3) se classent mieux que l'option sans dispositions spécifiques (option 1). Cela s'explique par une meilleure performance économique, environnementale, et procédurale (l'option 2 présente aussi une bonne performance sociale). Choisir ces 2 options impose d'établir le 'partage d'avantage' comme principe juridique général en Belgique.

En plus de l'instauration d'autorités nationales compétentes, l'option privilégiant un point d'entrée commun est clairement apparue comme l'option recommandée (option 2 de la **mesure 3)**. Cette option a une bonne performance sur tous les critères, offre un meilleure sécurité juridique et est plus efficace pour les utilisateurs et les fournisseurs de ressources génétiques, à bas coût.

Pour l'instauration des mesures de mise en conformité (**mesure 4),** l'option créant une disposition pénale générale se référant à la législation du pays fournisseur, avec la loi belge comme option de

rechange, obtient le meilleur résultat. En effet, cette option présente une meilleure adéquation aux pratiques existantes (dans le Code de droit international privé).

Quant à la désignation d'un ou plusieurs points de contrôle (**mesure 5**), l'option contrôlant le consentement préalable en connaissance de cause (PIC) de l'utilisateur dans le Centre d'Echange pour l'APA, est l'option recommandée. Cette option présente d'aussi bons résultats sur tous les critères que les autres options et présente un meilleur score sur le plan de la performance sociale et procédurale.

Enfin, en ce qui concerne le partage de l'information par l'intermédiaire du Centre d'échange pour l'APA (**mesure 6**), la préférence va à la nomination de l'Institut Royal des Sciences Naturelles de Belgique, qui récolte de meilleurs résultats que les autres options sur la plupart des critères.

Recommandations résultant de l'évaluation d'impact

Deux recommandations générales résultent de l'analyse d'impact, en même temps qu'un ensemble de recommandations plus spécifiques pour chacune des mesures.

D'abord, l'analyse montre que les options n'envisageant pas de changements de politique (les options « 0 » de chaque mesure) obtiennent clairement le résultat le moins bon. Ce score conduit à une première recommandation générale, qui est de mettre en œuvre à la fois le *'Consentement informé préalable'* (PIC) et le 'partage des avantages' (benefit-sharing) comme principes juridiques généraux en Belgique. Ensuite, l'analyse a confirmé la validité d'une approche par étapes pour la mise en œuvre du Protocole. Une approche par étapes permettra de mettre en place les principes de base dans les temps requis et de traiter les options plus précises à un stade ultérieur. De plus, l'approche par étapes est nécessaire pour être en mesure de ratifier le Protocole de Nagoya dans les temps requis et de permettre à la Belgique de participer comme Partie au Protocole à la première Conférence des Parties (COP/MOP1) en octobre 2014.

Enfin, l'évaluation d'impact a conduit à un ensemble de **recommandations spécifiques** pour chacune des six mesures :

1. La création d'autorités compétentes nationales (Competent National Authorities) devrait être accompagnée d'un système d'input centralisé pour les différentes autorités.
2. En ce qui concerne les mesures de conformité, des sanctions devraient être prévues en cas de non-respect des exigences du PIC et des conditions convenues d'un commun accord (MAT) fixées par le pays fournisseur. Pour la vérification du contenu des MAT, une disposition dans le Code de droit international privé devrait se référer à la législation du pays fournisseur, avec le droit belge comme option de rechange.
3. A ce stade de la mise en œuvre, la surveillance de l'utilisation des ressources génétiques et du savoir traditionnel par un point de contrôle devrait se faire sur base du PIC disponible dans le Centre d'échanges pour l'APA (ABS Clearing-House).
4. En ce qui concerne l'accès aux ressources génétiques belges, il est recommandé d'une part de préciser la législation en vigueur pertinente pour les zones et les espèces protégées, et d'autre part d'instaurer une obligation générale de notification pour l'accès aux autres ressources génétiques. Les étapes ultérieures de la mise en œuvre pourront alors introduire

des dispositions supplémentaires appropriées et prévoir que le traitement d'autres requêtes d'accès se fasse par les collections *ex-situ*.

5. A ce stade de la mise en œuvre, et indépendamment de l'obligation générale de partager les avantages, aucune disposition spécifique de partage d'avantages ne devrait être imposée pour les conditions convenues d'un commun accord (MAT). Un ensemble de règles plus standardisées, y compris la possibilité d'utiliser des accords types, peut être envisagée à un stade ultérieur de l'implémentation.
6. l'Institut Royal des Sciences Naturelles de Belgique devrait être mandaté pour remplir les tâches de partage d'information via le Centre d'échange pour l'APA (ABS Clearing-House), comme imposées par le Protocole de Nagoya.

Implémentation des recommandations

Pour réaliser ces recommandations, l'approche par étapes pourrait être organisée en par un processus en trois étapes :

1. Dans la **première étape**, un accord politique devrait être décidé entre les autorités compétentes, comprenant une déclaration claire quant aux principes juridiques généraux à mettre en place, en plus de certaines spécifications sur les actions à entreprendre par l'Etat fédéral et les entités fédérées pour mettre ces principes en application. Cet accord devrait inclure:
    a. Instauration du partage d'avantages comme principe juridique général en Belgique.
    b. Instauration d'un principe juridique général selon lequel l'accès aux ressources génétiques belges requiert un Consentement informé préalable (PIC).
    c. Instauration d'un principe juridique général concernant la création de quatre Autorités Nationales Compétentes.
    d. Engagement que des mesures législatives seront prises afin de s'assurer que les ressources génétiques utilisées sous la juridiction belge, ont été acquises moyennant un PIC et des MAT, comme fixé par la législation du pays fournisseur, et de répondre aux situations de non-respect.
    e. Désignation du Centre d'échange d'informations belge de la CDB (Clearing-House Mechanism), géré par l'Institut Royal des Sciences Naturelles, comme Centre d'échange pour l'APA, traitant les échanges d'information sur l'accès et le partages des avantages au titre du Protocole de Nagoya.

    La raison pour laquelle un tel accord politique est recommandé est double. D'une part, il offre un engagement politique clair quant aux obligations fondamentales du Protocole de Nagoya. En effet, il spécifie les intentions des autorités compétentes, dans la limite des décisions déjà prises aux niveaux européen et international au moment de l'accord. D'autre part, il ne préjuge pas des décisions politiques qui seront prises par les différentes autorités et offre ainsi une flexibilité suffisante pour ajuster le processus de mise en œuvre à un stade ultérieur. Ce dernier point est particulièrement important étant donné les nombreuse questions encore en suspens au stade actuel, tant au niveau européen qu'au niveau international, comme indiqué et pris en compte dans ce rapport.

2. Dans une **seconde étape**, les actions spécifiées devront être mises en œuvre, par exemple à l'aide d'un accord de coopération et/ou en ajoutant des dispositions dans la législation pertinente, comme les Codes de l'environnement des entités fédérées et de l'Etat fédéral, en plus d'autres conditions éventuelles.

3. Dans une **troisième étape**, des actions supplémentaires peuvent être entreprises, une fois qu'il y a plus de clarté aux niveaux européen et international.

SAMENVATTING

Algemene aanbevelingen

- **Zowel voorafgaande geïnformeerde toestemming (Prior Informed Consent, PIC) als de verdeling van voordelen (benefit-sharing) moeten worden ingevoerd** als algemene vereisten in België.
- **Een gefaseerde aanpak moet worden gevolgd** voor de implementatie van het Protocol van Nagoya. Op die manier kan voordeel worden gehaald uit de tijdige invoering van basisprincipes en kunnen specifiekere keuzes in een later stadium worden gemaakt.

Specifieke aanbevelingen

- Naast de oprichting van de Bevoegde Nationale Instanties, **moet ook een gecentraliseerd aanspreekpunt worden gecreëerd voor deze instanties.**
- Wat de maatregelen inzake naleving van wet- of regelgeving (compliance) betreft, moeten sancties worden voorzien voor situaties van vaststelling van niet-naleving van de PIC en van de Onderling Overeengekomen Voorwaarden (Mutually Agreed Terms, MAT), zoals opgelegd door het oorsprongsland. Voor het controleren van de inhoud van de MAT **zou een bepaling in het Wetboek van internationaal privaatrecht moeten verwijzen naar de wetgeving van het oorsprongsland**, met de Belgische wetgeving als een eventuele terugvaloptie.
- In de eerste uitvoeringsfase **zou het controleren van het gebruik van genetische rijkdommen en traditionele kennis moeten gebeuren op basis van de PIC die beschikbaar is via het ABS Clearing-House mechanisme.**
- Met betrekking tot de toegang tot Belgische genetische rijkdommen, is het aanbevolen **de bestaande relevante wetgeving inzake beschermde natuurgebieden en beschermde soorten te verfijnen**, in combinatie met een algemene **notificatievereiste voor de toegang tot andere genetische rijkdommen**. In latere uitvoeringsfasen kan bijkomende relevante wetgeving dan eveneens worden verfijnd, en kan het verwerken van toegangsaanvragen voor andere genetische rijkdommen overgelaten worden aan *ex-situ* collecties.
- In de eerste uitvoeringsfase, en los van de algemene verplichting om de voordelen te verdelen, zouden er **geen specifieke vereisten moeten opgelegd worden voor het opstellen van Onderling Overeengekomen Voorwaarden** (*Mutually Agreed Terms*). Een combinatie van meer specifieke vereisten, met de mogelijkheid om standaardakkoorden te gebruiken, kan in een latere uitvoeringsfase worden overwogen.
- **Het Koninklijk Belgisch Instituut voor Natuurwetenschappen zou moeten gemandateerd worden om de informatieuitwisselingstaken in verband met toegang en verdeling van de voordelen** in het kader van het Protocol van Nagoya te vervullen, via het ABS Clearing-House.

Het doel van deze studie is bij te dragen tot de ratificatie en implementatie in België van het Protocol van Nagoya inzake toegang en verdeling van voordelen (Access and Benefit-sharing, ABS), welke op haar beurt moet bijdragen tot het behoud van de biologische diversiteit en het duurzame gebruik van bestanddelen daarvan. De implementatie van het Protocol van Nagoya inzake "toegang tot genetische rijkdommen en de eerlijke en billijke verdeling van voordelen voortvloeiende uit hun gebruik" (2010), past in de algemene doelstelling die de implementatie van het Verdrag inzake biologische diversiteit (VBD) beoogt, daar het een protocol is bij het VBD.

Het VBD is het voornaamste internationale instrument voor de bescherming van de biodiversiteit. Het heeft drie doelstellingen: (1) het behoud van de biologische diversiteit, (2) het duurzame gebruik van bestanddelen daarvan en (3) de eerlijke en billijke verdeling van de voordelen voortvloeiende uit het gebruik van genetische rijkdommen. Het Protocol van Nagoya bepaalt hoe de derde doelstelling gerealiseerd kan worden.

ABS kan een breed scala van gerelateerde aangelegenheden omvatten die veel verder gaan dan louter milieuaangelegenheden, zoals regulering van en toegang tot de markt, internationale handel, landbouw, gezondheid, ontwikkelingssamenwerking, onderzoek & ontwikkeling, en innovatie. Bijgevolg zal de toekomstige implementatie van het Protocol relevant zijn voor verschillende departementen en verschillende beleidsniveaus in België.

Toegang en verdeling van voordelen in België

Na de opeenvolgende staatshervormingen sinds 1970, ligt de verantwoordelijkheid voor ABS-aangelegenheden vooral bij de deelstaten, zoals het milieubeleid, landbouwbeleid, onderzoek en ontwikkeling, en het economisch en industriebeleid. Binnen die domeinen heeft de federale overheid echter gereserveerde en residuaire bevoegdheden. Voorbeelden hiervan zijn o.a. de in-, uit- en doorvoer van inheemse planten- en diersoorten, industriële en intellectuele eigendom, en wetenschappelijk onderzoek dat nodig is voor de uitoefening van haar eigen bevoegdheden. Het brede scala aan gerelateerde aangelegenheden veronderstelt ook een ruime administratieve verdeling van ABS-bevoegdheden binnen elk bevoegdheidsniveau. Voor de implementatie van het Protocol van Nagoya, als een "dubbel gemengd vedrag"[6], spelen de bevoegdheden van zowel de federale overheid als de deelstaten dus een belangrijke rol, en zal een uitgebreide inter- en intradepartementale samenwerking nodig zijn.

De toegang tot genetische rijkdommen, zoals die in het Protocol van Nagoya is vastgelegd, is als dusdanig nog niet gereguleerd door Belgische publiekrechtelijke maatregelen. Toch worden gerelateerde aangelegenheden zoals het eigendomsrecht, de toegankelijkheid van (genetisch materiaal in) beschermde natuurgebieden en beschermde soorten, of het wijzigen van vegetatie, al gereguleerd door bestaande publiek- en privaatrechtelijke bepalingen. Deze bestaande bepalingen kunnen als basis worden gebruikt voor de implementatie van het Protocol van Nagoya in België.

Om het nut van deze bestaande maatregelen volkomen te begrijpen moeten vier belangrijke, voorafgaande opmerkingen worden gemaakt. Ten eerste wordt in deze studie de toegang tot en het gebruik van genetische rijkdommen en traditionele kennis onderzocht in het kader van het Protocol van Nagoya. Het Protocol betreft genetische rijkdommen en traditionele kennis die worden verschaft door Partijen die het land van oorsprong van deze rijkdommen en/of kennis zijn of door Partijen die genetische rijkdommen in overeenstemming met het VBD hebben verworven. Bijgevolg betreft dit rapport:

[6] Het Protocol van Nagoya werd dubbel gemengd verklaard door de Werkgroep Gemengde Verdragen (WGV) van de Interministeriële Conferentie voor Buitenlands Beleid op 22/11/2010. De instemming van de federale Staat, de Gewesten en de Gemeenschappen is vereist voor de instemming met het Protocol.

- genetische rijkdommen die een land bezit onder *in-situ* omstandigheden en waarop dat land soevereine rechten heeft; en
- genetische rijkdommen die een land bezit in *ex-situ* collecties en die verworven werden na de inwerkingtreding van het Protocol van Nagoya en/of overeenkomstig de verplichtingen uit het Verdrag inzake Biologische Diversiteit.

Ten tweede maakt het VBD een onderscheid tussen “genetisch materiaal” (m.a.w. alle materiaal van plantaardige, dierlijke, microbiële of andere oorsprong dat functionele eenheden van de erfelijkheid bevat) en “genetische rijkdommen” (m.a.w. genetisch materiaal van feitelijke of potentiële waarde).

Ten derde moet een onderscheid worden gemaakt tussen het juridisch eigendom van genetische rijkdommen als materiële goederen enerzijds, en het reguleren van de toegang tot en het gebruik van genetische rijkdommen overeenkomstig het Protocol van Nagoya in het kader van de uitoefening van een soeverein recht, anderzijds. De Belgische Staat heeft als soevereine staat het recht om het gebruik van haar genetische rijkdommen te reguleren door middel van publiekrechtelijke maatregelen, op voorwaarde dat die maatregelen gerechtvaardigd zijn. De fysieke toegang tot en het gebruik van genetisch materiaal wordt echter al gereguleerd door het eigendomsrecht en door de aansprakelijkheids- en schadeloosstellingsmogelijkheden van de burgerlijke en strafrechtelijke procedures die gebruikt kunnen worden voor het afdwingen van eigendomsrechten.

Ten vierde is het belangrijk te onderlijnen dat genetische rijkdommen, ook al kunnen ze als biofysische entiteiten worden beschouwd (*e.g.* een plantenspecimen, een bacteriële stam, een dier, enz.), ook een "informationele component” bevatten (*i.e.* hun genetische code).

Gelet op het voorgaande zijn de geldende nationale bepalingen met betrekking tot het wettelijke statuut van genetische rijkdommen in België vooral te vinden in het eigendomsrecht van genetisch materiaal. Het juridisch eigendom van genetisch materiaal als biofysische entiteit vloeit voort uit de voorwaarden en regels die de eigendom regelen van het organisme waarin dit materiaal kan worden gevonden, welke vastgelegd zijn door de basisprincipes van het eigendomsrecht in het burgerlijk wetboek. De eigendom op een organisme betekent dat de eigenaar het recht heeft om het organisme te gebruiken, ervan te genieten en er materieel en juridisch over te beschikken. Bovendien zou elke wettelijke maatregel waarin de regulering van de toegang tot genetische rijkdommen wordt overwogen, voordeel kunnen halen uit de bestaande wetgeving die de toegankelijkheid en het gebruik van genetisch materiaal reguleert. Deze wetgeving varieert naargelang het soort eigendom van het materiaal (roerend, onroerend of *res nullius*), het bestaan van beperkingen op het eigendomsrecht zoals een specifieke bescherming (beschermde soorten, beschermde natuurgebieden, bossen of mariene omgevingen) en de locatie van het genetische materiaal (de vier bevoegde instanties passen elk hun eigen regels toe).

In tegenstelling tot de fysieke componenten kunnen de informationele componenten van de genetische rijkdommen aanzien worden als *res communis*: “zaken die niemands eigendom zijn en door iedereen gebruikt mogen worden”. De toegang tot dergelijke informationele componenten valt niet onder een specifieke wetgeving, maar de uitoefening van bepaalde gebruiksrechten kan wel beperkt worden door het intellectuele eigendom dat werd toegestaan op uitvindingen die betrekking hebben op een voortbrengsel dat uit biologisch materiaal bestaat of dit bevat, of op een werkwijze

waarmee biologisch materiaal wordt verkregen, bewerkt of gebruikt. Deze intellectuele eigendomsrechten kunnen de vorm aannemen van octrooien, bescherming van kweekproducten of geografische indicaties.

Naast deze principes met betrekking tot het wettelijke statuut van genetische rijkdommen bieden enkele burgerrechtelijke, strafrechtelijke en internationale privaatrechtelijke regels ook aansprakelijkheids- en schadeloosstellingsmogelijkheden voor gevallen waarin een illegale verwerving van genetische rijkdommen wordt vastgesteld. Hun toepassing varieert naargelang de aard van het goed (fysieke goederen of informationele goederen), maar ook naargelang de plaats waar de illegale verwerving gebeurt.

Tot slot zijn er in België momenteel geen wettelijke bepalingen waarin de concepten "traditionele kennis", "traditionele kennis met betrekking tot genetische rijkdommen" en "inheemse en lokale gemeenschappen" uitdrukkelijk zijn vastgelegd. Traditionele kennis en de rechten van inheemse en lokale gemeenschappen werden echter wel aangekaart in enkele internationale akkoorden waarbij België partij is, zoals het Verdrag nr. 107 van de Internationale Arbeidsorganisatie (IAO) betreffende inheemse en in stamverband levende volken uit 1957, het Verdrag nr. 169 van de IAO betreffende inheemse en in stamverband levende volken, en de VN-verklaring over de rechten van inheemse volken.

Voorbereidende aanbevelingen met betrekking tot de opties voor de implementatie van het Protocol van Nagoya

Hoewel het Protocol van Nagoya een recent protocol is, is het niettemin de verdere uitvoering van de derde doelstelling van het VBD, welke basisprincipes en ABS aanverwante bepalingen bevat, zoals de soevereine rechten van Staten op hun natuurlijke rijkdommen, de eerlijke en billijke verdeling van voordelen en het belang van inheemse en lokale gemeenschappen en hun traditionele kennis. Verschillende Partijen bij het VBD wereldwijd hebben daarom ABS-maatregelen ingevoerd, welke nuttige ervaringen opleveren voor de implementatie van het Protocol. Op basis van deze ervaringen werden twee groepen voorbereidende aanbevelingen uitgewerkt in deze studie, die betrekking hebben tot de beschikbare opties voor de implementatie van het Protocol in België. De eerste groep aanbevelingen houdt verband met de vereiste instrumenten voor de naleving van de kernverplichtingen die voortvloeien uit het Protocol[7]. De tweede groep aanbevelingen houdt verband met belangrijke bijkomende maatregelen waarmee rekening moet worden gehouden bij de naleving van de verplichtingen, maar die verder gaan dan de kernverplichtingen.

Voor het implementeren van de kernverplichtingen worden de volgende aanbevelingen gedaan:

- **De toegangsvoorwaarden verduidelijken**: dankzij haar soevereine rechten op de genetische rijkdommen kan België kiezen of gebruikers al dan niet de voorafgaande geïnformeerde

[7] De kernverplichtingen zijn die verplichtingen die volgens de referentievoorwaarden van deze studie bijzondere aandacht verdienen: toegang tot genetische rijkdommen en traditionele kennis; batenverdeling; de Nationale Bevoegde Autoriteiten en de Nationale Contactpunten; naleving van de nationale wetgeving van het oorsprongsland en de contractuele regels; en naleving en monitoring.

toestemming (*Prior Informed Consent, PIC*) van de bevoegde instantie moeten verkrijgen om toegang te krijgen tot de genetische rijkdommen die onder haar bevoegdheid vallen.

- **De format van de onderling overeengekomen voorwaarden bepalen**: Eenmaal het Protocol van Nagoya in werking treedt in België, moeten gebruikers die op Belgisch grondgebied actief zijn de voordelen die voortvloeien uit het gebruik van genetische rijkdommen verdelen. Die verdeling moet gebeuren op basis van onderling overeengekomen voorwaarden (*Mutually Agreed Terms, MAT*). Het Protocol van Nagoya legt echter geen specifiek format op voor deze onderling overeengekomen voorwaarden. Deze kunnen worden overgelaten aan het goeddunken van belanghebbenden of voortvloeien uit richtlijnen en/of verplichte maatregelen die door de Staat worden opgelegd.
- **Ervoor zorgen dat ABS bijdraagt aan behoud en duurzaam gebruik van biodiversiteit**: men moet ervoor zorgen dat de implementatie van het Protocol bijdraagt tot de twee andere doelstellingen van het VBD: het behoud van de biologische diversiteit en het duurzame gebruik van bestanddelen daarvan. Dit is bijvoorbeeld mogelijk door aan de PIC verplichte voorwaarden te koppelen voor het verdelen van voordelen of door een "voordelenverdelingsfonds" op te richten waarbij de voordelen voor behoud en duurzaam gebruik van biodiversiteit worden bestemd.
- **De toegang faciliteren voor biodiversiteit gerelateerd onderzoek:** om onderzoek naar biodiversiteit te stimuleren en om niet-commercieel onderzoek met genetische rijkdommen niet te overbelasten, kunnen maatregelen worden uitgewerkt om de toegang tot genetische rijkdommen te faciliteren voor niet-commercieel en biodiversiteit gerelateerd onderzoek.
- **Een Bevoegde Nationale Instantie oprichten:** elke Partij moet een Bevoegde Nationale Instantie (*Competent National Authority*) aanstellen. Deze instantie is verantwoordelijk voor het verlenen van toegang, of, indien van toepassing, voor de afgifte van schriftelijk bewijs dat voldaan is aan de vereisten voor toegang en voor advisering over de toepasselijke procedures en vereisten voor het toegang krijgen tot genetische rijkdommen. Gelet op de institutionele realiteit in België kan meer dan één Bevoegde Nationale Instantie worden aangesteld. Deze aanstelling is van de hoogste prioriteit, aangezien België uiterlijk op de datum van inwerkingtreding van het Protocol het VBD Secretariaat in kennis moet stellen van de contactgegevens van haar bevoegde nationale instantie of instanties (en van haar nationale contactpunt, dat reeds is aangesteld).
- **De wetgeving van oorsprongslanden bindend maken:** als onderdeel van de implementatie van het Protocol moeten de basisverplichtingen worden vastgelegd waaraan gebruikers moeten voldoen bij het gebruik van genetische rijkdommen in België. Deze verplichting komt neer op het bindend maken van de wetgeving van het oorsprongsland inzake PIC en MAT. Dit zou kunnen gebeuren door in de Belgische wetgeving te verwijzen naar de ABS-wetgeving van het oorsprongsland, of door een op zichzelf staande verplichting vast te leggen in de Belgische wetgeving die PIC en MAT oplegt, indien vereist door het oorsprongsland.
- **Controlepunt(en) vastleggen om het gebruik van genetische rijkdommen te volgen:** om het Protocol van Nagoya na te leven moet minstens één instelling worden aangeduid die als controlepunt zal fungeren om het gebruik van genetische rijkdommen te volgen en de transparantie over het gebruik daarvan te vergroten. Het kan om een nieuwe of bestaande instelling gaan.

Wat bijkomende maatregelen betreft, moet het volgende worden overwogen: a) de vereisten voor de MAT verduidelijken; b) een duidelijke en transparante toegangsprocedure uitwerken; c) bijkomende rechten en plichten van de bevoegde nationale autoriteiten verduidelijken; d) een monitoringssysteem invoeren; e) aanmoedigingsmaatregelen voorzien voor de naleving van wet- of regelgeving door gebruikers; en f) de ontwikkeling van contractuele modelbepalingen, gedragscodes en richtlijnen stimuleren.

Geselecteerde opties voor de implementatie van het Protocol van Nagoya

Gelet op de hierboven beschreven voorbereidende aanbevelingen met betrekking tot de beschikbare opties voor de implementatie van het Protocol, werden zes maatregelen, elk inclusief verschillende beleidsopties, besproken op de eerste vergadering met belanghebbende partijen op 29 mei 2012[8]. Op basis van deze vergadering selecteerde het Stuurcomité van de studie deze maatregelen voor een grondigere analyse van ecologische, maatschappelijke, economische en procedurele gevolgen van hun implementatie.

Alvorens deze maatregelen in te voeren, moet worden besloten of PIC en de verdeling van de voordelen (benefit-sharing) als algemene vereisten moeten gelden in België. Hoewel dit laatste nodig is voor de naleving van het Protocol, vloeit het eerste voort uit de soevereine rechten die België bezit op haar genetische rijkdommen en is het niet nodig voor de naleving van het Protocol. Indien PIC als een algemeen principe wordt beschouwd, moet een procedure worden uitgewerkt voor de toegang tot de eigen genetische rijkdommen van België (**maatregel 1**). Dit kan door de bestaande wetgeving aan te passen, door op gekwalificeerde *ex-situ* collecties te vertrouwen, door een voorafgaande notificatie te vereisen of door een combinatie van deze instrumenten.

Maatregel 1: de toegang tot genetische rijkdommen operationaliseren

4. **Optie 0** – Geen voorafgaande geïnformeerde toestemming
   Een voorafgaande geïnformeerde toestemming is niet vereist voor het gebruik van genetische rijkdommen en traditionele kennis in België;
5. **Optie 1** – Het "bottleneck" model
   a. Voor beschermde genetische rijkdommen: de toegang wordt mogelijk gemaakt door de bestaande wetgeving relevant voor beschermde natuurgebieden en beschermde soorten te verfijnen;
   b. Voor niet-beschermde genetische rijkdommen: de toegang wordt mogelijk gemaakt via Belgische *ex-situ* collecties.
6. **Optie 2** – Het "fishing net" model
   a. Voor beschermde genetische rijkdommen: de toegang wordt mogelijk gemaakt door de bestaande wetgeving relevant voor beschermde natuurgebieden en beschermde soorten te verfijnen;
   b. Voor niet-beschermde genetische rijkdommen: de toegang wordt toegestaan na notificatie aan de bevoegde instantie.
7. **Optie 3** – Het aangepaste "fishing net" model

[8] Het verslag van deze vergadering is beschikbaar op het volgend adres: http://www.biodiv.be/implementation/cross-cutting-issues/abs/workshop-np-20120529/20120529-nagoya-stakeholder-workshopreport-final.pdf

a. Voor beschermde genetische rijkdommen en genetische rijkdommen die al onder een specifieke relevante wetgeving vallen: de toegang wordt mogelijk gemaakt door de bestaande wetgeving te verfijnen;
b. Voor niet-beschermde genetische rijkdommen: de toegang wordt toegestaan na notificatie aan de bevoegde instantie.

Indien de verdeling van de voordelen als een algemene vereiste wordt beschouwd, moeten de specifieke vereisten voor het opstellen van de Onderling Overeengekomen Voorwaarden (MAT) worden gespecificeerd (**maatregel 2**). Het bepalen van deze vereisten kan worden overgelaten aan de gebruikers en aanbieders (optie 1), of op een min of meer gestandaardiseerde wijze worden opgelegd door de staat (optie 2 en 3).

Maatregel 2: specificeren van de vereisten voor het opstellen van Onderling Overeengekomen Voorwaarden

4. **Optie 0**: Geen verdeling van voordelen voor het gebruik van genetische rijkdommen en traditionele kennis in België.
5. **Optie 1**: De bevoegde autoriteiten leggen geen specifieke vereisten op voor het opstellen van de MAT. Het staat gebruikers en aanbieders vrij om gezamenlijk te beslissen over de inhoud.
6. **Optie 2**: Specifieke vereisten voor het opstellen van MAT worden opgelegd, inclusief door middel van contractuele modelbepalingen die verschillen naargelang van het doel van de toegang.
7. **Optie 3**: Specifieke vereisten voor het opstellen van MAT worden opgelegd, maar zonder contractuele modelbepalingen. Die specifieke vereisten verschillen naargelang van het doel van de toegang Ze vormen de basis voor onderhandelingen over MAT door de gebruikers en aanbieders van genetische rijkdommen die geval per geval zullen plaatsvinden.

Met het oog op de naleving van het Protocol van Nagoya moeten een of meer bevoegde nationale instanties worden aangesteld (**maatregel 3**). Zij moeten toegang verlenen, schriftelijk bewijs verschaffen dat voldaan is aan de vereisten voor toegang en/of gebruikers adviseren over de toepasselijke procedures en vereisten voor het toegang krijgen tot genetische rijkdommen. Om die taken uit te voeren moeten de bevoegde nationale instanties aanspreekpunten voorzien voor de gebruikers van genetische rijkdommen. Dergelijke aanspreekpunten kunnen afzonderlijk worden voorzien, waarbij elke instantie zijn eigen aanspreekpunt heeft (optie 1), of gezamenlijk, waarbij er één enkel aanspreekpunt is voor de verschillende instanties (optie 2).

Maatregel 3: een of meer bevoegde nationale instanties aanstellen

3. **Optie 0**: Er wordt geen bevoegde nationale instantie(en) opgericht in België.
4. **Optie 1**: Er worden bevoegde nationale instanties opgericht, met een afzonderlijk aanspreekpunt voor elke autoriteit.
5. **Optie 2**: Er worden bevoegde nationale instanties opgericht, met één enkel, gezamenlijk aanspreekpunt.

Eenmaal het Protocol van Nagoya in werking is getreden in België, moeten nalevingsmaatregelen worden getroffen om ervoor te zorgen dat de genetische rijkdommen en traditionele kennis die op het grondgebied worden gebruikt, verkregen werden in overeenstemming met de wet van het oorsprongsland (**maatregel 4**). Dit kan worden bewerkstelligd door terug te verwijzen naar de wetgeving van het oorsprongsland in kwestie en de inhoud van de MAT te laten controleren op basis van deze zelfde wetgeving, met Belgische wetgeving als terugvaloptie (optie 1), of door een op zichzelf staande verplichting in te voeren in de Belgische wetgeving (optie 2). In het tweede geval zou de Belgische wetgeving enkel verwijzen naar de specifieke verplichting voorafgaande PIC en MAT te verkrijgen indien de wetgeving van het oorsprongsland dat vereist, zonder naar de feitelijke ABS-wetgeving van het oorsprongsland te verwijzen.

Maatregel 4: nalevingsmaatregelen voorzien

3. **Optie 0**: De Belgische wet voorziet geen wettelijke bepalingen in verband met de naleving van wet en regelgeving van het oorsprongsland
4. **Optie 1**: Een algemene strafrechtelijke bepaling wordt voorzien, die terugverwijst naar de wetgeving van het oorsprongsland inzake PIC en MAT. De staat voert een algemeen verbod in op het gebruik van genetische rijkdommen en traditionele kennis die in strijd met de wet van het oorsprongsland verkregen worden. Controle van de inhoud van de MAT door een rechter gebeurt op basis van de wetgeving van het oorsprongsland, met Belgische wetgeving als terugvaloptie.
5. **Optie 2**: Een op zichzelf staande bepaling wordt voorzien, die het verkrijgen van voorafgaande PIC en MAT van het oorsprongsland oplegt, voor het gebruik van buitenlandse genetische rijkdommen in België, indien de wetgeving van het oorsprongsland dat vereist.

Met het oog op de naleving van het Protocol van Nagoya door gebruikers moet minstens één controlepunt worden voorzien voor de monitoring van het gebruik van genetische rijkdommen en traditionele kennis in België (**maatregel 5**). Indien België besluit om controlepunten in te voeren, kan de invoering daarvan in verschillende fasen gebeuren. Gelet op het politieke engagement voor de tijdige ratificatie van het Protocol van Nagoya, zou in de eerste fase naar een minimale invoering kunnen worden gekeken, met de oprichting van één enkel controlepunt. Voor die eerste fasen lijken twee mogelijke opties relevant, nl. het monitoren van de PIC van de gebruiker, die beschikbaar is via de ABS Clearing-House (optie 1), en het upgraden van de bestaande verplichting van vermelding van de geografische oorsprong in de octrooiaanvragen (optie 2). Aangezien optie 1 en optie 2 elkaar niet uitsluiten, kan een gezamenlijke invoering worden overwogen.

Maatregel 5: een of meer controlepunten aanduiden

3. **Optie 0**: België voorziet geen controlepunten voor de monitoring van het gebruik van genetische rijkdommen en traditionele kennis.
4. **Optie 1**: het monitoren van de PIC van de gebruiker, die beschikbaar is via de ABS Clearing-House
5. **Optie 2**: Het octrooibureau wordt als controlepunt gebruikt voor de monitoring van het gebruik van genetische rijkdommen en traditionele kennis.

Tot slot zal een Belgische component van of aanspreekpunt voor het ABS Clearing-House worden voorzien, ter ondersteuning van de uitwisseling van informatie over specifieke ABS-maatregelen in het kader van het Protocol van Nagoya (**maatregel 6**). Hoewel er internationaal nog wordt gediscussieerd over de precieze modaliteiten van het ABS Clearing-House, werden de volgende drie kandidaten reeds geïdentificeerd: het Koninklijk Belgisch Instituut voor Natuurwetenschappen (optie 1), het Federaal Wetenschapsbeleid (optie 2) en het Wetenschappelijk Instituut Volksgezondheid (optie 3).

Maatregel 6: informatie uitwisselen via het ABS Clearing-House

4. **Optie 0**: Er wordt geen Belgisch component van of aanspreekpunt voor het uitwisselingscentrum voorzien.
5. **Optie 1**: Het Koninklijk Belgisch Instituut voor Natuurwetenschappen (KBIN) wordt aangesteld tot uitwisselingscentrum
6. **Optie 2**: Het Federaal Wetenschapsbeleid (BELSPO) wordt aangesteld tot uitwisselingscentrum
7. **Optie 3**: Het Wetenschappelijk Instituut Volksgezondheid (WIV) wordt aangesteld tot uitwisselingscentrum

Impact van de geselecteerde opties voor de implementatie van het Protocol van Nagoya

De mogelijke gevolgen van de invoering van de bovenvermelde opties werden geëvalueerd door middel van een vergelijkende multicriteria-analyse. Aan de hand van deze analyse konden ook de mogelijk betrokken belanghebbenden worden geïdentificeerd.

Wat de operationalisering van de toegang tot genetische rijkdommen betreft (**maatregel 1**), kwamen het "bottleneck" model (optie 1) en het aangepaste "fishing net" model (optie 3) als beste uit de analyse. De voorkeur voor deze opties kan verklaard worden door het feit dat ze verwacht worden meer rechtszekerheid te zullen bieden, een positiever impact te hebben op het milieu en beter bij de bestaande praktijken te passen dan de andere twee opties. Voor deze opties moet eerst als algemene vereiste worden ingevoerd dat voor de toegang tot Belgische genetische rijkdommen een voorafgaande geïnformeerde toestemming vereist.

Wat de specificering van de vereisten voor het opstellen van Onderling Overeengekomen Voorwaarden betreft (**maatregel 2**), scoorden de twee opties waarbij specifieke vereisten worden bepaald in Belgie (optie 2 en optie 3) beter dan de optie waarbij geen specifieke vereisten worden opgelegd (optie 1). De reden hiervoor zijn hun goede economische, ecologische en procedurele prestaties (optie 2 biedt ook nog goede maatschappelijke prestaties). Om deze opties te kunnen kiezen moet de verdeling van voordelen als een algemene vereiste worden ingevoerd in België.

Naast de oprichting van de bevoegde nationale instanties, was ook de oprichting van een gecentraliseerd aanspreekpunt duidelijk de aanbevolen optie (optie 2 van **maatregel 3**). Deze optie

scoort het best voor alle criteria; strikt genomen scoort ze ook beter op het vlak van rechtszekerheid en efficiëntie voor de gebruikers en aanbieders van genetische rijkdommen, met minder kosten.

Wat de uitwerking van nalevingsmaatregelen betreft (**maatregel 4**), scoort de optie om terug te verwijzen naar de wetgeving van het oorsprongsland (optie 1), met de Belgische wetgeving als terugvaloptie, het best. Dit valt voornamelijk te verklaren door de overeenkomst tussen deze optie en de bestaande praktijken (overeenkomstig het Belgische wetboek van internationaal privaatrecht).

Wat de aanduiding van een of meer controlepunten betreft (**maatregel 5**), is het monitoren, in het ABS Clearing-House, van de door de gebruikers verkregen voorafgaande geïnformeerde toestemming, de aanbevolen optie. Die optie scoort minstens even goed voor alle criteria, en biedt betere maatschappelijke en procedurele prestaties.

Tot slot, wat de uitwisseling van informatie via het ABS Clearing-House betreft (**maatregel 6**), gaat de voorkeur uit naar de aanstelling van het Koninklijk Belgisch Instituut voor Natuurwetenschappen (KBIN), dat voor de meeste onderzochte criteria beter presteert dan de andere opties.

Aanbevelingen volgend op de impactanalyse

Uit de impactanalyse van deze studie vloeien twee algemene aanbevelingen voort, alsook enkele specifiekere aanbevelingen voor elk van de bovenvermelde maatregelen.

Ten eerste blijkt uit de analyse dat de opties die geen beleidsverandering met zich meebrengen (de “0” optie voor elke maatregel) duidelijk de slechtste prestaties bieden. Dat resulteert in een eerste algemene aanbeveling, nl. dat zowel een voorafgaande geïnformeerde toestemming (PIC) als de verdeling van voordelen (benefit-sharing), als algemene vereisten moeten worden ingevoerd in België. Ten tweede bleek uit de analyse de meerwaarde van een gefaseerde aanpak voor de implementatie van het Protocol. Op die manier kan voordeel worden gehaald uit de tijdige invoering van de basisprincipes en kunnen specifiekere keuzes in een later stadium worden gemaakt. Bovendien is een gefaseerde aanpak nodig om het Protocol van Nagoya tijdig te ratificeren en België toe te laten om deel te nemen als een Partij bij het Nagoya Protocol tijdens de eerste bijeenkomst van de Partijen in oktober 2014.

Tot slot leverde de impactanalyse enkele specifieke aanbevelingen op voor elk van de zes maatregelen:

1. Naast de oprichting van de Bevoegde Nationale Instanties moet ook een gecentraliseerd aanspreekpunt worden uitgewerkt voor deze instanties.
2. Wat de maatregelen inzake naleving met wet- of regelgeving (compliance) betreft, moeten sancties worden voorzien wanneer de niet-naleving van de PIC en de MAT, zoals opgelegd door het oorsprongsland, wordt vastgesteld. Voor het controleren van de inhoud van de MAT zou een bepaling in het Wetboek van internationaal privaatrecht moeten verwijzen naar de wetgeving van het oorsprongsland, met Belgische wetgeving als een eventuele terugvaloptie.

3. In de eerste uitvoeringsfase zou het controleren van het gebruik van genetische rijkdommen en traditionele kennis moeten gebeuren op basis van de PIC die beschikbaar is via de ABS Clearing-House.
4. Met betrekking tot de toegang tot Belgische genetische rijkdommen is het aanbevolen bestaande relevante wetgeving inzake beschermde natuurgebieden en beschermde soorten te verfijnen, in combinatie met een algemene notificatievereiste voor de toegang tot andere genetische rijkdommen. In latere uitvoeringsfasen kan bijkomende relevante wetgeving dan worden verfijnd, en kan het verwerken van andere toegangsaanvragen overgelaten worden aan *ex-situ* collecties.
5. In de eerste uitvoeringsfase, en los van de algemene verplichting om de voordelen te verdelen, zouden er geen specifieke vereisten moeten worden opgelegd voor het opstellen van Onderling Overeengekomen Voorwaarden (*Mutually Agreed Terms*). Een combinatie van meer specifieke vereisten, met de mogelijkheid om standaardakkoorden te gebruiken, kan in een latere uitvoeringsfase worden overwogen.
6. Het Koninklijk Belgisch Instituut voor Natuurwetenschappen zou moeten gemandateerd worden om de informatieuitwisselingstaken in verband met toegang en verdeling van de voordelen in het kader van het Protocol van Nagoya te vervullen, via het ABS Clearing-House.

Implementatie van de aanbevelingen

Om deze aanbevelingen te implementeren kan voor de gefaseerde aanpak een driestappenproces worden gevolgd:

1. ALs eerste stap kan een politiek akkoord worden afgesloten tussen de bevoegde autoriteiten, die de algemene vereisten uitschrijft en een opsomming maakt van de acties die de federale overheid en de deelstaten moeten ondernemen om deze principes in de praktijk om te zetten. Hiertoe behoren onder andere:
    a. Het invoeren van de verdeling van voordelen (benefit-sharing) als algemeen vereiste in België.
    b. Het invoeren van een algemeen principe dat bepaalt dat voor de toegang tot Belgische genetische rijkdommen een PIC nodig is.
    c. Het bepalen dat van vier Bevoegde Nationale Instanties zullen worden opgericht.
    d. Het voorzien van wetgevende maatregelen die ervoor zorgen dat het gebruik van genetische rijkdommen onder Belgisch rechtsgebied onderhevig is aan voorafgaande geïnformeerde toestemming (PIC) en onderling overeengekomen voorwaarden (MAT), zoals vereist door de wetgeving van het oorsprongsland. Deze maatregelen moeten er ook in voorzien dat de niet-naleving van deze regels wordt aangepakt.
    e. Het aanduiden van het Belgisch knooppunt van het VBD Clearing-House Mechanisme, beheerd door het KBIN, als de Belgische deelname aan de ABS Clearing-House in het kader van het Protocol van Nagoya.

    De reden om een dergelijke politiek akkoord te gebruiken is tweeledig. Enerzijds verschaft het een duidelijk politiek engagement ten opzichte van de kernverplichtingen van het Protocol van Nagoya. Het vermeldt immers de intenties van de bevoegde autoriteiten, binnen de grenzen van de beslissingen die reeds op internationaal en Europees vlak werden

genomen op het moment van het akkoord. Anderzijds loopt een dergelijk akkoord niet vooruit op de politieke beslissingen die nog moeten genomen worden door de bevoegde autoriteiten en is het dus voldoende flexibel om het uitvoeringsproces in een later stadium verder aan te passen. Dit laatste is vooral belangrijk gezien de momenteel vele onbeantwoorde vragen, zowel op Europees als op internationaal vlak, die in het evaluatieverslag werden vermeld en behandeld.

2. In de tweede stap zouden de specifieke acties moeten worden geïmplementeerd, bijvoorbeeld aan de hand van een samenwerkingsakkoord en/of door bepalingen toe te voegen aan relevant wetgeving zoals de milieuwetgeving van de deelstaten en de federale overheid, naast andere mogelijke vereisten.
3. Als derde stap kunnen bijkomende acties worden ondernomen eens er meer duidelijkheid is op internationaal en Europees vlak.

1 INTRODUCTION

This study aims to contribute to the ratification and the implementation in Belgium of the Nagoya Protocol (NP) on Access and Benefit-sharing (ABS) of the Convention on Biological Diversity[9]. The need for this study was decided by the Interministerial Conference on the Environment of 31st March 2011 to allow for an early ratification by Belgium of the NP.

The objective of the study is to identify and evaluate the possible consequences for the Belgian national legislation and regulation, as well as for Belgian stakeholders, resulting from the implementation of the NP in Belgium.

The study involves four phases of work:

- Phase 1: Analysis of the regulatory framework of ABS in Belgium
- Phase 2: Identification of options and recommendations for possible measures and instruments (legal and non-legal) for the implementation of the NP in Belgium
- Phase 3: Impact analysis of the selected options
- Phase 4: Conclusions and recommendations

1.1 Background to ABS and the Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is a protocol to the UN Convention on Biological Diversity (CBD)[10]. The objective of the NP is expressed as follows:

> *The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.* (Article 1 NP)

The CBD is the main international framework for the protection of biodiversity. It has three objectives: (1) the conservation of biological diversity, (2) the sustainable use of its components and (3) the fair and equitable sharing of benefits arising from the utilization of genetic resources (GR), including through access. With currently 193 Parties, the CBD has almost universal membership. Since 1996, Belgium is a Party to the CBD, as is the EU and its other Member States.

[9] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Nagoya, 29th October 2010, available at http://www.cbd.int/cop10/doc/ (accessed 30th December 2010).

[10] United Nation Convention on Biodiversity, Rio, 5th June 1992, entered into force on 29th December 1993 and ratified by Belgium on 22nd November 1996 (*M.B.*, 2nd April 1997, pp. 7671 – 7692).

The Nagoya Protocol on ABS delineates the means of implementation of the third objective of the CBD. Its adoption reflects the accomplishment of an intensive and long-lasting negotiation inside the CBD. Negotiations on ABS in the framework of the CBD started in 1998, at the fourth Conference of the Parties (COP) of the CBD. At COP5 in 2000, an Ad Hoc Open-ended Working Group on Access and Benefit-sharing (ABSWG) was established. The ABSWG proposed a set of non-binding guidelines–the Bonn Guidelines–on access to GR and the fair and equitable sharing of the benefits arising from their utilization, for adoption by COP6 in 2002[11]. These guidelines aim to assist the CBD Parties, Governments and other stakeholders in developing an overall access and benefit-sharing strategy, establishing legislative, administrative or policy measures on ABS and/or when negotiating contractual arrangements for ABS.

Afterwards, Heads of State and Government attending the World Summit on Sustainable Development (WSSD) in August 2002 stressed the lack of tangible results in the implementation of the 3rd objective of the CBD. They included two ABS related paragraphs in the Johannesburg Plan of Implementation[12]:

- 44(n) Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization, as an input to assist the Parties when developing and drafting legislative, administrative or policy measures on access and benefit-sharing as well as contract and other arrangements under mutually agreed terms for access and benefit-sharing; and
- 44(o) Negotiate within the framework of the CBD, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources[13].

This led to the granting of a detailed negotiating mandate for the ABSWG by the CBD COP7 and negotiations were undertaken at CBD COP8 in March 2006. Guided by the Bonn Roadmap (adopted at COP8), Parties committed themselves to complete negotiations at the earliest possible time before CBD COP10 in October 2010. Formal agreement on the textual basis for the final negotiations was only achieved in July 2010, following numerous negotiation meetings between COP9 and COP10[14]. On 30th October 2010, the final plenary of CBD COP10 successfully adopted the Nagoya Protocol on "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization".

The NP elaborates on and implements the basic principles laid down in the CBD. Of relevance are its Articles 15 and 8(j), in particular:

- **States are sovereign over their natural wealth and resources**

[11] See Decision VI/24. Available at: http://www.cbd.int/decision/cop/?id=7198
[12] World Summit on Sustainable Development. Plan of Implementation. Available at: http://www.johannesburgsummit.org/html/documents/summit_docs/2309_planfinal.htm (accessed 26th March 2013)
[13] Paragraph 44(o) of the Johannesburg Plan of Implementation.
[14] For a more complete historical account of the latest months prior to the adoption of the NP see Chiarolla C. (2010), Making Sense of the Draft Protocol on Access and Benefit-sharing for COP 10. *Idées pour le débat*, Institut du Développement Durable et des Relations Internationales (IDDRI)

Article 15(1) of the CBD recognizes the sovereign right of States over their natural resources and that the authority to determine access to GR rests with the national governments and is subject to national legislation.

- **Fair and equitable sharing of benefits arising from GR utilization**
  Pursuant to Article 15(7) of the CBD, the results of research and development and the benefits arising from the commercial and other utilization of GR must be shared in a fair and equitable way with the Contracting Party providing such resources on Mutually Agreed Terms (MAT).
- **Role and importance of indigenous and local communities (ILCs) and their traditional knowledge (TK)**
  Article 8(j) of the CBD lays down that each contracting Party must, as far as possible and as appropriate and subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of ILCs embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. With the approval and involvement of the holders of such knowledge, innovations and practices, wider application should be promoted and the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices should be encouraged.

1.1.1 Adoption and entry into force of the NP

The text of the NP was formally adopted on 30th October 2010[15] and the NP was opened for signature on 2nd February 2011 till 1st February 2012[16]. Only Parties to the CBD can sign the NP and only States and Regional Economic Integration Organizations having signed the NP when it was open for signature, can proceed to ratify it[17]. Others will have to accede to the Protocol. Signature in itself does not establish consent to be bound, hence the necessity of an act of ratification[18] or accession[19].

The NP will enter into force on the ninetieth day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession by States or REIO that are Parties to the Convention[20]. The Secretary-General of the UN serves as the Depositary of the Protocol[21]. 50 ratifications or equivalent instruments are needed in order for the NP to enter into force. Consequently, there will be one single date of entry into force for the first 50 ratifying Parties, *i.e.* 90 days after deposit of the 50th instrument[22]. The ratifying Parties will be bound by treaty obligations upon entry into force. Another date of entry into force will apply for any Party depositing their act of accession after the

[15] COP 10 Decision X/1, Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. Available at: http://www.cbd.int/decision/cop/?id=12267. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Nagoya, 29th October 2010, available at http://www.cbd.int/ cop10/doc/ (accessed 30th December 2010).
[16] *Ibid*. 91 States and 1 regional economic integration organization (REIO), *i.e.* the EU, have signed the NP.
[17] The NP was open for signature by Parties to the CBD. See NP, *op. cit.*, Article 32.
[18] Ratification requires the deposit of a formal instrument following completion of internal procedures, as determined by the constitutional law of each Party.
[19] The NP remains open to accession for Parties who have not signed it during the time when it is open for signature.
[20] See NP, *op. cit.*, Article 34(1).
[21] COP 10 Decision X/1, *op. cit.*
[22] It should be noted that the EU instrument of approval is not to be counted as additional to those ratification instruments deposited by the EU Member States since the NP falls within an area of shared competences. See NP, *op. cit.*, Article 34(3).

date of deposit of the 50th instrument (*i.e.* 90 days after deposit of their instrument[23]). At the time of writing, 15 States had ratified the NP[24]. The entry into force of the NP also determines the date of the 1st Meeting of the Parties to the Nagoya Protocol (NP COP/MOP) and consequently also the decision-making capacity of this organ. COP/MOP1 is expected to be held in 2014, concurrently with CBD COP12.

Annex 1 of this report contains an analysis of the legal obligations emanating from the NP that has been provided with the terms of reference of this study, by the four Belgian environmental administrations that commissioned this study. This list serves as the background for this study.

1.1.2 Ratification process in the European Union

The EU and eleven Member States signed the NP on 23th June 2011. Eleven more did so during July/September 2011. Five Member States have not signed it (but can still accede to the Protocol)[25].

The ratification procedure is laid down in Article 218 of the Treaty on the Functioning of the European Union (TFEU). The expression of EU consent to be bound requires a Council Decision to "conclude" the NP with the consent of the European Parliament (EP). The procedure is triggered by a Commission proposal for a decision, which is submitted to the Council and the EP. The EP expresses its consent in a legislative Resolution, but not through the ordinary legislative procedure (does not involve extensive readings, the EP can only give or withhold its consent). It is for the Council to formally adopt the decision by means of Qualified Majority Voting. As required by Article 34 of the CBD, a declaration of competence is to be included in the instrument of approval, meaning that the EU must declare the extent of its competences with respect to matters governed by the NP.

Negotiations are currently on-going at EU level on the basis of a proposal from the Commission to implement the NP in the Union. The ratification of the NP by the EU is equally being prepared.

1.2 Structure of the report

Chapters 2 to 5 analyze the current state of the art of ABS in Belgium. **Chapter 2** takes stock of the current political and administrative distribution of ABS-related competences in Belgium. **Chapter 3** analyzes how genetic resources and traditional knowledge are currently addressed in Belgian law, including the legal implications of their ownership, access and use. **Chapter 4** describes currently existing policy measures and other initiatives in Belgium which are directly relevant to the implementation of the Nagoya Protocol and **chapter 5** discusses the conformity of the current situation with the obligations of the NP.

Chapter 6 then goes on by taking stock of existing measures and instruments (legal and non-legal) used for the implementation of ABS throughout the world. This allows, **in chapter 7**, for the establishment of preliminary sets of legal, institutional and administrative measures which could be

[23] The following 'acts' express the consent of a State to be bound by a treaty: ratification, accession, approval and acceptance. The legal implications, *i.e.* the binding nature of ratification, accession, approval, and acceptance are the same.
[24] Status of Signature, and ratification, acceptance, approval or accession, available at http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml (accessed 26 March 2013)
[25] Estonia, Latvia, Malta, Slovakia and Slovenia.

implemented in Belgium. The recommended measures are divided into two separate sets: the first one containing actions to be taken in case of minimal implementation of the core obligations stemming from the NP and the second one containing measures in case of additional implementation. The core obligations reflect the obligations identified in the terms of reference of this study as requiring special attention.

Chapter 8 presents and describes the different options for the minimal implementation of core measures stemming from the NP. Those options were discussed at the first stakeholder meeting on the 29th of May 2012[26]. Based on the results of the stakeholder meeting, the options to be further examined were selected by the Steering Committee of this study and submitted to an in-depth analysis of environmental, social, economic and procedural impacts.

Chapter 9 analyzes the implementation modalities of the options described in chapter 8, taking into account the existing legal and institutional situation in Belgium described in chapters 2 to 5.

Chapter 10 then analyzes the potential impact and compares the selected options through a multi-criteria analysis using the set of evaluation criteria described below. A ranking of the options is also established.

Finally, **chapter 11** outlines some recommendations for a set of instruments and measures (legal or non-legal) for the implementation of the Protocol in Belgium.

1.3 Scope of the study

In order to realize the objectives of the Convention on Biological Diversity and the Nagoya Protocol, this study aims to contribute to the ratification and implementation of the Nagoya Protocol in Belgium. It is based on the list of legal obligations emanating from the NP (Annex 1) provided with the terms of reference of this study, by the four Belgian environmental administrations that commissioned this study.

For this study, access and utilization of GR are analyzed in the context of the scope of the Nagoya Protocol. The Protocol applies to GR that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the GR in accordance with the Convention on Biological Diversity (Article 15.3, CBD). Countries of origin are countries that possess those GR in *in-situ* conditions (Article 2, CBD). In Belgium this means that these GR exist within ecosystems and natural habitats in Belgium, or, in the case of domesticated or cultivated species, in the surroundings in Belgium where they have developed their distinctive properties (Article 2, CBD). The status of the GR in *ex-situ* conditions that have been acquired before the entry into force of the Nagoya Protocol is still under discussion. Therefore, this report only considers the

- GR that a provider country possesses in *in-situ* conditions and
- GR in *ex-situ* collections acquired after the entry into force of the Nagoya Protocol and/or in accordance with the obligations of the Convention on Biological Diversity.

[26] Report of the stakeholder meeting is available here: http://www.biodiv.be/implementation/cross-cutting-issues/abs/workshop-np-20120529/20120529-nagoya-stakeholder-workshopreport-final.pdf

It is further important to highlight the provisional nature of the findings presented in this document, as the on-going discussions around the implementation of the Nagoya Protocol in international and European *fora* will further influence the application of the results of this study.

2 THE DISTRIBUTION OF ABS-RELATED COMPETENCES IN BELGIUM

In Belgium, competences relating to ABS are divided between the federal level, the Regions and the Communities. This distribution results from successive transfers of competences to federated entities through the five state reforms since 1970[27], the general contours of the sixth state reform having being enacted in 2011[28]. As a general principle, federated collectivities possess the full competence for matters that have been attributed to them, while the Federal State possesses those competences that have been reserved on its behalf by the Constitution or legislation enacted with special voting quorums, as well as those residual competences that have not been otherwise attributed to other entities[29]. ABS potentially encompasses a large range of issues extending far beyond sole environmental matters, including market regulation and access, international trade, agriculture, health, development cooperation, research & development and innovation. Consequently, several departments and several levels of competence could be responsible for the future implementation of the NP, at federal, regional and community level[30]. It should however be noted that in 1995, the Regions and the Federal Government have concluded a cooperation agreement on international environmental matters. This cooperation agreement provides inter alia for an Intra-Belgian coordination framework supplied by the Coordination Committee of the International Environment Policy[31] that is used for preparing the implementation of the Nagoya Protocol in Belgium.

[27] Belgian State reforms were performed in 1970, 1980, 1988, 1993 and 2001. The main provisions pertaining to these reforms are to be found in the "special law" dated 8th August 1980 related to the general institutional reforms, and the special law of 12th January 1989 pertaining to the institutions of the Brussels Region.

[28] The sixth reform will follow on the footsteps of the institutional agreement adopted on 11th October 2011 and operate additional transfers of competences towards federated entities, especially the Regions. However, this reform, which has not officially been transcribed into applicable legislative texts, shall not highly affect the distribution of competences that may be linked with ABS.

[29] This principle applies notwithstanding the future entry into force of Article 35 of the Constitution.

[30] The Nagoya Protocol has been declared a double mixed treaty by the Working Group on Mixed Treaties on 22/11/2010. A double mixed treaty indicates that the competent entities for its implementation are the Governments of the Regions (Flemish, Walloon and Brussels-Capital Region), the Governments of the Communities (Flemish, French and German Community) and the Federal Government (see also the analysis in chapter 2 on the distribution of ABS related competences in Belgium).

[31] Accord de coopération du 5 avril 1995 entre l'Etat fédéral, la Région flamande, la Région wallonne et la Région de Bruxelles-Capitale relatif à la politique internationale de l'environnement / Samenwerkingsakkoord van 5 april 1995 tussen de Federale Staat, het Vlaamse Gewest, het Waalse Gewest en het Brussels HoofdstedelijkGewest met betrekking tot het internationaalmilieubeleid.

2.1 The political distribution of ABS-related competences

2.1.1 Environmental policy

The main principle pertaining to the distribution of competences with regard to environmental policy and nature conservation is laid out in Article 6-§1, II and III of the special law (SL) of institutional reform dated as of 8/8/1980, which provides for the so-called exclusive regional "competence block" in accordance with Article 39 of the Constitution. This Article has been modified numerous times, especially in 1993, where the competences attributed to regions were notably strengthened. Today it is the three Regions (Flemish Region, Walloon Region and Brussels Capital Region) that are competent on overall environmental policy, and thus have the greatest responsibility in biodiversity-related issues. However, applicable legislation also reserves a number of competences to the Federal State, as an "exception" to the general competence on environmental policy and nature conservation of the Regions.

When reading the text through the lens of ABS issues, it becomes clear that the **Regions** are *inter alia* responsible for the following environmental matters[32]:

- the protection of the environment, notably of the soil, subsoil, water and air against pollution (…);
- nature conservation;
- the protection and conservation of nature;
- green area zones, park zones, green areas;
- forests;
- fluvial fishing and fish farming;
- non-navigable waterways, including verges, and polders.

Although environmental matters are in principle a regional competence, the **Federal Government** has retained some reserved competences on the following ABS-related environmental matters in accordance with the special law 8/8/80, as an exception to the general regional competence on environmental matters:

- Article 6§1, II indent 2 of SL 8/8/80: the establishment, for purposes of environmental protection, of product norms for market access (regional governments need to be consulted when drafting these norms).
- Article 6§1, III, 2° of the SL 8/8/80: the export, import and transit of non-indigenous plant varieties as well as non-indigenous animal species and their cadavers.

[32] Article 6§1, II of the SL 8/8/80, 1° and Article 6§1, III, 2°, 3°, 4°, 6° and 7° of the SL 8/8/80; See also Geeraerts K, Bursens P, Leroy P(2004) Vlaams milieubeleid steekt de grenzen over. De Vlaamse betrokkenheid bij de totstandkoming van Europees en multilateraal milieubeleid. *Steunpunt Milieubeleidswetenschappen*

As the Belgian territorial sea is not considered a part of the territory of (one of the) Regions, the exercise of environmental and nature conservation competences within the Belgian territorial sea is considered to fall under the residual competence of the Federal Government.

Having specific regards to the potential changes in the distribution of competences triggered by the current sixth reform of the State, competences regarding ABS related environmental policy are not expected to significantly change[33].

2.1.2 Agricultural policy and maritime fishery

Agricultural policy, including the application of the European CAP measures is a regional competence in accordance with Article 6-§1 V of the SL 8/8/80. However, Regions are not responsible for the standardization and monitoring of the quality of raw and vegetal material and the standardization and monitoring of animal welfare in order to ensure the security of the food chain, as these are reserved federal competences. The agreement of regional governments should be sought with regard to animal welfare measures affecting agricultural policy. It should be noted that animal welfare legislation shall be transferred to Regions in the near future, in accordance with the terms of the 2011 institutional agreement establishing the framework for the sixth State reform.

Furthermore, those quality or origin labels that possess a regional or local character (such as geographical indications for instance), are included within the realm of the regional competences (Article 6-§1 VI, alinea 5, 4°, of SL 8/8/80 that excludes these measures from those competences reserved to the federal level).

2.1.3 Research and development

Before the third 1988 state reform, the Federal Government was responsible for virtually all research and development (R&D) related activities. With these amendments, major research-related competences where transferred to the federated entities. Fundamental research and higher education, as well as the regulation of researchers' funding and the management of research institutions were transferred to the French and the Flemish Communities, as exclusively cultural subject-matters falling under the scope of Article 127 of the Constitution and Article 4 of the special law of 8/8/80. The 1993 state reform confirmed this evolution by making the federated entities the prime responsible authorities in matters of R&D[34].

[33] However, it might be relevant to note that the botanical garden located in Meise is mentioned in the transfers of competences that the reform would operate. This transfer is subject to the ratification of a cooperation agreement, the so-called "Peeters-Demotte" plan enacted in 2008 but that has not yet been adopted. The agreement states that the botanical garden's estate and management would fall within the federated competences (of the Flemish Region), under specific conditions. Indeed, the current collections would remain under federal ownership, as these would be considered as "leased" to the Flemish Region and the Flemish Community for a limited period, and the access to collections would be open and free of charge to "all researchers", while "mainstream collections" would be accessed at the same price for all visitors.

[34] Wautrequin J. (2011), Nouveaux Transferts de Compétences en Matière de Politique Scientifique? Critères D'appréciation. *Intervention au colloque 'Paroles de chercheurs. Etats des lieux et solutions'*, 4 mars 2011 ; Goux C. (1996), *La recherche scientifique dans la Belgique fédérale: examen de la répartition des compétences*, Série Faculté de droit de Namur Centre de droit régional, La Charte, Bruges.

With the insertion of Article 6bis into the special law of 8/8/80, **Communities and Regions** – and thus not only the federated entities falling under the scope of Article 127 of the Constitution - have become "competent with regard to scientific research within the framework of their respective competences, including research carried out in execution to international agreements or acts".

Communities and Regions became thus competent in the field of research related to the exercise of their respective Community competences. As for the **Regions**, they are notably responsible for R&D activities in the following fields[35]:

- economically oriented and industrial research, *i.e.* research or critical investigation aimed at discovering knowledge and skills to develop new products, processes or services, or a significant improvement of products, processes or services;
- support for R&D and innovation;
- research for technological development;
- knowledge diffusion in the industrial sector;
- research related to the exercise of other Regional competences.

Finally, the Federal Government, remains nonetheless "competent for scientific research that is necessary to the execution of its own competences, including those carried out in execution of international agreements or acts" (Article 6 bis-§2). In accordance with Article 6bis-§2 the federal level also remains competent with regard to[36]:

- the implementation and organization of data exchange networks between scientific institutions on the national and international level;
- the scientific and cultural federal institutions, including their research and public service activities;
- the programs and actions requiring a homogenous implementation on the national and international level in the fields and according to the modalities set out by the cooperation agreement aimed at in Article 92bis-§1 of the special law;
- the holding of a permanent inventory of the scientific potential of the country;
- the participation of Belgium to the activities of the international research organizations according the modalities set out by the cooperation agreements aimed at in Article 92bis-§1 of the special law;

Moreover, the Federal Government can take initiatives, establish structures and provide financial resources for scientific research for the matters that are of regional or community competence, but are related to national or international agreements to which Belgium is a Party, or are related to actions and programs exceeding the interest of a Region or a Community. In that case, the Federal Authority must first submit a proposal for cooperation to the Regions and Communities.

[35] *Ibid.*
[36] *Ibid.*

The sixth state reform contains a number of measures that might influence the vertical distribution of ABS related competences, as both interuniversity and technological attraction poles would respectively be transferred to Communities and Regions.

2.1.4 Economic and industrial policy

The second state reform of 1980 granted economic and industrial competences to the Regions[37]. Viewed in the ABS context, the relevant subject-matters of these exclusive **regional** competences are listed in Article 6§1 VI of the SL 8/8/80 and include (without being limited to):

- economic policy, (Article6-§1 VI, indent1°);
- export policy, without prejudice to **federal** competences in terms of both the grant of warranties against risks of import, export and investment, and of multilateral trade policy (Article 6§1 VI, indent3°b). The Federal Authority holds besides a full competence on the control and monitoring of import and export of goods and services;
- natural resources (Article6-§1 VI, indent5°).

Furthermore, Article 6§1 VI, alineas 4 and 5 designates some reserved competences of the **Federal Government**. With specific regards to the regulation of ABS-related economic matters, the Federal Authority is competent for the general rules related to the organization of business (Article 6§1 VI, alinea 4,3°). It conserves also a full competence for the following matters:

- Competition law and trade practices, excluding the assignment of quality labels and designations of origin, regional or local character, which are attributed to the **Regions** (Article6§1, VI, alinea 5, 4°);
- Industrial and intellectual property (Article6§1, VI, alinea5, 7°);
- contingent and permits, for import and export of industrial and agricultural products(Article6,-§1, VI, alinea 5, 8°);

2.1.5 Foreign policy and development cooperation

Since the 1993 revision of the Constitution, the regulation of international relations is divided according to the principle '*in foro interno, in foro externo*': the **Federal Government**, the Communities and Regions are all responsible for foreign policy related to their respective material competences[38].

Currently, the development cooperation is a shared competence between the Federal Authority, the Regions and the Communities. In this framework, the Federal Authority holds a general competence,

[37] Article 6,-§ 1er, VI de la loi spéciale du 8 août 1980 de réformes institutionelles / Artikel 6,-§ 1st, VI van de wet van 8 augustus 1980 tot hervorming der instellingen

[38] Duran M. & Criekemans D. (2008), *Een vergelijkend onderzoek naar en bestedingsanalyze van het buitenlands beleid en de diplomatieke representatie van regio's met wetgevende bevoegdheid en kleine staten. Rapport*, Antwerpen: Steunpunt Buitenlands Beleid, 418 p

whose scope is thus not limited to the other federal material competences. As for them, the Regions and Communities are only competent for the matters related to their material competences[39].

2.2 The administrative distribution of ABS-related competences

2.2.1 At the federal level

The main public service at the federal level competent for the implementation of ABS is the **Federal Public Service for Health, Food Chain Safety and Environment** (FPS Health, Food Chain Safety and Environment). The Directorate-General for the Environment (DG5) is involved in the negotiation and follow-up of a number of international environmental treaties related to its competences. In order to set up the Belgian position at EU and international level, a coordination process with other federal departments and with the federated entities is established since 1995 through the Belgian Coordination Committee on International Environmental Policy (CCIEP). The DG5 is also responsible for the protection of the North Sea and deals with trade in animals and plants through the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Two of its civil servants currently serve respectively as the "Belgian Focal Point for Access and Benefit-sharing" to the CBD and as Belgian Focal Point for Genetically Modified Organisms (GMO) issues related to the Cartagena Protocol. The DG Animal, Plant and Food (DG4) of the FPS Health, Food Chain Safety and Environment, is responsible for the protection against plant diseases, the standardization of food and cosmetic products and the part of the regulation of GMOs.

ABS measures might however encompass much more than environmental competences. Hence, a lot of other federal services and administrations might need to contribute to the implementation of ABS in Belgium. The **Science Policy** (BELSPO) of the **Federal Public Planning Service** is in charge of the scientific aspects of sustainable development at the federal level and of the implementation of the international obligations of the CBD. It manages long-term scientific support schemes for the federal sustainable development policy. It assures the financing of research activities and makes funds available for CBD implementation and overarches several scientific institutions, including the Royal Belgian Institute of Natural Sciences (RBINS) and the Royal Museum for Central Africa (RMCA), which are major players in Belgian scientific expertise in the field of biodiversity. RBINS ensures the function of Belgian National Focal Point (NFP) to the CBD and the Clearing-House Mechanism (CHM). BELSPO also supports the Federal Council for Sustainable Development (CFDD-FRDO). This council advises the Federal Government on its policy on sustainable development. Particular attention is given to the implementation of international obligations, such as those under the Convention on Biological Diversity. The Interministerial Conference on Science Policy serves as the consultative body between Federal Government and federated entities.

[39] As for the development cooperation field, the State Reform of 2001 intended to further clarify the distribution of competence between the federal and federated entities through the new Article 6ter of the SL8/8/80 that reads: "certain fragments of development cooperation will be transferred on 1st January 2004, to the extent which they concern competences attributed to Communities and Regions (Inserted by Article 41 of the special law of 13th July 2001 (*M.B.*, 3rd August 2001), which has entered into force on 1st January 2002). A specific working group is constituted to propose a list of subject-matters concerning Community and Regional competences at the latest on 31st December 2002. Such a working group was created in 2004 to solve the issue but has not yet led to any conclusion.

Another relevant public service is the **Federal Public Service for Economy, SMEs, Middle Classes and Energy** (FPS Economy), which is responsible for the overall functioning of markets and the commercialization of (biodiversity-related) goods and services as well as for the regulation of their market approval. Its Directorate-General for Market Regulation and Organization (E3) is responsible for the functioning of the markets for goods and services. Its mission is to create a legal and regulatory environment favorable to business, and to promote effective and fair competition between them. Through the "Immaterial Economy" Service, E3 covers the legal and regulatory framework of intellectual property rights. This service is also responsible for the dissemination of information on these rights and on the technical information to be found in patents. The Directorate-General for Economic Potential (E4) is competent for the follow-up and monitoring of key economic sectors which fall under the competences of the Federal Government. It represents and coordinates Belgian efforts in the international economic institution such as the WTO. This DG is also responsible for allowing or denying the right to import and export goods and services. The FPS Economy also hosts the National Institute of Statistics, which is in charge of compiling the Belgian data on biodiversity, as well as the Belgian Office for Intellectual Property (DIE/OPRI). The DIE/OPRI manages the attribution of industrial property titles, informs users regarding intellectual property, advises Belgian governments and represents Belgium at the WIPO. The Office is advised by field-experts and specialists gathered in thematic councils. Relevant councils include the Council for Plant Variety Rights and the Council for Intellectual Property.

The **Federal Public Service for Finances and the Administration of Customs and Excises**, is responsible for the collection of excise duties on imported products, for the monitoring of trade in exotic and endangered plant and animal species under CITES and for the monitoring of import of timber under the Forest Law Enforcement Governance and Trade (FLEGT).

The **Federal Public Service for Foreign Affairs, Foreign Trade and Development Co-operation** regroups different sections which are directly related to the CBD and ABS. Foreign Affairs is responsible for the diplomatic aspects of international negotiations such as those at the CBD. It makes sure the Belgian position in different international forums is consistent. Foreign Trade is in charge of the regulation of international trade of goods and commodities. This service also coordinates the Belgian representation for multilateral trade policy (WTO, OECD) and European trade policy. For foreign economic missions, the FPS is assisted by the parastatal Belgian Foreign Trade Agency which coordinates federal and regional efforts in this matter. The Directorate-General for Development Cooperation (DGD) implements Belgian development cooperation projects. Together with associated research institutions it manages and provides funding and structural assistance for research, capacity building and awareness-raising projects under the CBD. The DGD also manages the Belgian financial contribution to the CBD and the Global Environmental Facility (GEF). It is supported by the Belgian Technical Cooperation (BTC) which is exclusively responsible for implementing direct bilateral cooperation set up by DGD, including biodiversity related cooperation.

The **Federal Service for Justice** regroups various missions which includes the preparation of legislation for the Minister of Justice, the supervision of the operational support to the judiciary power and the monitoring of the execution of administrative and judicial decisions.

2.2.2 At the regional level

Regional environmental administrations, the Bruxelles Environnement/Leefmilieu Brussel (IBGE-BIM), the Departement Leefmilieu, Natuur en Energie (LNE) of the Flemish government and the Direction générale opérationnelle Agriculture, Ressources naturelles et Environnement (DGARNE) of the Service public de Wallonie are the main official authorities for conservation and sustainable use of biodiversity and genetic resources. These administrations are generally flanked by specialized public agencies such as the Flemish Instituut voor natuur - en bosonderzoek (INBO) or the Flemish Agency for Nature and Forest (ANB) (http://www.natuurenbos.be/), or specific internal administrative units like the Walloon Département de l'Etude du milieu naturel et agricole (DEMNA) among many others.

But these power levels also have a strong (and heterogeneous) horizontal breakdown when it comes to ABS-related competences. In Flanders, environmental matters are separated from agricultural matters, for which the Department Landbouw en Visserij is responsible. This is not the case in Wallonia, while in Brussels it is managed by the economic department (Bestuur Economie en Werkgelegenheid, BEW/ Administration de l'Economie et de l'Emploi, AEE).

The **administrations responsible for foreign trade** on the one hand, **and for innovation and research policy** on the other could play a major role in the regulation and monitoring of non-public research activities, as they are responsible for economically oriented, industrial and innovation research. The following administrations are responsible for these competences:

- In Flanders, Departement Economie, Wetenschap en Innovatie (EWI);
- in Wallonia, Direction générale opérationnelle Economie, Emploi et Recherche (GDO 6);
- in Brussels, BEW/AEE.

Each region has its own **foreign policy administration**, as well as agencies in charge of development cooperation:

- In Wallonia, Wallonie-Bruxelles International (WBI) ;
- in Flanders, Departement Internationaal Vlaanderen and Vlaams Agentschap voor Internationale Samenwerking (VAIS);
- in Brussels, foreign policy is taken care of by the Secretariat General of the Region.

Partly linked to these foreign policy administrations are the regional bodies promoting foreign trade. The Agence wallonne à l'Exportation et aux Investissements étrangers (AWEX), Flanders Investment and Trade (FIT) and Brussels Export, are responsible for the management of international entrepreneurship of regional companies and the accommodation of international companies in Belgium.

Finally, **Communities** are also competent for **research, related to the exercise of other Community competences**. The following administrations are specifically responsible for research related competences:

- In the French community, the General Administration for Education and Scientific Research (Fédération Wallonie-Bruxelles).
- In the Flemish community: Administration of Higher Education and Research.

No specific administration is assigned with research in the German Community, but if necessary the Ministry of the German Speaking Community could take the required administrative steps to exercise this competence.

2.3 The inter- and intra-level coordination of the exercise of ABS-related competences

The conclusion of international agreements that fall under the competence of the federal and of federate entities is regulated by the coordination agreement for mixed treaties. This agreement considers three types of international treaties in Belgium[40]: (1) treaties under the exclusive federal competence, (2) treaties under the exclusive competence of the Regions and/or Communities and which are concluded and ratified by the regional and/or community Governments and (3) "mixed" treaties when the agreement covers both the competence of the federal and federate entities. The first two types of treaties do not necessarily require coordination between federal and regional authorities. The "mixed" treaty however, must be concluded by a special procedure, agreed on by all concerned Governments, and must also be approved by all competent parliaments.

The different power levels coordinate their environmental policy in cross-departmental ways through the **Belgian Coordination Committee on International Environmental Policy** (CCIEP), for which the secretariat is provided by the Federal Public Sevice for Environment. The CCIEP assigns the task to a specific coordination body (*e.g.* an existing CCIEP Steering Committee, an ad-hoc Steering Committee, or a coordination group) and appointed experts of the different relevant governments for dealing with specific issues[41]. Considering the distribution of competences described previously, the CBD and the NP are obviously "mixed" treaties. The federal and federated governments coordinate issues related to the CBD and the NP through the Biodiversity Steering Committee of the CCIEP. For ABS-related matters, a specific ABS contact group was created under the CCIEP Biodiversity Steering Committee. In cases in which no consensus can be reached through the CCIEP, contentious issues or political issues can be transferred to the Interministerial Conference on the Environment.

[40] Paquin S. (2003), Paradiplomatie identitaire et diplomatie en Belgique fédérale : le cas de la Flandre. *Canadian Journal of Political Science/Revue canadienne de science politique* (2003), 36 : pp 621-642

[41] Geeraerts, K., Bursens, P., Leroy, P. (2004), *Vlaams milieubeleid steekt de grenzen over. De Vlaamse betrokkenheid bij de totstandkoming van Europees en multilateraal milieubeleid,* Steunpunt Milieubeleidswetenschappen, Antwerp, UA.

3 LEGAL STATE OF THE ART REGARDING ABS IN BELGIUM

3.1 Access and use of genetic resources under national jurisdiction in Belgium

For the analysis below, there are important preliminary distinctions to be highlighted. First, a distinction has to be made between the question of legal ownership of genetic resources in their quality of material goods on the one hand, and the regulation of the access and use of genetic resources according to the Nagoya Protocol as an exercise of a sovereign right (pursuant to Article 15.1 CBD) on the other.

Second, it is important to recall the definitions included in the text of the CBD. Article 2 clearly distinguishes between “genetic material” that is defined as any material of plant, animal, microbial or other origin containing functional units of heredity on the one hand, and “genetic resources” that are defined as genetic material of actual or potential value on the other. These definitions make it clear that "genetic resources" are a subset of "genetic material”. The distinction between the two terms on the basis of whether or not the material is "of actual or potential value" seems to signify that genetic material only becomes a genetic resource when a use can be or is likely to be ascribed to it[42].

The Belgian State holds sovereign rights over its genetic resources and as such can regulate the access and use of these resources by public law measures, as long as these are justified (which in this case would be in particular in the context of the objectives of the CBD and the Nagoya Protocol) and are proportionate to those objectives.

Access to genetic resources in their generality (as genetic material having actual or potential value) is not as such yet regulated by Belgian public law measures. However, physical access to genetic material is regulated through various private law provisions and through public regulation of access to genetic materials in national parks and protected species. As this might be relevant in enacting public law measures on genetic resources, physical access to genetic material, including the question of legal ownership over genetic materials as biophysical entities, is briefly discussed hereafter, as well as the legal stakes related to the “informational component” of the genetic resources.

3.1.1 Legal status of genetic resources under Belgian legislation

The major part of the currently available national provisions addressing the status of and access to genetic resources relates to the regulation of physical access to the genetic material itself, as found in property law and the liability and redress options made available under both civil and criminal procedures related to the enforcement of property rights. The conditions and rules surrounding the legal ownership of genetic material follow from those governing the ownership of the organism as a whole. Eventual restrictions of use can be put upon genetic resources’ informational component

[42] Glowka, L., Burhenne-Guilmin, F., Synge, H., in collaboration with McNeely, J., A. and Gündling, L. (1994), *A guide to the convention on biological diversity*, Environmental Policy and Law Paper No. 30, IUCN Environmental Law Center

through intellectual property rights. The violations of both property rights and intellectual property rights are sanctioned through criminal and civil liability procedures, mainly directed at theft charges. Unauthorized access to the informational component of genetic resources is as such today not sanctioned by legislation pertaining to property rights, but should rather be sought under the umbrella of concealment or breach of trust proceedings.

3.1.1.1 Physical access to genetic material subject to property law

Belgium is a civil law country, with a property regime centered on the exercise of three categories of prerogatives that follow from legal ownership of goods: the right to use the good (*usus*), to perceive its benefits and fruits (*fructus*) and to alienate it (*abusus*).

The central tenets of the right to property established by Articles 544 to 546 of the civil code are as follows[43]:

- The property of soil includes the property above and beneath (Article 552 of the civil code), limited in its concrete application by laws and regulations pertaining for instance to the exploitation of mines (as by the Decree of Walloon Regional Council of 7th June 1988, *M.B.,* 27th January 1989)
- The property extends to all the fruits and the products generated by the material good (Article 546 of the civil code), except when the production is the result of a third party's activity, in which case the proprietor would have to reimburse the costs of labor and seeds borne by the third party, in accordance with the theory of unjust enrichment of Article 548 of the civil code ("enrichissement sans cause")
- The property of soil extends to all that is united and incorporated to it, to everything that constitutes its accessory through mechanisms coined natural or artificial accessions regulated by Article 546 of the civil code[44].

Therefore, the conditions and rules surrounding the legal ownership of the genetic material as a biophysical entity (such as a plant specimen, a microbial strain, an animal, etc.) follow from those governing the ownership of the organism as a whole:

- If the organism as a whole is "***res nullius***": then the *bona fide* possession of the organism or the specimen leads to legal ownership of the genetic material.
    - Example: bees as governed by Article 14 of the rural code, which states that when a swarm is in liberty, it is *res nullius*, until it settles on a specific beehive, where it becomes the property of the person who owns the land to which the hive is attached; also fish in rivers, wild animals, etc.
- If the organism as a whole is **personal property** that is by definition movable: then the legal ownership of the genetic material is a consequence of the legal ownership of the organism as a whole.

[43] Van Den Haselkamp-Hansenne V. (2011), L'étendue de la propriété immobilière. In X., *Guide de droit immobilier*, 2011, liv. 64, Kluwer, Waterloo, sections I.5.-1 to I.5.3.-4

[44] Hansenne J. (2011), L'accession immobilière, *in* X., *Guide de droit immobilier*, 2011, liv. 64, Kluwer, Waterloo, sections I.8.-1 to I.8.4.-1.

- Example: flowers bought on the market

- If the organism as a whole is a **real property (immovable) by incorporation or destination** falling under the realms of full private property: then the legal ownership of the genetic material is a consequence of the legal ownership of the organism as a whole. The holder of this private property can be the state (if the good is on state land) or a private person (if the good is on private land)
  - Example: Article 524 of the civil code governing domestic animals in cages; trees; etc.

Property over a specimen and/or its genetic code means that the proprietor possesses, in accordance with the central tenets of Belgian national law, the rights to use, perceive the benefits and alienate the specimen.

3.1.1.2 Access to the informational component of genetic resources

In today's growingly digitalized world, access to the informational, rather than the biophysical component of genetic resources can be quite easily provided for, yet difficultly controlled. As opposed to genetic resources' physical specimens, these resources' informational components may constitute a *res communis* viewed as "things (as light, air, the sea, running water) incapable of entire exclusive appropriation, thereby owned by no one and subject to use by all". However, these resources might also be viewed within a property regime parallel to that of the material components of GR for reasons of clarity and legal coherence.

As such, access to such informational components is today not covered by subject-specific legislation, as it does not fall under property laws. The exercise of some use rights can however be limited through intellectual property rights that have been recognized on portions, functions, or uses of biological material resulting from innovations on these materials (precluding thus the material or the information as it directly found in nature)

3.1.1.3 Genetic resources subject to intellectual property law

In the context of the discussion on the relevant legislation on intellectual property law, it is important to remember the scope of this study. This report only considers the genetic resources that a provider country possesses in *in-situ* conditions or has acquired in accordance with the obligations of the Convention on Biological Diversity. Moreover, for these resources, it considers possible measures for implementing the Protocol in relation to the exercise of national sovereignty of States over these resources in their generality.

Therefore, the discussion on intellectual property rights (IPR) is relevant insofar it is related to the further downstream utilization of genetic resources. This discussion will be particularly useful for evaluating the best available options for the monitoring process, *e.g.* a patent application might be an indication of commercial interest in the genetic resource and an upgraded patent application could potentially be used as a checkpoint.

The competence pertaining to intellectual property rights is reserved to the federal level, as a formal exception to the attributed competence of regions in terms of economic policy (Article 6§1 VI, indent

4, 7° of SL8/8/80). However, protection tools which constitute designations of origin with a regional or local character fall under regional competence (Article 6§1 VI, indent 4, 4° of SL8/8/80).

In this framework, three categories of IPR protection can be distinguished: **patents**, **plant variety rights** and **geographical indications**.

In Belgium, **patents** are regulated mainly by the law of 28th March 1984. A patent is an "exclusive and temporary right to exploit any novel invention that also implies an inventive step while being susceptible of industrial application" (Article 2).

The law states that "inventions are patentable even when they relate to biological material or contain a process that enables the production, treatment or use of the biological material" (Article 2). Furthermore, "a biological material isolated from its natural environment can be subject to patent protection, even when it pre-existed under its natural state". Patents are for instance quite often granted for molecular markers that are developed to assist plant breeders in the identification of interesting genetic sequences. Recent European case-law has however reduced the possibilities surrounding the patentability of so-called "native traits" and of "conventional breeding techniques"[45].

However, a general research exemption to the rights granted by patents is provided by the law. These rights do not extend to "acts accomplished in a private environment and for non-commercial purposes, nor to acts accomplished for scientific purposes on and with the object of the patented invention" (Article 28§1 (indents 1 and 2) of the 1984 law, as amended by the law of 28th May 2005). The exact scope of "research on and with" has been defined in the "travaux préparatoires" of the 2005 amendments of the law, indicating that "research on" relates to "acts accomplished for experimental reasons that verify the function, the efficiency or the operational nature of the patented object". "Research with" relates to "acts accomplished for experimental reasons where the patented invention is used to research something else, as a tool or instrument"[46]. Scientific purposes should in this regard be understood in a large sense.

Following obligations stemming from the CBD (particularly its Articles 8(j), 15 and 16), the patent law has been amended to include a (qualified) origin indication requirement, if the origin of the material is known (Article 15§1(6))[47]. In order for the patent application to be admissible, the filing must

[45] Indeed, according to the European Patent Office, a process for plant production that contains steps of crossing the entire genome of plants followed by the selection of obtained plants is not patentable. These steps should be seen as "essentially biological", as mentioned in Article 53 (b) of the 1973 Convention on the European patent; See DEN HARTOG, J., (2011), "Interpretatie van Article 53(b) EOV; werkwijzen van wezenlijke biologische aard", *BIE,* pp. 20-23.

[46] Projet de loi modifiant la loi du 28 Mars 1984 sur les brevets d'invention, en ce qui concerne la brevetabilité des inventions biotechnologiques, Rapport fait au nom de la Commission des Finances et Affaires Economiques par Mme Zrihen, *Doc.Senat*, sess. 2004-2005, no.3-1088/3, p.3.
See also Van Overwalle G. (2004), Van groene muizen met rode oortjes: de EU-Biotechnologierichtlijn en het Belgisch wetsontwerp van 21st September 2004. *IRDI,* pp. 357-386 (at p.378)

[47] This clause is a transposition of Directive 98/44/EC of 6th July 1998 on the legal protection of biotechnological inventions, which takes Articles 8(j) and 15 of the CBD into consideration. Its preamble notes that in case an invention is based on biological material of plant or animal origin or if such material is used, the patent application should, where appropriate, include information on the geographical origin of such material, if known. The Directive furthermore stresses that Member States must give particular weight to Article 8(j) of the CBD when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive. The Directive is motivated by the need to develop a

contain a statement regarding the geographical origin of the biological material that has been used as a basis for the invention, if known[48].

Plant variety right protection is granted to those new, distinct, stable and uniform plant varieties. A variety is defined in Article 2 of the law of 10th January 2011[49] as "a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeders' rights are fully met, can be:

- defined by the expression of the characteristics resulting from a given genotype,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged".

As a consequence, the production, reproduction, conditioning for the purpose of propagation, sale, marketing, import, export or stocking of this variety would need the authorization of the breeder (Article 12 of the law of 10th January 2011), with the exception of certain specific prerogatives granted for research on the material and breeding with the variety, as well as for certain flexibilities recognized towards small farmers (Articles 14 and 15).

Plant variety rights also enjoy research and breeding exemptions. The plant variety rights do not extend to "acts accomplished in a private capacity and for non-commercial purposes, acts accomplished in an experimental capacity or acts accomplished in view of creating or discovering and breeding new varieties" (Article 15 of the law of 10th January 2011on plant variety rights).

Plant variety rights were formerly regulated in Belgium by the law of 20th May 1975, which has been recently abrogated and replaced by the law of 10th January 2011. The law of 10th January 2011 has not yet entered into force[50], but gives nonetheless the necessary general framework so as to put Belgium in conformity with the provisions of the 1991 UPOV Convention (Union for the protection of plant variety rights).

Geographical Indications (GI) are names used to describe a specific agricultural product or a foodstuff that is protected due to its regional and local nature, within general agricultural quality

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common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPS Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

[48] This requirement is much narrower than the first proposed Bill, which stated that non-compliance with CBD provisions would be considered as contrary to the public order and morality, while the Council of State declared that such obligation would deviate from the initial objective of transposition measures and run counter to the objective of achieving effective harmonization throughout the European Union. See Van Overwalle G. (2006), Implementation of the Biotechnology Directive in Belgium and its After-Effects*. International Review of IP and Competition Law*, 37:8,pp. 889-1008 (especially at pp. 895-897)

[49] Loi du 10 janvier 2011 sur la protection des obtentions végétales

[50] See. Article72 of the law for the conditions of its entry into force, which render the mandatory force of the text conditional to the adoption of a royal decree, which has to this day not yet been adopted. As long as the required Royal Decree has not been adopted, the relevant legal framework is still the law of 1975.

policies. GI's are usually distinguished between protected designation of origin (PDO), protection of geographical indication (PGI) and traditional specialty guaranteed (TSG) in the European Union[51].

GI's may relate to ABS since the product specification includes a description of the product, comprising the raw materials (and if appropriate the principal physical and microbiological characteristics of such material), and might be stacked on later to the bundle of property rights that surround one particular genetic resource if it is used to produce foodstuff protected by a GI.

They are protected in Belgium through different legislative texts, including:

- Federal law of 6th April 2010 on trade practices and consumer protection, chapter 7 on geographical indications and protected designations of origin
- Decree of the Walloon Region of 7th September 1989 related to the local geographical indication and designated Walloon certificate
- Ministerial Decree of the Flemish Government of 19th October 2007 on the protection of geographical indications

3.1.2 Liability and redress opportunities in cases of illicit acquisition of genetic resources (material and informational components)

Alongside the above legal principles surrounding the legal status of genetic resources, there are a number of rules found in civil, criminal and private international law, that are relevant for the regulation of ABS in cases where an illicit acquisition of genetic resources is established. These legal provisions would indeed be of importance when read in concordance with the obligations related to compliance in the Nagoya Protocol. Liability and redress prospects, when referring to GR, should be analyzed both as physical specimens and as informational goods, through a national lens, and in an international context.

3.1.2.1 Liability and redress for illicit acquisition of GR as physical specimen

As with the discussion on the existing legislation on physical access to genetic material as biophysical entities, this legislation concerns access to biophysical specimens and therefore is not directly relevant for the regulation of access and utilization of genetic resources under the Nagoya Protocol. Nonetheless, the discussion on this legislation might be useful when assessing possible overlap and/or inconsistency with the measures that would be proposed for implementing the compliance

[51] Regulations 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, *JOL, 93, 31.3.2006, p. 12–25,* and 509/2006 on agricultural products and foodstuffs as traditional specialties guaranteed, *JOL 93, 31.3.2006, p. 1–11;*

- A "designation of origin" refers to the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff originating in that region, specific place or country, if the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and the production, processing and preparation of which take place in the defined geographical area.
- A "geographical indication" refers to the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff originating in that region, specific place or country, and which possesses a specific quality, reputation or other characteristics attributable to that geographical origin, and the production and/or processing and/or preparation of which take place in the defined geographical area.

provisions of the Nagoya Protocol. When assessing which legal principles should address the issues of liability and redress when facing illicit acquisitions of genetic resources as physical entities, it should first be noted that most conflicts will bear an international dimension, thereby precluding any analysis of applicable legal principles to the determination of actually applicable law and competent authorities. This assessment is made in accordance with the principles of private international law that have been favored by the country where litigation is brought. If Belgian law is deemed applicable to the conflict, then liability and redress opportunities will depend on the existence of a contractual relationship or not, in which case extra-contractual liability schemes both in civil and criminal law should be analyzed.

A. Contractual breach

If a contract has been used between the user and the provider of the genetic material, then any conflict, whether of a national or an international dimension, will be settled in accordance with the clauses set out by the parties with regard to dispute settlement.

A number of national and European legislative texts govern the cases where no applicable law has been set by the parties. In Belgian national law, Article 98 of the private international law code refers to Regulation (CE) No. 593/2008 of 17th June 2008 on the law applicable to contractual obligations (Rome I) (transposing the 1980 Rome Convention), which states that the law of the country of residence of the principal executor of the contract should apply in times of contractual silence.

B. Extra-contractual liability and redress (absence of contract)

If no contract has been signed by the user and provider of the genetic material, then positive law will come in to fill the void and establish the terms governing dispute settlement if Belgian law is found to be applicable to the conflict in accordance with the principles of either Belgian private international law (if the case is filed in Belgium) or another country's rules on conflicts of laws and the designation of applicable legislation (if the case is filed in another country)[52].

In the absence of a contract, the illicit appropriation of material goods may qualify as a "simple theft" (in accordance with Articles 461 al 1 and 463 of the criminal code), thereby triggering **both criminal and civil liability** vis-à-vis the perpetrator. The proprietor of the material good can respectively:

(1) Seek injunction against a conduct that is judged to be in contradiction with the social order as a violation of property rights, (CRIMINAL PROCEEDINGS)

In accordance with Article 461 of the criminal code, an act corresponding to an "unauthorized/ fraudulent removal of the material good that belongs to a third party" shall qualify as a theft, a criminal offense that shall be repressively punished[53]. The concealment of these objects by third parties knowing of their illegal acquisition is also punished through the concealment offense (Article

[52] The determination of applicable law and juridical competence will be studied with greater detail in part C of this section devoted to the implementation of the route taken by Belgium with regard to private international law.
[53] There are three constitutive elements to "theft": « soustraction, chose d'autrui et intention frauduleuse »

505 of the criminal code)[54]. Criminal law is regulated by separate provisions which determine under which circumstances Belgian courts have jurisdiction to hear cases over the alleged infringement of Belgian criminal law. The effectiveness of judgments can be complicated in an ABS context by lack of resources and the priorities of criminal prosecution, as well as issues regarding the execution of judgments[55].

(2) and/or seek compensation for the damage caused by the loss of the material good or by the fault of the person having wrongfully appropriated the good (CIVIL PROCEEDINGS).

According to the Belgian Court of Cassation, the *res nullius* character of material goods cannot exempt the perpetrator from repairing the damage resulting from illicit acts[56]. The physical or legal person that is the legal owner of material goods, can therefore also seek civil compensation/damages ("actions en dommages et intérêts") in parallel to the criminal case being prosecuted ("constitution de partie civile", in accordance with Articles 63 and 70 of the criminal instruction code)[57], or start civil proceedings before criminal jurisdictions if the prosecutor has dropped the case (in accordance with Article 162 of the criminal instruction code). Both intentional and non-intentional torts engage the extra-contractual responsibility of the perpetrator, when the constitutive elements of civil liability are proven; *i.e.*, the fault, damage, and causal link between the fault and the damage.

- With fraudulent intention, an illicit appropriation of genetic resources would qualify as an **intentional tort or offense** ("délit"), triggering delictual liability under Article 1382 of the civil code.
- Without fraudulent intention, an illicit appropriation would qualify as **a non-intentional tort** ("quasi-délit"), a tort/offense committed by imprudence or negligence, and triggering civil liability. This would lead to a civil procedure concerned with the attribution of compensatory damages under Article 1383 of the civil code.

C. Specificity of ABS context: an omnipresent international dimension in conflicts

The illicit acquisition of material goods, whether with fraudulent intent or not, can have an international dimension. In an ABS context where the actors would most probably be of different nationalities, and where the contentious access or use of genetic resources might occur in a different country than the country where the alleged owner of the resource is established, it is useful to study

[54] Concealment will be further analyzed in part 3.1.2.2. of this section.

[55] Aside from the complex issues of competence and applicable law dealt with by private international law, criminal proceedings might also be hindered and further complexified due to the international nature of the conflict brought before the courts at the stage of decision implementation. Indeed extradition procedures would in principle need to be initiated in order to execute the judgment against the person convicted for theft55, or that there would need to be control over his property in order to execute the judgment against his property) These procedures would be expedited depending on the international conventions that have been adhered to by the States concerned (CASTIAUX, J., "Extradition en Belgique", in Chome P., Klees O., Lorent A. (eds.), *Droit penal et Procédure pénale*, Kluwer, Malines, 2011, p. 155). For instance, the Second Protocol to the 1959 European Convention on mutual assistance in criminal matters provides for transboundary observation when there are suspicions of aggravated theft (Article 17).

[56] Cass., 28 janvier 2009, *Amén*., 2009, p.309 (in this case, damage caused by beavers)

[57] The State could also directly start civil proceedings before civil courts, however, it would need to wait for the criminal verdict, in accordance with Article 4 of the code of criminal procedure ("le crimineltient le civil en l'état").

extra-contractual liability[58] through the lens of private international law, which would apply, "in default of particular rules" adopted by the legislator in this regard. **Private international law** determines both the rules pertaining to the conflicts of laws and jurisdiction, respectively determining the legal rules that apply to the case, and the judiciary that would be competent to rule on the subject-matter for civil and commercial matters.

A number of specific legal provisions of the private international law code[59] govern material goods and the case of their theft. It is in this framework that private international law reveals itself relevant for regulating the illicit acquisition and use of foreign genetic material. The international private law legal principles can contribute in particular to uphold the conditions specified in private law access agreements, in situations where the procedures for mutually agreed terms, established by the country of origin include private law contracts. However, even if these principles are a useful contribution, they are certainly insufficient. In particular, in the ABS context, utilization of GR often occurs on the information components (the DNA code, published research results, databases etc.). Moreover, utilization is often based on the use of a copy of the GR (a clone of the entire biological material or a clone/reproduction of a component of it), even when the GR is not situated in Belgium. These frequent cases of research done on/utilization of GR that are not physically in Belgium are not covered by the legal dispositions the private international law code which does not explicitly refer to the use of GR under the Nagoya Protocol in its current scope[60]. In addition, compliance with PIC obligations will involve public law requirements and/or administrative acts in the country of origin of the GR, which fall out of the scope of private international law. Therefore, additional measures might be needed to comply with the obligations under Articles 15, 16 and 18.

- **Conflict of Jurisdictions** (Which jurisdiction is competent?)
  Article 85 of the code of private international law states that the Belgian judiciary is competent to rule on disputes involving a physical access to a material good "if the good is located in Belgium at the time the claim is made". However, the application of this Article to the situations covered by the Nagoya Protocol is quite limited. Indeed, as stated above, utilization often involves the informational component of GR and/or physical components of GR (copies/clones) of which the original GR is not situated in Belgium.

- **Conflict of Laws** (Which laws to apply?)
  - **Property rights** related to a material good are governed by the laws of the State where the good is situated at the time the claim is made, in accordance with Article 87-§1 of the code of private international law. The acquisition and loss of property rights are established by the laws of the State where the good was situated at the moment these acts or facts have occurred.

[58] Indeed, by virtue of the principle of "pacta sunt servanda" ("principe de la convention-loi", Article 1134 al.1 of the civil code), the procedure following breaches of contract and the compensation for the violation shall be determined by the contractual clauses themselves.
[59] Law of 16th July 2004 related to the code of private international law, *M.B.,* 27th July 2004, pp. 57344
[60] Concerns can also be raised for the lack of reference in these legal dispositions of important issues of "access to justice" addressed in the Nagoya Protocol, such as the legal standing of ILCs before Belgium courts.

- If the good is an integral part of an ensemble of goods affected to a particular use, it is presumed to be situated in the State that has the strongest ties to the patrimony, in accordance with Article 8-§2 of the code of private international law.

- **Specific provisions exist for stolen material goods**, which could be possibly applied in the ABS framework in the case potential users of genetic resources would come to possess resources that have not been obtained through a legal means of property or possession transfer pursuant to Article 92 of the code of private international law
  - The "native" proprietor has the choice to refer the case to be ruled by
    - Either the laws of the State where the material good was situated at the moment of its disappearance,
    - Or the laws of the State where the material good is located at the moment of the claim.

  However, in the first scenario, if a possessor in good faith is not protected by the internal legal order of the State, he may invoke the protection offered by the laws of the State where the material good is located at the moment of the claim.

3.1.2.2 Liability and redress for illicit acquisition of GR as informational goods

A. <u>Contractual breach</u>

As is the case with physical specimens of GR, contractual provisions will prevail in terms of liability and redress if such a contract does exist. In the absence of any contractual relationship, torts law and criminal law will apply.

B. <u>Extra-contractual liability and redress (absence of contract)</u>

Theft of information is not a qualified infraction under Belgian law, and should most probably be fought through provisions related to breach of trust if the informational component is accessed by third parties without the transfer of actual material possession of the specimen. The use of informational components of genetic resources without PIC or MAT will most probably not be covered by those remedies addressing theft. Indeed, if the informational component of genetic resources is viewed as res communes, the usage of which is common to all, such component may not be subject to theft as long as it is not appropriated[61]. Furthermore, theft provisions apply solely to corporeal objects. However, there exists prominent jurisprudence regarding the theft of computer programs, where these have been considered as corporeal because of their economic value and because of them constituting an element of the patrimony of the original software's proprietor[62]. Neither the doctrine nor the jurisprudence is nonetheless unanimous on this issue, as the fraudulent copying of software has been ruled not to constitute a theft or a breach of trust due to its

[61] See A. Lorant, "Le vol de la chose d'autrui", *op.cit.*

[62] Anvers, 13 dec. 1984, Bruxelles, 5 dec. 1986,
See for instance Corr. Bruxelles 24 juin 1993 J.L.M.B. 1994, which states that *"Un logiciel - ou programme informatique - indépendamment même de son support (disquette) ne constitue pas un bien immatériel: il possède une valeur économique propre et est susceptible d'un transfert de possession qui peut être constaté matériellement. Le fait que le propriétaire du logiciel reste, en cas de duplication illicite de celui-ci, en possession des données originaires, n'exclut pas l'application des Article 461 et 505 C. pénal ».*

incorporeal nature, precluding the possibility to cede its ownership[63]. These controversies have in this instance led to the draft of Article 504quater of the criminal code on informatics fraud.

Other possibilities of redress recognized in Belgian criminal law may be exploited besides.

Thus, a first option that might be envisaged is the concealment offense, which normally only applies to corporeal objects. "An offense punished through the criminal code's Article 505" concealment punishes the act of a third party to fraudulently conceal a contentious good, knowing that such good has been acquired through a crime or infraction. Concealment therefore implies the preliminary recognition of a crime. It could therefore only be relevant in the ABS context to genetic resources viewed as informational goods if the criminal code is amended to constitute the "use of the informational component of genetic resources in contradiction to PIC and MAT" as a criminal offense. Indeed, concealment proceedings require that the author of the infraction possesses materially or legally the good, knowing of its illicit acquisition; and both the existence of possession and of such knowledge is appreciated by the judiciary[64].

Another possible – but non-exclusive – option would be the breach of trust. As an infraction against property rights, the breach of trust is enshrined in Article 491 of the criminal code, which punishes diverts or dispels goods of any kind from the initial usage or determined use that had been convened, with a prison sentence of one month to five years and a fine from 26 to 55 EUR. This provision could for instance be applied in an ABS context with regard to the exceptions that ought to be provided for research purposes (Article 8a NP), but most importantly against uses of genetic resources contrary to MAT or in absence of MAT in countries where the NP has been ratified and MAT has been requested in national legislation. The turning point for the constitution of this infraction is considered as the moment where the user cannot restore the genetic resources, or use them in a manner consistent with the initial destination[65].

All of these approaches require an important stretch from currently applicable legislation so as to address specifically the use of informational components of genetic resources without PIC or MAT. However, breach of trust may be adequately used in cases of change of intent in the use of GR. In order to achieve a high level of dissuasion, the opportunity of addressing "information theft" or "genetic resources" theft should be assessed by law-makers, drawing perhaps on experience acquired with regard to software. Civil proceedings drawing on Articles 1382 and 1383 of the civil code might also be envisaged provided that the existence of damage, fault (negligence or imprudence) and causal link is adequately proven.

Specificity of ABS context: an omnipresent international dimension in conflicts

With regard to the international dimension of ABS conflicts and the determination of competent jurisdictions and applicable law vis-à-vis informational components of GR, since property rights are

[63] Liège, 25 avr. 1991, *Rev. dr. pén.*, 1991, p. 1013.
[64] Cass. (2e ch.) RG P.98.0082.N, 5 octobre 1999 (Indestege)
[65] Cass. RG 2941, 9 avril 1991 (Marchand / Strubbe) One can for instance foresee the starting point of breach of trust at the change of nature of the recipient institution, turning for instance from a public non-profit organisation into a commercial structure.

not recognized as such components, Articles 87 and 92 of the private international law code are not applicable. Answers may be found in the provisions of the aforementioned code on contractual and extra-contractual obligations, especially Articles 103 and 104 dealing with conflicts of jurisdiction and laws with regard to torts and liability deriving from a damaging act.

3.2 Legal consequences for access to genetic material

Under the current legislation in Belgium, the access to genetic resources for their utilization is not subject to a Prior Informed Consent. However, any legal measure that would consider introducing Prior Informed Consent could benefit from building upon existing legislation on physical access to and use of genetic material. That is why legal consequences for physical access to genetic material are investigated in some more detail in this section. Legislation relevant to physical access depends upon the type of ownership (private, public or *res nullius*), the existence of restrictions to the ownership, such as specific protection (protected species, protected areas, forests or marine environments) and the location (all four authorities apply their own rules) of the genetic material.

3.2.1 Private ownership or *res nullius*

In case of private ownership or *res nullius* (*cf.* chapter 3.1.1), access to the territory on which the genetic material (*i.e.* the specimen) is situated requires consent of the legal owner of the territory to get into his territory for the purpose of physically accessing the genetic material (*i.e.* the specimen). If a disagreement arose *ex-post* on the consent, the legal property rights would prevail in absence of proof of the consent (for example in the absence of a written contract)

As for access to the genetic material (*i.e.* specimen) itself:

- If it is ***res nullius*** (*e.g.* a bee swarm in liberty): then by law no access permits or contracts are needed. Moreover, if you take possession (that is material deeds of controlling the good for exclusive use), then you automatically become the legal owner of the specimen (Article2279 of the Civil Code)
- If it is on territory in **private ownership** of an individual or a non-state organization: then you need a contract with the private owner, except if special restrictions apply to the legal ownership, which is the case of protected species (*cf.* discussion below)
- If it is on territory in **state ownership**: then there is the need of an access permit (*cf.* discussion below on protected areas and territory and on territory in the public domain)

3.2.2 Protected species

3.2.2.1 Protected species in the Flemish Region

In the Flemish Region, protection of species is regulated by the 'Soortenbesluit'[66] of the 13th August 2009. Under this act, it is forbidden to:

[66] Besluit van 15 mei 2009 van de Vlaamse Regering met betrekking tot soortenbescherming en soortenbeheer, (B.S.,13 augustus 2009).

- deliberately capture specimens of protected animal species, or to collect their eggs (Article 10-§1)
- deliberately pick, collect, cut, uproot, destroy or transplant specimens of protected plant-species or other types of organisms (Article 10-§2)
- transport, sell or exchange or offer for sale or exchange specimens of protected animal species, of protected plant-species or other types of organisms (Article 12)
- take away nests of protected birds and breeding sites or resting places of protected animals other than birds (Article 14-§1)

The act specifies that, if no other satisfactory solutions exist and if it does not affect the conservation of these species, exceptions can be made for purposes related to research or education, repopulation or reintroduction, for the necessary breeding (Article 20-§1) as well as for reasons of economic, social or cultural nature (Article 20-§2). Request for exceptions needs to be addressed and approved by the "Agentschap voor Natuur en Bos" of the Flemish authorities (Article 22).

3.2.2.2 Protected species in the Walloon Region

Protection of species in the Walloon Region is regulated by the nature conservation law of 12th July 1973[67], which contains a general prohibition to:

- Capture, kill, detain or transport animal species that are protected (Article 2 for birds, with a number of exceptions according to the species; Article 2bis to 2sexies for other animals)
- Collect, pick up, cut, uproot, detain or transport specimens or portions of specimens that belong to those plant species that are listed in Annex 6 of the law (Article 3). Management and maintenance activities do not fall under this prohibition.

For partially protected species the prohibition is attenuated by Article 3bis, which states that the "aerial parts of the specimens of the plant species listed in Annex 7 can be collected, picked up or cut in small quantities", but they cannot be sold or intentionally destructed.

Derogations to the general prohibition can be awarded in accordance with Articles 5 and 5bis of the 1973 law. These are in principal unique (individual, personal and un-transferrable) but annual derogations can be awarded for physical or moral persons conducting research on one or more biological groups on the entire territory of the Walloon Region (with additional conditions in Article 5bis-§3).

Derogations with regard to birds can only be awarded if there is no other satisfying condition and if they do not endanger the population concerned (Article 5§2) and only for reasons of public health and security, research and education, protection of wild animal or plant species, air security, prevention of important damages to cultures, farm animals, forests or water, as well as allowing the

[67] Loi du 12 juillet 1973 sur la conservation de la nature: Région wallonne (M.B., 11 septembre 1973)

capture, detention or other sound exploitation of small quantities of certain birds selectively, in strictly controlled conditions[68].

Similarly, derogations to the general prohibition with regard to mammals, amphibians, reptiles, fish and wild invertebrates, as well as wild plant species (Article 5§3)[69] can only be awarded if there is no other satisfactory solution and if such derogation does not harm the maintenance of the population's favorable conservation status in their natural repartition area. These derogations can only be obtained for reasons of protection of wild animal or plant species, prevention of important damages to cultures, farm animals, forests or water, research and education, as well as allowing the taking or detention of certain specimens listed in Annex 2 point A selectively and in limited steps.

Article 4 of the same law on nature conservation also mandates the government to regulate the modalities of collection and analysis of biological information on wild animal or plant varieties and the natural habitats falling under the scope of the law by the Walloon government. An administrative order was adopted on 24th July 2003[70], stating that the agents of the "Centre[71]" and their collaborators are authorized to enter private property, with prior notification of the owner, to proceed to operations that are indispensable to the collection of biological information (Article 4).

3.2.2.3 Protected species in the Brussels-Capital Region

The protection of species is regulated in the region of Brussels-Capital by the Ordinance of 1st March 2012 regarding nature conservation[72].

With regard to animal species, this act awards strict protection to animal species listed in its Annex II.2.1° throughout the Region's territory, and to species cited in Annex II.3 part 1A throughout protected zones established in the Region (Article 6-§1 of the Ordinance). Such protection implies the interdiction, amongst other acts, to hunt or capture specimens, transport, pick up their eggs, sell, or expose in public spaces (Article 68-§1), except if they fall within the scope of management activities foreseen in the protected zone's management plan (Article 68-§3). Exceptions are made for imports, exports or transit of non-indigenous species, which is a federal competence (see chapter 2.1).

With regard to plant species, the Ordinance awards strict protection to plant species listed in its Annex II.2.2° throughout the Region's territory, and to species cited in its Annex II.3 B part 1 B and II.3 part 2 throughout protected zones established in the Region (Article 70-§1 of the Ordinance).

1.1.1.1 [68] An additional executive order exists for the derogations to the general prohibition with regard to birds : Arrêté du Gouvernement wallon du 27 novembre 2003 fixant des dérogations aux mesures de protection des oiseaux, (M.B., 23 février 2004)

[69] On exceptions to protection measures of animal and plant species, except for birds, see also Arrêté du Gouvernement wallon du 20 novembre 2003 relatif à l'octroi de dérogations aux mesures de protection des espèces animales et végétales, à l'exception des oiseaux (M.B. du 03/02/2004, p. 6370)

1.1.1.2 [70] Arrêté du Gouvernement wallon du 24 juillet 2003 relatif aux modalités de récolte et d'analyze des données biologiques sur les populations wallonnes des espèces animales et végétales sauvages et des habitats naturels (M.B., 1er septembre 2003)

[71] Centre de recherche de la nature, des forêts et du bois de la Direction générale des ressources naturelles et de l'environnement du Ministère de la Région wallonne.

[72] Ordonnance du 1 mars 2012 relative à la conservation de la nature, (M.B., 16th March 2012).

Such protection implies the interdiction, amongst other acts, to pick up, cut, uproot, unplant or harm the species in their natural repartition zones or within zones where they benefit from active protection and to detain, transport, or sell specimens collected within these active protection zones (Article 70-§2). Exceptions are made for imports, exports or transit of non-indigenous species, which is a federal competence (see chapter 2.1), except if these acts fall within the scope of management activities foreseen in the protected zone's management plan (Article 70§3).

For species presenting a regional or community interest active protection zones can be set out in accordance with Article 72 of the Ordinance. The measures adopted may for instance include prescriptions restricting the access to certain zones, preserving reproduction or resting areas, or regulating the periods, zones or methods of the sampling and exploitation of Annex II.3 specimens outside protected areas (Article 72-§1, 4°).

Special dispensations can be awarded to the above interdictions in accordance with Article 83-§1 of the Ordinance, and the rationale include imperative reasons of major public interest (whether of a social or economic nature) and that would entail primordially beneficial consequences for environmental protection, as well as research or educational purposes. The Article also states that derogations might be granted in order to permit the capture and detention of a limited and specified number of specimens determined by competent authorities, in a strictly controlled, selective and limited fashion.

The violation of these rules is punished by imprisonment from 10 days to 1 year, and/ or an administrative fine from 150 EUR to 150.000 EUR.

The 2012 Ordinance on nature conservation in the Brussels-Capital Region also contains an Article on **the sampling and exploitation of specimens** in nature as a whole, stating that the Government is habilitated to take the measures necessary to ensure that the sampling and exploitation of species listed in Annex II.5 are compatible with their maintenance in favorable conservations status, including measures pertaining to the interdiction of capture, detention, transport or sale (Article 82).

3.2.3 Protected areas and forests

3.2.3.1 Protected areas and forests in the Flemish Region

Nature conservation in the Flemish Region is regulated through the "Natuurdecreet" of 21st October 1997[73], through which the Flemish Government can take all necessary measures for nature conservation, regardless of the type of area. This includes regulating access (Article 13-§1, 6°), prohibiting certain activities or subject them to conditions (Article 13-§3, 6°). These conditions and activities may require a permit.

[73] Decreet betreffende het natuurbehoud en het natuurlijk milieu

A permit is required for the transformation[74] of the vegetation[75] or the modification of all or part of small landscape elements or their vegetation in the following areas: green areas; park areas; buffer areas; forest areas; nature development areas; valley areas; source areas; agricultural areas with ecological importance or value; and agricultural areas of special value or similar areas designated as such in spatial implementation plans (Article 13). However, it is not allowed to change all types of vegetation, nor do all actions producing change require a permit[76]. The prospecting of GR is not included in the actions requiring a permit. If a permit is delivered, the competent authority shall ensure that no avoidable damage to nature may arise by imposing reasonable conditions to prevent damage, to minimize or, if not impossible, to recover (Article 16).

Certain areas in the Flemish Region enjoy a "special" status, where different rules apply. In the Flemish Ecological Network (Vlaams Ecologisch Netwerk, VEN) it is forbidden to change vegetation, including perennial crops or small landscape elements. In the nature reserves (natuurreservaten) it is forbidden to deliberately pick, collect, cut, uproot or destroy plants (Article 35).

It should be noted that public servants working in relation to matters governed by the "Natuurdecreet" (*i.e.* nature conservation), may access real property (excluding houses and buildings intended for private or business use) to make measurements and to conduct research (Article 57bis).

Forest areas in the Flemish Region are regulated by the "Bosdecreet" of 13th June 1990. Although it applies to public access for social and educational purposes[77], forests can only be accessed through the forest roads ('boswegen'). The Flemish Government can however decide to allow access to the forests outside of the roads for other activities (Article 10-§2). Physical access cannot lead to any reduction of the surface covered by the forest (Article 11). It is regulated through an "access regulation" ("toegankelijkheidsregeling") for forest for which a management plan ("beheersplan") is required[78]. Forest for which no management plan is needed do not need "access regulation" (Article 12).

Part of these forest areas can be designated by the Flemish Government as protected "forest reserves" ("bosreservaten") because of the ecologic or scientific function these parts fulfil (Article22). In these "forest reserves" it is not allowed to remove plants or parts of plants (Article 30.1) or to extract material from soil or from the substrate (Article 30.2). Violation of this provision is punishable by a fine of 50 to 200 Euros (Article 30).

[74] Change of small landscape elements and vegetation are all acts or works that are not understood to include the normal maintenance. Actions to be considered as normal maintenance are described in Annex 1 of Omzendbrief LNW/98/01 betreffende algemene maatregelen inzake natuurbehoud en wat de voorwaarden voor het wijzigen van vegetatie en kleine landschapselementen betreft volgens het besluit van de Vlaamse regering van 23 juli 1998 tot vaststelling van nadere regels ter uitvoering van het decreet van 21 oktober 1997 betreffende het natuurbehoud en het natuurlijk milieu

[75] Vegetation has to be understood as the natural and semi-natural vegetation with all spontaneously established herb, bushes and forest covers, and this independently of possible influence of the abiotic environment by humans (Omzendbrief LNW/98/01)

[76] This has been regulated by: Besluit van de Vlaamse Regering betreffende de vergoeding van wildschade of van schade door beschermde soorten en tot wijziging van hoofdstuk IV van het besluit van de Vlaamse Regering van 23 juli 1998 tot vaststelling van nadere regels ter uitvoering van het decreet van 21 oktober 1997 betreffende het natuurbehoud en het natuurlijke milieu.

[77] The social and educational function of the forest includes the accessibility of the forest to the public for the purpose of recreation or education.

[78] A management plan is required for all public forests and for private forests of at least five acres.

Further provisions for physical access to both forest and nature reserves in the Flemish Region are provided by a specific Executive Order[79] which applies only to pedestrians, cyclists, horse riders, fishermen, swimmers, skaters, divers, kayakers, sailors, rowers and windsurfers (Article 5-§2)

3.2.3.2 Protected areas and forests in the Walloon Region

In the Walloon Region there is a general obligation to request a permit (for land planning) for acts that consist of "clearing the ground or transforming the vegetation of a zone that is judged by the government to be in need of protection, with the exception of the specific management plan of national and aggregated natural reserves", in accordance with Article 84-§1, 12° of the Walloon code for urban and land planning.

Furthermore, Article 136 of the same code states that the execution of acts may be "either prohibited or subject to specific conditions for the protection of persons, goods or the environment when those acts relate to **national natural reserves**, a **humid zone of biological interest**, an **underground cavity of scientific interest**, a **Natura 2000 site** or a **forest reserve** (Article 452/27)".

In **natural reserves and national natural reserves** physical access is regulated by Article 12 of the 1973 nature conservation law, in accordance to which the ministerial decree of 23rd October 1975[80] has been enacted. Access to the non-protected material found in these zones is regulated by Article 11 of the nature conservation law, which states that it is forbidden to take out, cut, destroy or harm trees or the vegetative soil as such, or to modify the soil. For national natural reserves, in addition to those acts prohibited by Article 11 of the nature conservation law, it is also forbidden to "take out plants or vegetal parts, notably moss; or to pick up blueberries or cranberries with the help of a hairbrush", in accordance with Article 5 of the ministerial decree.

In **humid zones of biological interest**, in accordance with Articles 2 and 3 of the Walloon Government decree of 8th June 1989[81] regulating humid zones of biological interest, it is "forbidden at all times to pick up, unplant, harm or destroy all indigenous species of the flora growing in a wild state in the humid zone". For fauna, it is forbidden to hunt, kill, destroy, capture or disturb all indigenous species, except those for which hunting or fishing is authorized and those listed in the Annex of the decree.

In **underground cavities of scientific interest**, in accordance with Article 3 of the Walloon Government Decree of 26th January 1995[82], it is the ministerial decrees establishing the specific protected zone that regulates both the physical access and conditions for research or other utilization of GR. In general[83], the decrees state that access to the site is only authorized for

[79] Besluit van de Vlaamse Regering betreffende de toegankelijkheid van de bossen en de natuurreservaten, 05/12/2008

[80] Arrêté ministériel du 23 octobre 1975 établissant le règlement relatif à la surveillance, la police et la circulation dans les réserves naturelles domaniales, en dehors des chemins ouverts à la circulation publique (M.B., 31 décembre 1975)

1.1.2 [81] 8 juin 1989 - Arrêté de l'Exécutif régional wallon relatif à la protection des zones humides d'intérêt biologique (M.B. 12.09.1989)

1.1.2.1 [82] Arrêté du Gouvernement wallon du 26 janvier 1995 organisant la protection des cavités souterraines d'intérêt scientifique, (M.B., 18 mars 1995)

[83] The texts of these ministerial decrees may be found on http://environnement.wallon*i.e.*be/legis/consnat.htm, for an example, see the decree of 18th September 2001 on the Ivoz-Ramet Vegetation grotto, http://environnement.wallon*i.e.*be/legis/cavites%20souterraines/cavite041.htm

management and scientific follow-up operations with the mandate of the managing committee. Scientific and speleological research can be done with the consent of the managing committee, with due respect for the integrity of the cavity and the scientific follow-up measures.

In **natural parks**, regulated by the Decree of 16th July 1985[84], the particular terms of access shall be managed by the Managing commission set up in accordance with Articles 11 and 12. In accordance with the interpretation made by the high administrative authority, that is the Council of State, the Walloon code for urban planning defines the acts that are subject to a permit in natural parks as those that are susceptible of having a significant impact on the landscape and the environment[85].

In **forest reserves**, in accordance with Article 20 of the Walloon forest code of 15th July 2008[86], the access of pedestrians is forbidden outside roads and resting areas. However, access can be granted by the agents designated by the Walloon Government (in accordance with Article 92 of the forest code), under the conditions set out by these agents, for medical, pedagogic, scientific, cultural or nature conservation purposes. In accordance with Articles 32 and 34, it is forbidden to cut out, take out or tear down trees, or take out their sap without the authorization of its owner. Furthermore, Article 50 states that no sampling of any product of the forest can be undertaken without the consent of the owner and without respecting the conditions that could be adopted by the government (implying that such conditions may not be adopted). The fine for violation ranges between 25 and 100 Euros (Article 102).

What about those acts that do not require permits?

The establishment and prescription of protected zones is considered to be a "servitude légale d'utilité publique", restricting the use and affectation of a specific portion of land. The notions of "acts and works" should be understood as those activities characterized by a physical link to the soil or the vegetation, or causing a physical modification of the soil or the vegetation[87]. Therefore, utilization of GR as such may in certain cases not be considered as a modification or transformation of the ecosystemic balance set out by the protected zone. However, if this is the case, this needs to be specified in the general access rules of the protected zone or the permit.

Further, within this understanding of passive obligations, those acts that are normally not subject to a permit might, according to doctrinal and jurisprudential thought, still have to respect the destination of the zone, otherwise they would fall under administrative sanctions[88].

3.2.3.3 Protected areas and forests in the Brussels-Capital Region

The access to natural areas (both protected and non-protected) in Brussels is regulated by the Ordinance of 1st March 2012 regarding nature conservation.

1.1.2.2 [84] Décret du 16 juillet 1985 relatif aux parcs naturels, (M.B., 12 décembre 1985)
1.1.2.3 [85] Jadot B., Vagman A. (2011), Avis de la section de législation du Conseil d'État [urbanisme et environnement]. *Amén.* 2011, liv. 2, pp. 147-153 (at p. 152).
1.1.2.4 [86] Décret de la Région wallonne du 15 juillet 2008 relatif au Code forestier, (M.B., 12 septembre 2008).
[87] Born C.H. (2004), *Guide Juridique des Zones Protégées en Wallonie*, Ministère Région Wallonne, 2004, p.325.
[88] *Ibid*, p. 326.

In **non-protected areas** the Government may regulate public access and behavior applicable to the regional parks, gardens, squares, green areas and unoccupied land managed by the Region and publicly available (Article 66-§2). There is no general prohibition/permit requirement on the collection of natural resources in these areas.

According to Article 82 of the Ordinance, the Government has to take the necessary measures to make sure the prospecting and use of specimens of species listed under Annex II of the Ordinance is compatible with the conservation of these species. Measures include the prohibition or limitation of their capture, detention, transportation and sale.

In **protected areas**[89] it is forbidden to:

- pick, remove, collect, cut, uproot, transplant, damage or destroy native plant species and bryophytes, lichens and macro-fungi, and destroy, damage or transform the vegetation (Article 27-§1, 1°);
- leave the roads and paths open to public traffic (Article 27-§1, 10°).

If no other satisfactory solutions exist and if it does not affect the conservation of native species, derogations to Article 27 can be made for purposes related to research or education, repopulation or reintroduction, and for the necessary breeding (Article 83). The requests for derogations, including information on the purposes of the request, need to be addressed and approved by the Brussels Institute for Environmental Management (IBGE/BIM), which delivers a permit (Article 84).

Non-compliance with Article 27 is punishable by imprisonment from 10 days to 1 year and a fine of 150 EUR to 150 000 EUR (Article 93).

3.2.4 Marine environment

There are two main legal sources regarding the protection of the marine environment: the so called **"MMM" Law** of 20th January 1999 and the **"EEZ" Law** of 22nd April 1999[90]. The first one establishes a general regime of protection of animal and plant species. The second one specifies the rights Belgium detains on the exclusive economic zone and the territorial sea.

3.2.4.1 The "MMM" Law

The law of 20th January 1999 defines the legal principles to be respected in order to preserve the Belgian part of the North Sea against marine pollution, and to conserve and develop its natural environment[91]. To this end, the law of 20th January 1999 integrates within the Belgian legal order the different general principles of the environmental law: prevention principle, precaution principle, «polluter-pays» principle, etc.

[89] Applies to all protected areas found in the Brussels Region: Regional Natural Reserves, Certified Natural Reserves, Forest Reserves, Natura 2000 Reserves.
[90] Law of 20th January 1999 aiming to protect the marine environment falling under the jurisdiction of Belgium, M.B. 12th March 1999 ; Law of 22nd April 1999 M.B., 20 July 1999
[91] Law of 20th January 1999 aiming to protect the marine environment falling under the jurisdiction of Belgium, *M.B*. 12th March 1999

The "MMM" Law sets up a general regime of protection of natural resources and marine areas. In this regard, the Federal Government can take all the necessary measures concerning the **protection of marine spaces**[92], including – amongst others – the obligations resulting from the CBD (Article 6).

The Federal Government can also create **protected marine areas** (Article 7). The law so organizes and determines the categories and physical borders of the protected zones. It introduces moreover a categorization of the different potentially concerned zones:

- In the integral and "directed" marine areas, any activity is forbidden, except for those areas specified in Article 8[93]. However, some specific activities are authorized in exceptional cases for the "directed" marine areas[94].
- A general authorization is given to the special protection zones and special conservation zones even if some activities can be punctually forbidden. Thus, the 2003 federal Masterplan led to delineate five marine zones designed to specifically protect animal species. The access to and use of these zones are submitted to specific conditions determined by the various users of the North Sea for specific periods of the calendar year.

The Federal Government establishes a list of **protected species in the marine areas**[95], which benefit from a strict prohibition regime forbidding to capture, kill, detain or transport animal species that are protected, and to collect, pick up, cut, uproot, detain, transport or intentionally destruct specimens or portions of specimens that belong to the plant species that are listed as protected (Article 10§1). Derogations to the general prohibition can be nonetheless awarded for the needs of public health, scientific research, education, restocking or reintroduction of these species (Article 10§2). Lastly, the deliberate introduction of non-indigenous organisms is forbidden unless otherwise stated by the Government, as is the deliberate introduction of GMO (Article 11).

Finally, the law stipulates that any construction activity or industrial, commercial and advertising activity taking place in marine spaces requires a license (Article 25-§1). The granting of this license depends on an environmental impact assessment of the expected activity (Article 28)[96]. However it should be noted that some activities remain excluded from the scope of Article 25-§1, such as professional fishing, or marine scientific research – whose implementation is regulated in the EEZ law hereafter described (Article 25-§3).

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[92] See. Article 2§1. The marine spaces are defined as « the territorial see, the exclusive economic zone and the continental shelf aimed par the Law of 13th June 1969 on the continental shelf of Belgium »

[93] The following activities are accepted in the marine areas: (i) surveillance and control; (ii) monitoring and scientific research carried out for or with the consent of the authority;(iii) sailing; (iv) professional fishing, notwithstanding the restrictions or prohibitions imposed by the Government; (v) nature conservation and development activities; (vi) military activities (Article 8)

[94] For an example of directed marine area, see : Executive order of 5th March 2006 créant une réserve marine dirigée dans les espaces marins sous juridiction de la Belgique et modifiant l'Arrêté royal du 14th October 2005 créant des zones de protection spéciales et des zones de conservation spéciales

[95] See Annex I of the Government Executive Order of 21st December 2001 aiming for the protection for species in the marine areas under the jurisdiction of Belgium (M.B., 14th February 2002)

[96] The specific devices organising the license granting process are defined in the executive order of 7th September 2003 establishing the granting procedure of the permits and authorizations required for some activities carried out in marine areas, M.B.,17th September 2003

3.2.4.2 The "EEZ" Law

The law of 22nd April 1999[97] specifies the legal status of the territorial sea and broadens the sovereign rights of Belgium to a maritime zone located beyond the territorial sea and adjacent to it: the Economic Exclusive Zone (EEZ). The regulation of the economic exclusive zone concerns the exploration and exploitation of the natural resources of the waters in contact with ("*surjacent*") the marine soils, i.e. the marine soils themselves as well as their subsoil[98].

Belgium has **sovereign rights** for the exploration and exploitation, conservation and management of natural, biological and non-biological resources found within the EEZ, as well as for other activities tending to the exploration and the exploitation of the zone to economic ends (Article 4-§1). Belgium also has **jurisdiction** with regard to the settlement and utilization of artificial islands, installations and construction works, to the marine scientific research and to the protection and preservation of marine environment (Article 4-§2).

In this framework, any scientific research in territorial sea and in the exclusive economic zone must be submitted to the consent of the Minister of Foreign Affairs, who has then to consult the different involved ministers (Article 40)[99]. Such consent is supposed to be given if Belgium is part of the institutional organization or of the bilateral agreement on the basis of which the scientific research project is developed – unless Belgium objects to it within the two months following the official research request. Finally, the scientific research carried out by foreign ships in the territorial sea and the economic exclusive zone is under the jurisdiction of the Belgian Law related to the protection and conservation of marine environment (Article 42).

In **the territorial sea**, **the exclusive economic zone and in high sea,** the Federal Government can take the necessary measures to ensure the conservation of biological resources (Article 1-§1, al.1 of the law of 12th April 1957 entitling the King to prescribe measures in order to conserve the marine biological resources, as modified by Article 6 of the law of 22nd April 1999). The fishing in the territorial sea and in the exclusive economic zone is forbidden for foreign fishing boats (Articles 10 and 17), except in the exclusive economic zone and in the territorial sea if allowed by the rights deriving from the Treaty of the European Union and the applicable rules of international law. In this framework, the Federal Government can take the necessary measures ensuring the respect of this general prohibition[100].

Finally, Belgium exercises sovereignty on territorial sea and holds sovereign rights on the continental shelf as for the exploration and exploitation of mineral and non-living resources (Article 27).

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[97] M.B., 20th July 1999

[98] The limits of the economic exclusive zone are fixed through different bilateral agreements : Agreement between the Government of the Kingdom of Belgium and the Government of the Kingdom of England and North Ireland related to the delimitation of the continental shelf between the two countries, signed in Brussels on 29th May 1991 and approved by the the Law of 17th February 1993 (M.B., 1st December 1993) ; Agreement between the Government of the Kingdom of Belgium and the Government of the French Republic related to the delimitation of the continental shelf between the two countries, signed in Brussels on 8th October 1990 and approved by the law of 17th February 1993 (M.B., 18th December 1993) ; Agreement between the Government of the Kingdom of Belgium and the Government of the Netherlands related to the delimitation of the continental shelf between the two countries and Annexes, signed in Brussels on 18th December 1996 and approved by the law of 10th August 1998 (M.B., 19th June 1999).

[99] For the general regulation of the matter, see Article40-44 of the law of 22nd April 1999

[100] See Article 10 and foll.; 17 and foll.

3.2.5 Access in state owned land outside of protected zones

Access to genetic material on state owned land outside protected zones also requires the authorization of the competent state authority, except if the land is explicitly designated as public domain. In the latter case, under the current legislation it is still unclear how access to genetic material is regulated. In general the public domain encompasses "the goods specifically assigned for public use or arranged with the view to realize a public service objective". The specificity of the destination of such goods requires "a specific legal protection and therefore the application of a specific administrative legal regime"[101]. Access to genetic material is not explicitly mentioned in the current legal framework applicable to public domain goods. However, each public entity has its own public domain that it regulates in accordance with the competences attributed or granted by the Belgian legal order. For instance, with regard to the public domain at the municipal level, the regulation of the administrative police of Gesves in the province of Namur, states in its Article 1 that it is forbidden to pick the flowers found on the public domain, as well as to take out grass, soil, rocks or materials belonging to the public domain without prior authorization. In the absence of such specific regulation by the competent authority, access to genetic material in public domain is still a grey legal zone. This question certainly deserves further clarification.

1.1.2.5 [101] Willieme C., Boland M., Simon V. (2010), Valorization des biens situés dans le domaine public : Quel encadrement juridique ?. *Rec. gén. enr. not.*, 2010, pp. 253-271 (at p. 256).

3.3 The status of traditional knowledge associated to genetic resources under national legislation in Belgium

Traditional knowledge in the context of the CBD is usually understood as "knowledge, innovations and practices of indigenous and local communities" that "embody "traditional lifestyles relevant for the conservation and sustainable use of biological diversity" (Article 8(j) of the CBD). Traditional knowledge is "developed from experience gained over the centuries and adapted to the local culture and environment" and "transmitted orally from generation to generation". Moreover traditional knowledge "tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds"[102].

There are no contemporary legal provisions in Belgium explicitly governing the concepts of "traditional knowledge", "traditional knowledge associated with genetic resources" and "indigenous and local communities". One might argue that some types of knowledge could be qualified as "knowledge, innovations and practices" that "embody traditional lifestyles relevant for the conservation and sustainable use of biological diversity". One example would be knowledge involved in the conservation and use of old seed varieties by farmers. However, this knowledge is not related to specified local communities and their traditional lifestyles as specified in the CBD's understanding of the concept.

Nevertheless, concerns over traditional knowledge and the rights of indigenous and local communities have been addressed in some international instruments, especially in the area of development cooperation and sustainable development, to which Belgium is a Party[103]. Three international instruments broach the rights of indigenous and local communities and recognize the importance of traditional knowledge:

- the 1957 International Labor Organization (ILO) Convention No. 107 on Indigenous and Tribal Populations;
- the ILO Convention No. 169 on Indigenous and Tribal Peoples; and

[102] CBD Secretariat, Traditional Knowledge and the Convention on Biological Diversity, available at http://www.cbd.int/doc/publications/8j-brochure-en.pdf

[103] Overeenkomst tot wijziging van de partnerschapsovereenkomst tussen de leden van de groep van Afrika, het Caribisch gebied en de stille oceaan, enerzijds, en de Europese gemeenschap en haar lidstaten, anderzijds, ondertekend te Cotonou op 23 juni 2000, BS: 30-04-2008; Overeenkomst inzake politieke dialoog en samenwerking tussen de Europese Gemeenschap en haar Lidstaten, enerzijds, en de Andesgemeenschap en haar Lidstaten (Bolivia, Colombia, Ecuador, Peru en Venezuela), anderzijds, en met de Bijlage, gedaan te Rome op 15 december 2003, BS: 03-06-2008; Internationaal Verdrag inzake plantgenetische hulpbronnen voor voeding en landbouw, gedaan te Rome op 6 juni 2002, BS: 21-12-2007; Verdrag van de Verenigde Naties ter bestrijding van desertificatie in de landen die te kampen hebben met ernstige verdroging en/of woestijnvorming, in het bijzonder in Afrika, BS: 10-12-1997; 17 JUNI 1994. - BIJLAGE II (Bijlage inzake regionale uitvoering van Azië) aan het Verdrag van de Verenigde Naties ter bestrijding van desertificatie in de landen die te kampen hebben met ernstige verdroging en/of desertificatie, in het bijzonder in Afrika, gedaan te Parijs op 17 juni 1994, BS: 10-12-1997; BIJLAGE III (bijlage inzake regionale uitvoering voor Latijns-Amerika en het Caraibisch gebied) aan het Verdrag van de Verenigde Naties ter bestrijding van desertificatie in de landen die te kampen hebben met ernstige verdroging en/of desertificatie, in het bijzonder in Afrika, gedaan te Parijs op 17 juni 1994.

- the United Nations Declaration on the Rights of Indigenous Peoples.

The UN Declaration on the Rights of Indigenous People might have a practical and a political interest as it is explicitly "noted" in the preamble of the Nagoya Protocol and might therefore provide a framework in the further elaboration of decisions under the Nagoya Protocol relevant to the rights of indigenous and local communities. It nonetheless remains a non-binding instrument, whose provisions do not create any legal obligations.

A fourth instrument of relevance is Agenda 21, following the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil, 3rd to 14th June 1992. Its chapter 26 focuses on the role of indigenous people and their communities. It is provided that such communities possess a unique knowledge of their environment and the natural characteristics thereof. Consequently, indigenous people and their communities should acquire the right of self-determination, manage their own resources and participate in the decision-making on development programs affecting them[104]. This instrument is not legally-binding and merely addresses issues of potential future action.

As pointed out in the fourth National Report on the implementation of the Convention on Biological Diversity in and by Belgium (2009), certain policy initiatives have been adopted or identified in order to support actions[105] of indigenous and local communities situated in developing countries. Also the ratification of ILO Convention 169 (Indigenous and Tribal Peoples Convention) was put on the agenda. Bilateral official cooperation provides limited direct support to indigenous and local communities, since this is not often taken up as a priority by the partner countries, neither in their national development and poverty reduction policies, nor in their policy dialogue with donor countries.

Belgium ratified the ILO Convention No. 107[106] but not the ILO Convention No. 169.

3.3.1 The 1957 ILO Convention No. 107 on Indigenous and Tribal Populations

The 1957 Indigenous and Tribal Populations Convention (No. 107) was a first attempt to codify international obligations of States in respect of indigenous and tribal populations. It was the first international convention on the subject, and was adopted by the International Labor Organization.

ILO Convention No. 107 is a broad development instrument, covering a wide range of issues such as land; recruitment and conditions of employment; vocational training, handicrafts and rural industries; social security and health; and education and means of communication. Particularly the provisions of Convention No. 107 with regard to land, territories and resources have a wide coverage and are similar to those of Convention No. 169.

[104] See: Belgian Senate, *parl. sess*. 1995-1996, Bulletin 1-2 à, 18th June 1996, vraagn°43 (Mrs. V. Dua), 26th March 1996.
[105] See: Federal Plan for Sustainable Development (2000-2004)
[106] Convention concerning the Protection and Integration of Indigenous and Other Tribal and Semi-Tribal Populations in Independent Countries , 26th June 1957, Genève, ILO, ratified by Belgium on 19th November 1958, (M.B., 6th December 1958), entered into force on 2nd June 1959.

Convention No. 107 was ratified by 27 countries. It was revised during 1988-1989, through the adoption of Convention No. 169. Although since the adoption of Convention No. 169, Convention No. 107 is no longer open for ratification, it is still in force for 28 States, including Belgium, a number of which have significant populations of indigenous peoples, and remains a useful instrument in these cases as it covers many areas that are key for indigenous and local communities.

3.3.1.1 Relevant provisions of the ILO Convention No. 107

The Convention does not avail itself of the concept of indigenous and local communities, rather it applies to indigenous tribal or semi-tribal populations in independent countries whose social and economic conditions are at a less advanced stage than the stage reached by the other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations (Article 1).

This convention entails certain obligations incumbent on Belgium, but which have not been addressed by it. Three particular provisions are however of particular relevance for the implementation of the NP by Belgium. These concern:

- **Article 7(1):** In defining the rights and duties of the populations concerned regard shall be had to their customary laws.
- **Article 11:** The right of ownership, collective or individual, of the members of the populations concerned over the lands which these populations traditionally occupy shall be recognized.
- **Article 13:**
  1. Procedures for the transmission of rights of ownership and use of land which are established by the customs of the populations concerned shall be respected, within the framework of national laws and regulations, in so far as they satisfy the needs of these populations and do not hinder their economic and social development.
  2. Arrangements shall be made to prevent persons who are not members of the populations concerned from taking advantage of these customs or of lack of understanding of the laws on the part of the members of these populations to secure the ownership or use of the lands belonging to such members.

4 EXISTING ABS-RELATED POLICY MEASURES AND OTHER INITIATIVES IN BELGIUM

4.1 Measures resulting from coordination between the three regions and the federal level

In 2006, Belgium adopted its **National Biodiversity Strategy 2006-2016**[107], which established 15 strategic objectives and 78 operational objectives to reduce and prevent the causes of biodiversity loss. The 6th strategic objective aims to contribute to an equitable access to and sharing of benefits arising from the use of genetic resources. This objective is projected to be realized mainly through capacity building of national ABS stakeholders and further implementation of the Bonn Guidelines on ABS. In 2006, a study on the awareness of Belgian users of GR concerning the CBD and the level of implementation of ABS dispositions and the Bonn Guidelines in their activities has revealed mixed knowledge within stakeholder groups[108]. The Convention seemed to be 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 dispositions, the report showed that PIC-related dispositions seem to be relatively widespread, whereas benefit-sharing provisions are nearly inexistent[109]. Other operational objectives of the National Biodiversity Strategy include the enhancement of synergies between actors for addressing ABS, the protection of local communities and their traditional knowledge and the establishment of an international regime on ABS. However, these seem to be general goals the government wants to strive for, rather than specific delineated strategic actions. The strategy has been evaluated at the end of 2011 and is currently under review in order to bring it into line with the new multilateral and European biodiversity objectives (the Biodiversity Strategic Plan 2011-2020 and its Aïchi Targets, the EU biodiversity Strategy and other national and international commitments) and to extend subsequently the reviewed strategy until 2020.

As part of the present impact-study, two stakeholder workshops have been organized. The aim of the workshops was to identify the wide range of stakeholders concerned with the implementation of the Protocol in Belgium, to make them aware of the content of the Protocol and its obligations, and to

[107] CCIEP (2006) Belgium's National Biodiversity Strategy 2006-2016. Belgian Coordination Committee for International Environment Policy, Directorate-General for the Environment. The process of drafting the National Biodiversity Strategy was initiated by the Interministerial Conference for the Environment in June 2000. The Strategy was elaborated by a team representing the major actors in the field of biodiversity in Belgium. It acted as a contact group under the "Biodiversity Convention" Steering Committee. This Steering Committee was established under the Belgian Coordination Committee for International Environment Policy (CCIEP) under the auspices of the Interministerial Conference for the Environment, which endorsed the strategy the 26th October 2006.

[108] C. Frison and T. Dedeurwaerdere (2006) Infrastructures publiques et régulations sur l'accès aux ressources génétiques et le partage des avantages qui découlent de leur utilisation pour l'innovation de la recherche des sciences de la v*i.e.* Accès, conservation et utilisation de la diversité biologique dans l'intérêt général. Enquête Fédérale Belge. Centre de Philosophie du Droit, Université Catholique de Louvain.

[109] *Ibid.*

give stakeholders the possibility to exchange views and provide input on the options for and consequences regarding the implementation of the Protocol[110].

4.2 Federal measures

The National Biodiversity Strategy followed the **Second Federal Plan for Sustainable Development 2004-2008** [111]**.** It calls for a coherent national position on access and benefit-sharing. A third Federal Plan for Sustainable Development, calling for an "equitable distribution of the commercial exploitation of biological resources", was drafted for the period 2009-2012 but never adopted. The second plan was instead extended until 2012.

The two plans above are partly concretized by the **Federal Plan for the integration of biodiversity in four key sectors**, adopted by the Federal Government in 2010. Three of these key sectors are particular relevant for ABS-implementation: the economy, the development cooperation and the scientific policy. For each of these sectors a separate and detailed action plan has been developed for integration of biodiversity, including several ABS-related measures. For the economic sector the plan mainly focuses on awareness-raising and capacity building of the private sector and call for a pro-active participation of the Federal Government in the establishment of an international ABS-regime. The plan also calls for an increased participation of the customs administration in biodiversity policy, albeit not directly linked to ABS. This stronger understanding of biodiversity-related issues inside the customs could however be beneficial for and facilitate the implementation of the NP.

Several ABS-related actions are also planned in the context of development cooperation. These include awareness-raising and capacity-building actions with ABS stakeholders in developing countries; inter-university cooperation programs on traditional knowledge associated with genetic resources and on conservation of biodiversity; the monitoring on effective biodiversity efforts in the development cooperation; the creation of toolkits to support implementation of biodiversity conventions; and the support of gene banks and *ex-situ* conservation techniques for genetic resources. In the development cooperation sector the Federal Plan for the integration of biodiversity in four key sectors makes direct links with existing initiatives established or supported by the Belgian authorities. Both the RBINS and the RMCA have established biodiversity-related capacity-building initiatives in developing countries, although they do not directly focus on ABS. In 2003, the RBINS started supporting ILCs in developing countries in their implementation efforts of the CBD, through a convention with the Federal DGD[112]. The first phase of this convention has been running from 2003 to 2007, but has been renewed in 2008 and runs until 2012. In April 2008, the RMCA, together with the Belgian Technical Cooperation (BTC), has launched the **Central African Biodiversity Information Network** (CABIN). The aim of this project is to establish a network of databases on biodiversity information, in collaboration with several Central African research institutions[113]. Awareness-raising on ABS could easily be added to such programs. Also, the FPS Environment and the DGD have

[110] Report of the first stakeholder meeting is available here: http://www.biodiv.be/implementation/cross-cutting-issues/abs/workshop-np-20120529/20120529-nagoya-stakeholder-workshopreport-final.pdf

[111] CIDD/ICDO (2008) Federaal plan inzake duurzame ontwikkeling 2004-2008/Plan Fédéral de DéveloppementDurable 2004-2008. Interdepartmental Commission for Sustainable Development

[112] More information on http://www.biodiv.be/info0405/activities/

[113] More information on http://www.africamuseum.be/museum/about-us/cooperation/index_html

contributed to the creation of the **TEMATEA Project** that was managed by the United Nations Environment Program (UNEP) and the International Union for Conservation of Nature (IUCN)[114] until 2011. TEMATEA is a web-based capacity-building utility to support the coherent implementation of international and regional biodiversity related conventions and provides an overview of national obligations regarding ABS, as derived from several international agreements.

In the science policy field, the first proposed action of the Federal Plan for the integration of biodiversity in four key sectors is particularly relevant to ABS as it calls for an inventory of the national collection of plant germplasm. This objective will directly benefit from existing projects and initiatives. For instance, the BELSPO, together with the Ghent University, developed **straininfo.net**[115], a pilot project using bioinformatics tools (web crawlers and search engines) to access and make available data and information stored in 60 biological resource centers worldwide. A standard format to allow for culture collection catalogue information to be exchanged easily has also been developed. **PLANTCOL**[116]is another similar Belgian initiative, taken by the Association of Botanical Gardens and Arboreta. It has developed a navigation system for sharing plant information from different databases in a common format. It is also worth noting that a **Belgian Biodiversity Platform**[117]was created by BELSPO in 2003, in the context of the Second Multi-annual Scientific Support Plan for a Sustainable Development Policy. The Platform functions as an interface between providers and users of biodiversity information. Other proposed ABS-related actions in this field closely relate to those in the development cooperation field, including capacity-building initiatives in Central Africa and the promotion of *ex-situ* conservation.

In accordance with COP Decision V/26 of the CBD, a civil servant of the DG Environment of the FPS Environment currently ensures the function of national focal point on ABS.

At federal level, a "long term strategic vision for sustainable development to 2050" is currently under development. ABS concerns should be included.

4.3 Regional measures

Regions each have separate biodiversity policy-plans, mostly as part of a broader environmental strategy, in which ABS measures could be taken up. Although these plans all explicitly refer to the CBD as guidance for biodiversity policy, none of them contain ABS-related provisions. In its recently released Environmental Policy Plan 2011-2015 (MINA-4), as well as in the latest Flemish Strategy for Sustainable Development[118], the Flemish Government also refers to the 10th COP of the CBD as an important watershed moment, but without identifying or emphasizing the need for ABS-related actions.

[114] More information on http://www.tematea.org
[115] More information on http://straininfo.net
[116] More information on http://www.plantcol.be/
[117] More information on http://www.biodiversity.be
[118] Samen Grenzen Ver-Leggen. Vlaamse strategie duurzame ontwikkeling, Vlaamse Regering, 2011. Available at http://do.vlaanderen.be/sites/default/files/VSDO2_3.pdf

4.4 Research institutions' and private initiatives and policies on ABS

In 1997, the Belgian Coordinated Collection of Micro-organisms (BCCM) launched the **Micro-organisms Sustainable Use and Access Regulation International Code of Conduct** (MOSAICC) initiative. MOSAICC 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. 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.

BCCM uses a standard **BCCM Material Transfer Agreement** (MTA) for getting access to the genetic resources of its public collection. If necessary, the MTA can be amended with additional conditions 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 hold 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.

The National Botanic Garden of Belgium (NBGB) is member of **International Plant Exchange Network (IPEN)**, a network of Botanic Gardens that organizes the exchange of living plant specimens. IPEN's members have adopted a Code of Conduct regarding access to genetic resources and benefit-sharing. The NBGB only supplies seed material to other IPEN-members, unless the "Agreement on the supply of living plant material for non-commercial purposes leaving the International Plant Exchange Network" is signed by authorized staff.

Although not explicitly linked with ABS, stakeholder conferences and workshops have been organized in 2010 by the Association for Forests in Flanders (Vereniging voor Bos in Vlaanderen) on the importance of preservation of autochthonous genetic bush and tree material. This initiative led to the **Plant van Hier** project, which included the development of study material[119] and the creation of a product label[120] encouraging the commercialization of native bushes and trees.

4.5 Existing ABS-related EU instruments and other initiatives

Implementation of the Bonn Guidelines

The EU Biodiversity Action Plan (BAP) lays down the political commitment to promote full implementation of the CBD Bonn Guidelines on ABS and other agreements relating to ABS such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

[119] VBV (2011) Plant van Hier. Praktisch vademecum met oog op het behoud en de promotie van autochtone planten. Available on http://www.vbv.be/projecten/plantvanhier/Vademecum_PlantVanHier_web.pdf
[120] http://www.plantvanhier.be/

With regard to the implementation of Article 8(j) of the CBD, the EU BAP put forward the political commitment to apply from 2006 onwards the principle of PIC when commercially using TK relating to biodiversity and encourage the equitable sharing of benefits arising from the use of such knowledge. Therefore, Member States were encouraged to implement the relevant aspects of the Bonn Guidelines in MS when granting access to TK relating to biodiversity.

In particular Member States were encouraged to enhance awareness of stakeholders to effectively participate in and contribute to EU preparations for international ABS negotiations and to effectively contribute to on-going negotiations of the Standard Material Transfer Agreement (SMTA) under the International Treaty on Plant Genetic Resources for Food and Agriculture.

In order to assess the status of ABS within Europe, the European Commission undertook to calculate the percentage of European patent applications for inventions based on GR. Indicators were to be developed under the lead of the joint Secretariat of the Pan European Biological and Landscape Diversity Strategy (PEBLDS) with the assistance of the European Patent Office and the World Intellectual Property Organization.

In 2010, in the context of its reporting obligations to the EU, Belgium qualitatively monitored the implementation of BAP actions and achievement of targets. It was noted that over the period 2006-2009:

- Belgium did not provide funding for the ABS Working Group;
- no national legislation implementing the CBD Bonn Guidelines on Access and Benefit-sharing existed;
- no national activities that raise awareness of the CBD Bonn Guidelines had been implemented;
- no national legislation implementing the MTA Agreement of the ITPGRFA existed;
- no national activities raising awareness of the MTA of ITPGRFA had been implemented.

The EU funds the BIOPOMA project for ABS capacity building in ACP countries (twenty million Euros) in order to enhance existing institutions and networks by building their capacity to strengthen policy and to implement well informed decisions on biodiversity conservation and protected areas management.

The project has two components. Firstly, enhancing the effective planning and management of protected areas in ACP countries through the intensive use of scientific and policy information accessible from appropriate database reference systems combined in one information tool and the establishment of a “Centre for Protected Areas and Biodiversity” in each of the 3 regions.

The second component aims to contribute to the Access and Benefit-sharing Capacity Development Initiative. This initiative aims to further build the capacities of stakeholders in the access and benefit-sharing in each of the 3 ACP regions and is implemented through a trust fund managed by the German Cooperation Agency (GIZ).

Proposal for a Regulation on ABS

In October 2012, the European Commission proposed a Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union[121]. The proposal was based on two previously conducted impact assessments[122]. The proposal was discussed during the first Environment Council of the European Union under the Irish Presidency, on 21st March 2013[123], as well as during a workshop on Access to Genetic Resources and Fair and Equitable Sharing of Benefits held on the 19th March 2012 in the European Parliament. Negotiations on the Regulation are still ongoing in the Council's Working Party on Environment. The European Parliament committee vote is scheduled for July 2013.

Preceding the impact assessments, from October 2011 to December 2011, the European Commission also held a public consultation on the implementation and ratification of the Nagoya Protocol, with the aim of exploring the possible effects of the Protocol and to gather concrete proposals on the practical challenges of the implementation. Results of this public consultation are publicly available on the European Commission website[124].

[121] EC (2012b), *Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*. COM(2012) 576 final

[122] EC (2012), *Impact Assessment accompanying the document "Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, European Commission Staff Working Document, COM(2012) 576 final; IEEP, Ecologic and GHK (2012), *Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union*, Final report for the European Commission, DG Environment. Institute for European Environmental Policy, Brussels and London, April 2012

[123] Council of the European Union (2013). Press Release of the 3233rd Council meeting Environment. Brussels, 21st March 2013

[124] http://ec.europa.eu/environment/consultations/abs_en.htm

5 CONFORMITY OF THE EXISTING NATIONAL LEGISLATION AND MEASURES WITH THE OBLIGATIONS OF THE NAGOYA PROTOCOL

To the best of our knowledge, no existing national legislation or measures are in contradiction with the obligations under the Protocol. However, existing legislation that addresses physical access to genetic material and instruments regulating benefit-sharing between users and providers of genetic resources need to evolve and be complemented by additional instruments in order to implement the obligations of the Protocol. As indicated above, this analysis is based on the list of legal obligations summarized in annex 1 to this report.

5.1 Conformity of existing instruments in Belgium that already address obligations of the Protocol

Articles 6.1 + 6.3

Under the current legislation in Belgium access to GR is not subject to Prior Informed Consent (PIC) by the Belgian State as a Party to the NP (that is based on a written decision by a Competent National Authority (CNA) on access and benefit-sharing). Even if it is not compulsory, under the Nagoya Protocol, the Belgian State can decide that access is subject to PIC if it so wishes and take the necessary legislative, administrative or policy measures, as appropriate, to provide for access permits by one or more Competent National Authorities and establish the mutually agreed terms for these access permits.

Articles 13.1, 13.2 and 13.4

The ABS national focal point already exists. Belgium nominated a civil servant of DG Environment of the FPS Environment that currently ensures the function of national focal point on ABS. However, the obligations related to the CNA still have to be implemented.

Articles 15.1 and 16.1

Under the current legislation in Belgium (more specifically the provisions of private international law), the acquisition and the loss of property rights over genetic materials are established by the laws of the State where the good was situated at the moment these acts or facts have occurred (that is at the moment of the acquisition).

However, as discussed in chapter 3, even if these principles are a useful contribution to comply with private law contracts over genetic materials, they are certainly insufficient for the Nagoya Protocol, as the compliance with PIC obligations involves public law requirements and compliance with administrative acts of the Country of Origin of the GR, which fall out of the scope of private international law. Furthermore, at present, “use of GR under the Nagoya Protocol” is not explicitly mentioned within the scope of the Belgian code of private international law. In particular, as stated above, utilization of GR often occurs on the information components (the DNA code, published

research results, databases etc.) or might be based on the use of a copy of the GR (a clone of the entire biological material or a clone/reproduction of a component of it), even when the GR is not situated in Belgium. These frequent cases of research done on/utilization of GR that isnot physically in Belgium is not covered by the legal dispositions of the private international law code. Therefore, additional measures will be needed to comply with the obligations under Articles 15 and 16.

Article 17.1

One measure to monitor use of genetic resources has already been taken, which is the disclosure of the information on the country origin in patent application under Belgian law, whenever this information is available (cf. detailed discussion in 3.1.1.). However, this measure still needs to be completed by other measures in order to comply with Article 17.1 as it is not organized nor designated as a formal checkpoint.

Articles 18.2 and 18.3

Regarding the concrete measures linked to the international ABS regime, three main issues would have then to be addressed: (a) determining the jurisdiction that is internationally competent to deal with disputes raised within ABS agreements; (b) determining the applicable law which has to be applied in the case of ABS-related disputes; (c) recognizing and enforcing in another country, party to the NP, judgments' rendered by a jurisdiction in the ABS context.

The first two points (a) and (b) are related to Articles 18.1 and 18.2 of the Protocol, of which the provisions seem to state the obvious and have little added value. Most if not all countries in the world with a legal system provide for an opportunity to seek recourse in cases of breach of contract, and have established specific provisions regulating lawsuits involving a "foreign" law element. See chapter 3.1.2 on the existing Belgian private law and international private law provisions regarding contractual breach, amongst which the EC Regulation 44/2001 (Brussels 1) and the Rome Convention on contractual obligations (as well as the Council Regulation "Rome I")[125].

The third point (c) relates to Article 18.3 from a strict reading of which emerges that a Party could demonstrate compliance by proving ratification - or any effort leading to it - of certain international legal arbitration instruments. First, as convincingly put forward by the IUCN Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing, "it is important to note that it is not for the Parties jointly to take the measures referred to […] it is for "each Party" to enact such measures at the domestic level. Second, the measures shall be taken (only) if it is judged by the Party "appropriate" to do so".[126]

[125] To broach it more specifically, Article 18.1 does not need to be analyzed under "existing legislation" as it refers to MAT between Parties to NP: let us also note that the Article 18.1 only "encourages" providers and users of genetic resources to include dispute resolution provisions. Article 18.2, however, sets and obligation for each Party at the domestic level to ensure that recourse is available under its legal system if a dispute arises in the framework of a contractual obligation such as the one established by MAT. Moreover Article 18.2 is drafted in such a way that it does not mention whether the opportunity shall also be granted to foreign citizens. It makes clear though that such recourse has to be consistent with applicable jurisdictional requirements of the Party concerned, leaving this issue to national legislation.

[126] Greiber T., Peña Moreno S., Åhrén M., Carrasco J.N., Kamau E.C., Cabrera Medaglia J., Julia Oliva M., Perron-Welch F. in cooperation with Ali N. and Williams C. (2012), *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing*. IUCN, Gland, Switzerland.

However, taking a more comprehensive understanding of Article 18.3, the recognition and enforcement of decisions on civil and commercial matters are ruled by the EC Regulation 44/2001 (Brussels 1) as well as the 2007 Convention of Lugano on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters. The 2005 Convention on Choice of Court Agreements adopted in the framework of the Hague Conference on Private International Law is also a useful tool in this regard, as it sets rules for when a court must take jurisdiction or refuse to do so, where commercial parties have entered into an exclusive choice of court agreement. The Convention also provides for the recognition and enforcement of resulting judgments, with an option for States Parties to agree on a reciprocal basis to recognize judgments based on a choice of court agreement that was not exclusive.

Moreover, various conventions could act as “effective measures regarding access to justice" (Article 18.3.a). Regarding the investigation procedure, Belgium did not ratify the 1970 Hague Convention on the taking of evidence abroad in civil or commercial matters. This convention is mainly referring to “*commissions rogatoires*”, through which a judge delegates his investigation powers through a limited mandate allowing another judge or judicial officer to execute an investigation act on his behalf in another jurisdiction. Nonetheless Belgium ratified, amongst other applicable conventions, the Second Protocol to the 1959 European Convention on mutual assistance in criminal matters[127] and the 1965 *Hague Convention* on *notification* and communication abroad of *judicial* and *extra-judicial acts* in *civil* or *commercial matters. Taking* an extensive definition of “access to justice”, it is relevant to mention that Belgium ratified also the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters[128].

Article 20.1

Existing measures that deserve to be mentioned are the codes of conduct of IPEN and MOSAICC. These will be further discussed in the action cards below under section 6.2.

[127] Extradition procedures would in principle need to be initiated in order to execute the judgment against the person convicted for theft, or that there would need to be control over his property in order to execute the judgment against his property. These procedures would be expedited depending on the international conventions that have been adhered to by the States concerned (Castiaux J. (2011), Extradition en Belgique. In Chome P., Klees O., Lorent A. (red.), *Droit pénal et procédure pénale*, Mechelen: Kluwer, p. 155). Here, the Second Protocol to the 1959 European Convention on mutual assistance in criminal matters more peculiarly provides for transboundary observation when there are suspicions of aggravated theft (Article 17).

[128] This convention, negotiated at the European Union level, requires user countries to take effective measures to ensure that provider countries have recourse to their legal system to obtain redress. It includes an obligation to provide access to administrative or judicial procedures to challenge breaches of national law in a similar way as provided for by Article 18(2) of the Protocol.

5.2 Obligations of the Nagoya Protocol currently not addressed by legal or non-legal instruments in Belgium

To the best of our knowledge, no other obligations of the Nagoya Protocol are explicitly and specifically addressed by existing legal or non-legal instruments in Belgium. Therefore additional instruments will be needed to implement these obligations. These possible legal and non-legal measures will be considered in a systematic manner in the next section.

For the purpose of the analysis, a distinction is made however between the Articles that need to be considered most urgently, because of their core nature in the implementation of the Protocol, and additional measures that are important elements during implementation of the obligations, but that are less urgent.

The **core measures** that are considered are the measures specified in the terms of reference of this study ("measures requiring special attention"):

1. General
    - The National Competent Authorities and the National Focal Points (Article 13)
    - Legal conformity: the conformity with the national legislation of the provider country and the contractual rules (Articles 15, 16, 17 and 18)
- Access to genetic resources and traditional knowledge (Articles 6, 7 and 8).
- Benefit-sharing (Articles 5 and 9)
- Compliance and monitoring
    - Monitoring of the use of genetic resources and the designation of one or several checkpoints (Article 17)
    - The compliance with the legislations or the requirements of the provider country (Articles 15 and 16)
    - The compliance with the Mutually Agreed Terms (MAT) (Article 18)

6 REVIEW OF EXISTING MEASURES AND INSTRUMENTS ON ABS IN OTHER COUNTRIES

In the next section, a brief overview of measures adopted in other countries is presented. It is based on the review of primary and secondary information related to existing ABS regulations in other countries. In order to provide a clear and structured overview, they are grouped under the following broad themes: access, benefit-sharing, conservation activities and biodiversity research, competent National Authority, and user compliance and monitoring. Under each theme, a number of issues found in the consulted information and which are relevant for the discussion on implementation in Belgium are listed, with a particular focus on the measures listed in the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising out of their Utilization. Whenever possible, detailed reference is made to how these issues have been solved in other countries in existing legislation or in detailed assessments of possible legislation.

Relevant actions for the implementation of the NP in Belgium are summarized for each theme and a distinction is made between actions which are relevant in case of minimal implementation of the core obligations and actions which are relevant in case of additional implementation (beyond the minimal implementation of the core obligations and beyond the core obligations). This overview of existing ABS measures is by no means exhaustive, nor does it imply anything for the implementation at Belgian level. It rather serves as a base for the reflection on the identification of the possible implementation measures for Belgium. Therefore issues which have been identified as being already present in Belgium (*e.g.* the designation of a NFP) or which have already been discussed previously are not repeated in this section, even if they will be used in the further assessment of the measures. Furthermore, it has to be noted that most of the options identified below are not mutually exclusive. If necessary and/or desirable, a combination of the options also represents a possible outcome.

6.1 Access

First, as part of the core obligations, each Party to the Protocol will have to determine if access to GR will be subject to PIC by the State or not, and, if requiring PIC for access, will have to take legislative, administrative or policy measures, as appropriate, containing minimum requirements for access rules and procedures (Article 6 of the NP).

To determine the applicable access rules for GR, legal ownership of GR under national legislation will need to be fleshed out in order to decide which access conditions and procedures can and need to be implemented in relation to the prior informed consent requirements. In most countries that have ABS legislation in place, ownership of GR is derived from ownership of natural resources, which is defined by the Constitution or the civil code, or by common law[129]. This ownership applies to the physical component of these resources. In the exceptional case where patents are already attached to genetic components of natural resources at the moment of accessing a natural resource in its *in-situ* environment (because the same genetic sequence exists in the organism that is accessed and in another organism that was accessed earlier in relation to the patent), an additional layer of ownership rights can be claimed on the genetic information, but only in relation to the specific genetic component as used for the specific industrial use claimed in the patent. In all other cases, under the current Belgian legal framework it seems that no legal ownership could be claimed on the informational component due to its nature. (*cf.* the analysis in chapter 3.1.1).

As shown by a study of national legislation in selected countries[130], two ownership systems are generally in place with regard to natural resources: they can fall under private and/or communal property, they can be property of the state or they can be both. In both situations, it depends on national legislation in place how these property rights relate to the genetic components of these natural resources. In some countries, these directly derive from the ownership of the natural resources. Other countries have decided to explicitly create legal measures to limit the extent of private ownership of natural resources and to place all GR under state ownership. This option is not an obvious one. In particular, according to some scholars, it would require a modification of the property rights system which could infringe on the existing system for regulating private ownership rights[131].

Second, improperly conceived access legislation can be a major cause of legal uncertainty and/or "scare off" potential applicants. The measures to be created should hence establish a predictable and clear situation. As such, the following measures are considered in countries with ABS legislation:

[129] CBD (2007) Report on the Legal Status of Genetic Resources in National Law. Including Property Law, where applicable, in a Selection of Countries.UNEP/CBD/WG-ABS/5/1.
[130] *Ibid.*
[131] Wynberg R, Taylor M (2009) Finding a Path Through the ABS Maze – Challenges of Regulating Access and Benefit-sharing in South Africa. In Kamau EC and Winter G (Eds.) *Genetic Resources, Traditional Knowledge & the Law*. Solutions for Access & Benefit-sharing. London: Earthscan

- **the conditions under which access will be granted:** Most countries, having access legislation in place, require both PIC from the providers of GR and the proof of MAT to grant access to prospective users. However, in order to ease the access procedure, some countries have "decoupled" the access requirement and the benefit-sharing requirement. The South African Government amended its 2004 Biodiversity Act with a distinction between the "discovery phase" and the "commercialization phase" of utilization of GR. As such, it acknowledges the unpredictability of the scientific process and allows for benefit-sharing agreements to be made at a later stage in the research process, once results are clearer and potential value is easier to evaluate. The discovery phase only requires a notification to be made to the relevant Minister, while prospective "commercial users" need to apply for a permit, linked to a BS agreement, before entering in the commercialization phase[132].
- **the types of utilization requiring an access permit/PIC:** Although not always easy to make, some countries have been trying to differentiate between access for commercial and non-commercial reasons, in order to facilitate access to the latter. This has been done through different approaches. In Brazil, the Genetic Patrimony Management Council (CGEN), responsible for granting access to the country's GR, established a list of the types of research and scientific activities exempted for access requirements[133]. In Australia, access for non-commercial purposes such as taxonomy is free, while the permit fee for commercial purposes is AUD $50[134]. In Costa Rica, biodiversity related research conducted in public universities has been left out of the ABS law's scoop, except if it has commercial purposes[135]. Some countries also established differential treatment depending on the type of commercial purpose[136].
- **the actors requested to have an access permit:** access requirements can be different for domestic and foreign users. Three approaches are being used for this matter. In India, access requirements only apply to foreign individuals, institutions or companies or any Indian organization which has "non-Indian participation in its share capital or management"[137]. In South Africa, foreign nationals can only apply for access jointly with a juristic person registered in terms of South African law[138]. Most countries, however, do not make this distinction. Moreover, when countries do not require access permits for domestic researchers and companies, they still expect these actors to comply with BS[139].
- **the access procedure:** a transparent and non-arbitrary procedure needs to be set up in order to provide legal certainty to users. The main steps of an access procedure include: (1) the

[132] Sections 29, 38 and 39 of the National Environmental Laws Amendment Act, Government Gazette No. 14 of 2009, Republic of South Africa.

[133] Santili J. (2009), Brazil's Experience in Implementing its ABS Regime – Suggestions for Reform and the Relationship with the International Treaty on Plant Genetic Resources for Food and Agriculture. In Kamau E.C. and Winter G. (Eds.) *Genetic Resources, Traditional Knowledge & the Law*. Solutions for Access & Benefit-sharing. London: Earthscan ;

[134] Burton G. (2009), Access and Benefit-sharing: ABS Law and Administration in Australia. *Revista Internacional de Direito e Cidadania*, n. 5, p. 93-101, October 2009; Burton G. (2009), Australian ABS Law and Administration – A Model Law and Approach? In Kamau E.C. and Winter G. (Eds.) *Genetic Resources, Traditional Knowledge & the Law*. Solutions for Access & Benefit-sharing. London: Earthscan ;

[135] Article 4 of the Biodiversity Law, No 7788, Legislative Assembly of the Republic of Costa Rica, 30th April 1998

[136] Carrizosa S., Brush B.S., Wright B.D., McGuire P.E. (2004), Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity. *IUCN Environmental Policy and Law Paper* No. 54

[137] Article 3(2) of the Biological Diversity Act 2002. No 18 of 2003, Republic of India.

[138] Article 9(c) of the Regulations on Bio-Prospecting, Access and Benefit-sharing. Government Gazette No. 30739, 8th February 2008, Republic of South Africa

[139] Suneetha M.S., Pisupati B. (2009), *Benefit-sharing in ABS: Options and Elaborations*. UNU-IAS Report

submission to the CNA; (2) the review of the application; (3) the negotiation of PIC and possibly MAT; (4) approval or denial of the application; (5) appeal[140]. Some countries have chosen to enshrine the procedure in a legal act in order to enhance legal certainty. This is the case in Costa Rica for example, where a "General Access Procedure" was developed as a by-law to the Biodiversity Law[141].

Table 1 - Summary of relevant measures for access

Relevant measures for the minimal implementation of core obligations
Clarify access conditions (Article 6) • Option 1: no PIC required by the State but clarification of national legislation regulating legal ownership of genetic material for access to GR as provided for in the NP • Option 2 : PIC required by the State with a change in national legislation
Relevant measures for additional implementation
Clarify access requirements • Option 1: "One-size-fits-all" requirement (same access procedure for all applicants and situations) • Option 2: Differentiate access requirements depending on type of projected utilization (for example by allowing stakeholders to agree on some MAT/BS conditions at later stage than moment of access) • Option 3: Differentiate access requirements depending on type of actors (for example foreign / national) **Establish clear and transparent access procedure** • Option 1: Enshrine procedure in legal act • Option 2: Develop administrative guidance • Option 3: Provide assistance procedure to facilitate transaction between applicant and private stakeholder

[140] Young TR (2009), Legal Certainty for Users of Genetic Resources under Existing Access and Benefit-sharing (ABS) Legislation and Policy. In Young T (Ed.) *Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime*. IUCN Environmental Policy and Law Paper No. 67/5

[141] Medaglia JC (2009) The Role of the National Biodiversity Institute in the Use of Biodiversity for Sustainable Development – Forming Bioprospecting Partnerships. In Kamau E.C. and Winter G. (Eds.) *Genetic Resources, Traditional Knowledge & the Law*. Solutions for Access & Benefit-sharing. London: Earthscan

6.2 Benefit-sharing

An important debate in the literature concerns the benefit-sharing requirements laid down in the mutually agreed terms. This is also clearly mentioned as a core measure in the "Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising out of their Utilization" (Article 41 to 50). In the context of developing straightforward legislation and provide legal clarity, the following set of issues are addressed in the literature:

- **the format of MAT**: Most countries tend to have an ad-hoc approach for MAT, where the content of the MAT is negotiated on a case-by-case basis. However some countries also strived to go further by providing indicative sets of guidelines for the establishment of MAT[142]: the Australian Government has thus published two model agreements on benefit-sharing for public and privately owned material[143]. Finally, some countries decide to opt for a more coercive approach. In Australia, the Environmental Protection Diversity Conservation Regulations 2000 (Regulation 8A.10) imposes different substantial and procedural conditions to the MAT. Two model-agreements are provided, one for publicly owned areas and the other for privately owned lands. These models serve as guidelines: parties to a contract are free to set up their own format, based on bilateral negotiations[144]. The third approach imposes a standard model to be used by all the users. In South Africa, the Biodiversity Act lays down the mandatory content of the MAT, composed of a benefit-sharing agreement (BSA) and a material transfer agreement (MTA). A prescribed format is provided by the Competent National Authority for both the BSA and the MTA[145].
- **the types of utilization of GR leading to BS**: BS could be claimed for all types of access, notwithstanding the prospects of utilization (commercial and non-commercial) flowing from this access. However, in order to avoid to putting too much of a burden on non-commercial research, some countries have limited their benefit-sharing requirements only to those utilization activities with prospects for commercial use[146]. The access application however generally includes a "return clause", obliging researchers to return to the negotiation table and settle benefit-sharing terms if and when they enter into a commercialization phase[147].
- **the moment in the procedure at which BS agreements need to be settled**: In 2007, Brazil amended its domestic ABS legislation to allow users and providers to set-up a benefit-sharing contract at a later stage than the moment of access. The aim was to make the result of the planned research clearer and allow for an easier evaluation of the value generated by the GR[148].
- **the type of benefits to be shared**: Some countries set out the types of benefits to be shared. These include participation of domestic institutions, joint ownership of patents, royalties,

[142] Burton G (2009), *op. cit.*
[143] See : http://www.environment.gov.au/biodiversity/science/access/model-agreements/index/html
[144] Burton G (2009), *op. cit.*
[145] Wynberg R., Taylor M. (2009), *op. cit.*
[146] Santili J. (2009), *op. cit.*
[147] Burton G. (2009), *op. cit.*
[148] Santili J. (2009), *op. cit.*

technology transfer, etc. In India, the National Biodiversity Authority (NBA), responsible for benefit-sharing, determines possible benefit-sharing options[149].

- **making BS fair and equitable**: Whether shared benefits are fair and equitable is up for debate between the stakeholders agreeing on MAT. However, to avoid unequal bargaining power between users and providers, some countries have set-up minimum benefit-sharing criteria, such as the creation of a minimum royalty rate[150]. Other countries created a trust fund which collects all money arising from benefit-sharing agreements[151]. Although a promising solution to guarantee an equitable distribution of benefits between stakeholders, in some cases the fund only serves to channel benefits to the involved stakeholders in accordance with the provisions of the BS agreement[152]. In India, only those types of benefits determined by the National Biodiversity Authority can be considered as being fair and equitable[153].

Table 2 - Summary of relevant measures for benefit-sharing

Relevant measures for the minimal implementation of core obligations
Determine format of MAT • Option 1: Leave full discretion on how to execute the BS obligation to users and provider of genetic material • Option 2: Develop mandatory MAT terms and conditions and/or default MAT provisions • Option 3: Impose standard MAT(s)
Relevant measures for additional implementation
Clarify benefit-sharing requirements • Option 1: "One-size-fits-all" requirements • Option 2: Differentiate BS requirements depending on type of projected utilization • Option 3: Differentiate BS requirements depending on type of actors • Option 4: Utilize the actual trigger of MAT/BS, instead of access • Option 5: Specify types of benefits to be shared **Ensure benefit-sharing is fair and equitable**

[149] Article 21(2) of the Biological Diversity Act 2002. No 18 of 2003, Republic of India.
[150] Ruiz M., Lapeña I., Clark S.E. (2004), The Protection of Traditional Knowledge in Peru: A Comparative Perspective. *Washington University Global Studies Law Review*, 3(3): 755–97
[151] Carrizosa *et al.* (2004), *op. cit.*
[152] Wynberg R, Taylor M (2009), *op. cit.*
[153] Article 2(g) of the Biological Diversity Act 2002. No 18 of 2003, Republic of India.

- Option 1: Impose minimum “royalty rates” for BS
- Option 2: Establish clear standards for the valuation of resources
- Option 3: Establish a “benefit-sharing” fund
- Option 4: Impose types of benefits to be shared

6.3 Conservation activities and biodiversity research

Creating conditions to foster biodiversity-related research and making sure ABS serves a conservation purpose and encourages sustainable use of natural resources is a transversal objective. Most of the issues addressed in the literature in relation to this objective do not concern stand-alone measures, but a set of measures listed under various obligations of the NP that contribute to conservation activities and biodiversity research. The following measures are considered in relation to other objectives to make sure they serve the national biodiversity interest:

- **Ownership**: If the ownership of GR is vested in the state and the state collects all benefits arising from their use, it is much easier to make sure resources are accessed in a sustainable way and that benefits are redirected towards conservation activities[154].
- **Geographical scope:** The management of ABS and of protected areas/natural parks presents interesting synergies which could be promoted. Protected areas play a crucial role in the conservation of biodiversity as they host unique habitats, species and genetic resources. These could be of interest to users. As such, linking protected areas and ABS could be an innovative funding source for biodiversity conservation[155].
- **Benefit-sharing**: Several initiatives have been taken to redirect benefit-sharing towards conservation and sustainable use. Both Costa Rica and Peru require a fixed percentage (10%) of the value of gross sales, before tax (Peru) or of the research budget (Costa Rica) to be invested in conservation activities or capacity building initiatives for indigenous communities[156]. In South Africa, ABS regulations stipulate that surplus generated by the benefit-sharing fund should be directed towards conservation and capacity building initiatives[157]. An additional measure could be to allow the administrations responsible for the management of nature and/or biodiversity to handle sharing of benefits. This would establish a link between biodiversity conservation activities and the use of benefits. In Costa Rica, the National Commission for the Management of Biodiversity (CONAGEBIO), for example, is responsible for both the development and coordination of the national strategy concerning biodiversity conservation and the management of the utilization process[158].
- **Access**: Access conditions can be a major leverage for the sustainable use of GR and for the encouragement of biodiversity related research. Firstly, non-commercial biodiversity related research could be exempted from any access requirements, or their access requirement could be simplified, as is explicitly foreseen in Article 8a of the NP. Secondly, the granting of access permits could, for example, be subjected to a mandatory environmental impact

[154] Wynberg R, Taylor M (2009), *op. cit.*

[155] UNEP, Natural Justice and IUCN (2011) Report of the International Experts Meeting on Access & Benefit-sharing and Protected Areas, Gland, Switzerland, 6th – 8th July 2011

[156] Article 8 of Ley que Establece el Régimen de Protección de los Conocimiento Colectivos de los Pueblos Indígenas vinculados a los Recursos Biológicos, 2002. Ley No 27811, Comisión Permanente del Congreso de la República del Perú; Article 76 of the Biodiversity Law, No 7788, Legislative Assembly of the Republic of Costa Rica, 30th April 1998

[157] However, it is unlikely that the fund generates any significant surplus as it is no more than a conduit for money due to stakeholders; See Wynberg R, Taylor M (2009), *op. cit.*

[158] Article 5 of the General Rules for the Access of Genetic and Biochemical Elements and Resources of Biodiversity. Executive Decree No. 31514, Republic of Costa Rica; See also http://www.conagebio.go.cr/quienes/Funciones.html

assessment for users, as is currently being done in several countries having ABS legislation in place[159]. In Kenya, for example, the holders of an access permit are required to provide reports on the environmental impacts of the collection of genetic resources or their intangible components[160].

Table 3 - Summary of relevant measures for conservation activities and biodiversity research

Relevant measures for the minimal implementation of core obligations
Ensure ABS serves conservation activities/sustainable use (Article 9) • Option 1: Link access permit to mandatory conditions that direct benefits towards conservation activities/sustainable use • Option 2: Require environmental impact assessment prior to access • Option 3: Establish a "benefit-sharing" fund or other mechanism which redirects the benefits **Facilitate access for biodiversity-related research (Article 8a)** • Option 1: Exempt (non-commercial) biodiversity-related research from any access requirement • Option 2: Facilitate access for biodiversity-related research
Relevant measures for additional implementation
/

[159] Carrizosa et al. (2004), *op. cit.*

[160] Article 15.2(g) of the Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit-sharing Regulations 2006 of the Environmental Management and Co-ordination Act, Republic of Kenya, 2006

6.4 Competent National Authority

The CNA is the official institution that grants access, issues written evidence that access requirements have been met and advises users on applicable procedures and requirements to get access to GR[161]. In order to do so, the CNA has to be designated on behalf of the Party and given powers to fulfill its tasks as listed in the NP. The following two issues are addressed in the literature:

- **Designation:** Two approaches are considered in the literature in regard to the establishment of the CNA. The first one consists of the creation of a new institution, which is then designated as the CNA, and possibly also as the authority fulfilling other related tasks, as is the case with CONAGEBio in the national ABS legislation in Costa Rica[162]. The second approach, as used in South Africa, is the designation of an existing institution as CNA, in this case the Ministry of Environmental Affairs and Tourism[163]. According to the used wording in Article 13 of the NP, a Party may also designate more than one CNA. The African Model legislation, for example, includes the possibility for other institutions to take over the role of the CNA[164].
- **Empowering**: In order to provide users with legal certainty, the role and mandate of the CNA should be clearly defined. Under current ABS measures, the CNA takes on three types of roles. First, it can function as a "one-stop shop", *i.e.* as a single point of contact for potential users applying for an access permit, granting the ABS permit, but also channeling the applications of other related permits to the competent authorities and the outcome of the procedure back to the user[165]. Secondly, in addition to the roles under the first option, the CNA could exercise the general responsibility on coordinating/facilitating the access procedure, including the coordination of the procedures of ABS and other ABS related permits, such as the granting of related environmental (non-ABS) permits. Third, it could be the responsible authority not only for channeling, coordinating or facilitating the application and permit delivery for ABS related permits, but also be the competent authority for directly granting all ABS and ABS related permits. This latter option might require an in-depth integration with other power-levels and processes. Additionally, it might provide an opportunity to create synergies between the access granting authority and the authority responsible for compliance monitoring[166]. Another important issue to be solved is the clarification of the powers of the CNA in relation to the confidential treatment of data

[161] Article 13(2) of the Nagoya Protocol
[162] Article 14 of the Biodiversity Law, No 7788, Legislative Assembly of the Republic of Costa Rica, 30th April 1998
[163] Article 6 of the Regulations on Bio-Prospecting, Access and Benefit-sharing. Government Gazette No. 30739, 8th February 2008, Republic of South Africa
[164] Article 7(1) of the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, 2000
[165] For example in Kenya, the National Environment Management Authority (NEMA) collects all the necessary permits, issued by other authorities, before granting access permit. See Kamau E.C., Winter G. (2009), Streamlining Access Procedures and Standards. In Kamau E.C. and Winter G. (Eds.) *Genetic Resources, Traditional Knowledge & the Law*. Solutions for Access & Benefit-sharing. London: Earthscan
[166] Young TR (2009), *op.cit.*

supplied during the access procedure. The Andean Community's model law, for example, describes the conditions under which such confidential data can be treated[167].

It is worth recalling that the first upcoming task of the existing NFP and/or of the newly designated CNA will be to comply with the obligation notify the contact information of the NFP and the CNA and, in case of the designation of more than one CNA, of the relevant information on the division of responsibilities between them.

Table 4 - Summary of relevant measures for the Competent National Authority

Relevant measures for the minimal implementation of core obligations
Establish CNA (Article 13) • Option 1: Designate an existing institution as CNA • Option 2: Establish and designate a new institution as CNA • Option 3: Establish more than one CNA
Relevant measures for additional implementation
Additional legal rights and duties for the CNA • Option 1: CNA responsible for access permit acting as a single stop shop for all ABS related permits, that it channels through to the competent authorities for granting these permits; • Option 2: CNA has full and sole responsibility for the access application (as in option 1), but also coordinates/facilitates the procedure and the granting of ABS related permits; • Option 3: CNA directly grants all ABS and ABS related permits.

[167] Article 19 of Decision 391 on the Common Regime on Access to Genetic Resources. Cartagena Agreement Official Gazette No. 213 of 17th July 1996

6.5 Compliance

Efficient compliance measures, in particular through monitoring the use of GR, are key to a successful implementation of the NP. The following issues are considered in the literature for the design of compliance measures and monitoring systems:

- **Giving binding effect to domestic legislation of the provider country:** A critical step in the regulation of ABS is to lay out the basic obligations domestic users have to comply with when importing and/or utilizing genetic resources. This obligation comes down to give binding effect to the provider country's PIC and MAT. A first approach would be to consider that the prime responsibility for regulating ABS lies with the provider country. In such a case, a Party would only require users under its jurisdiction to act in accordance with the foreign legislation. A second option would be to establish a self-standing obligation in the legislation of the user country. As such, the legislation does not refer to the actual ABS legislation of the provider country, but only to the specific obligation of requiring PIC and MAT for access to its GR[168], if so requiered by the provider country.
- **Monitoring the utilization of GR:** Very few monitoring systems for ABS are operational yet. The following issues need to be addressed to serve as a basis to implement a monitoring system:
    - **Checkpoints:** at least one institution has to be designated by each Party to function as a checkpoint to monitor the use of PIC and MAT during the valorization process of GR. This can be an existing institution, such as the IPR office amongst others, or a newly created institution. The wording of Article 17.1(a) suggests that more than one checkpoint can be designated/created.
    - **Monitoring system:** The heterogeneity of utilization activities makes it very difficult to establish a 'one-size-fits-all' monitoring system. Three approaches are generally considered for the implementation of such a system. The less stringent one is the establishment of a 'voluntary monitoring system' where users would be required to report to the checkpoint(s) on a voluntary basis. It requires a strong commitment and understanding of ABS by private users as well as close collaboration between the monitoring authority and these users. In Australia, a "Biodiscovery Industry Panel" was established to foster this type of collaboration[169]. The second option is the so-called "due-diligence" monitoring system[170]. This system is a self-monitoring system requiring that users make sure they are using GR that has been accessed in compliance with the national and/or foreign ABS legislation. This type of system can be particularly relevant when GR is being transferred to third parties during the

[168] Tvedt M.W., Fauchald O.K. (2011), Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit-sharing in Norway. *The Journal of World Intellectual Property,* 14(5): 383-402

[169] Australian Government Response to CBD Notification 2011-216 on Access to Genetic Resources and Benefit-sharing. Ref.: SCBD/ABS/VN/SG/74553

[170] Kamau E.C., Fedder B. and Winter G. (2010) The Nagoya Protocol on Access to Genetic Resources and Benefit-sharing: What is New and What Are the Implications for Provider and User Countries and the Scientific Community? *Law, Environment and Development Journal*, 6(3): p.246

valorization process. A cost-effective way to support such an approach has been set-up in Australia by creating the Genetic Resources Information Data Base (GRID), where all existing ABS agreements are freely viewable online[171]. It creates a transparent system, allowing any prospective investors to verify the legal status of the genetic resources acquired on Australian territory at no cost. A third approach would rely on monitoring by previously established checkpoints at specific stages of the valorization chain. Particularly relevant here is the choice of the time at which the right of use of GR should be controlled. Possible stages are the research fund granting, the patent granting, the market access authorization and the moment of import into the country[172]. This choice would also influence the type and number of checkpoints to be established.

- **Foster compliance among users:** The strength of the motivation of users to comply is likely to be a determinant factor of the regime's effectiveness. Therefore, the state might want to create incentives and motivations for its users to comply. This could be done by offering financial benefits (*e.g.*, tax deductions, rebates, and other rights), opportunities (*e.g.*, special priority for other filings, permits or opportunities, access to special materials or programs that cannot be accessed by others) and positive publicity to complying users[173]. The latter measures are also clearly mentioned in Article 51 of the "Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising out of their Utilization".

Table 5 - Summary of relevant measures for compliance

Relevant measures for the minimal implementation of core obligations
Give binding effect to domestic legislation of provider country (Article 15, 16, 18) • Option 1: Leave responsibility to the provider country • Option 2: Create a self-standing obligation **Designate checkpoints (Article 17.a)** • Option 1: Designate existing institution as checkpoint • Option 2: Establish and designate new institution as checkpoint • Option 3: Establish more than one checkpoint
Relevant measures for additional implementation

[171] https://apps5a.ris.environment.gov.au/grid/public/perrep.jsp
[172] Kamau EC, Fedder B and Winter G (2010), *op. cit.*
[173] Young T (2006) Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime. *IUCN Environmental Policy and Law Paper* No. 67/5

Establish monitoring system

- Option 1: Voluntary monitoring system
- Option 2: “Due-diligence” monitoring system
- Option 3: Monitoring by checkpoints at specific stages of the valorization chain

Create incentives for users to comply

- Option 1: Set up financial incentives (tax reductions, rebates, …)
- Option 2: Set up structural incentives (*e.g.*, special priority for other filings, permits or opportunities, access to special materials or programs that cannot be accessed by others)
- Option 3: Set up positive publicity measures (*e.g.* label)

7 RECOMMENDATIONS FOR LEGAL, INSTITUTIONAL AND ADMINISTRATIVE MEASURES IN BELGIUM

Based on the preliminary assessment of existing ABS measures (chapter 6) and the legal gap analysis (chapter 5), this section lists a set of recommendations to support identification of policy options for the implementation of the NP in Belgium. Each recommendation is listed as an "action card", including different options for implementation. For each implementation option, a number of advantages and disadvantages are identified, which are the basis of a first selection of the recommended measures for the impact assessment and which can serve as guidelines for a more in depth discussion. Most of these implementation options are not exclusive: they should be combined in order to achieve an efficient implementation of the NP. Each action card also provides a short description of the rationale behind the action to be taken and shortly states some of the existing Belgian measures which are relevant for the action.

The action cards have been divided into two groups.

- The first set of actions comprises measures related to the core obligations for the implementation of the NP in Belgium, as specified above (*cf.* chapter 5.2). They form the basis of compliance with the NP and represent a case of 'minimal implementation' for Belgium (addressing the minimal implementation of the core obligations).
- A second set of additional measures which are important elements during implementation of the obligations, but that are less urgent (going beyond the minimal implementation of the core obligations or going beyond the core obligations).

For each of the action cards a preliminary recommendation is provided, based on the arguments advanced and organized according to the following categories:

- recommended measure
- preferred measure, potentially interesting and meriting further analysis
- more than one of the suggested measures potentially interesting and meriting further analysis
- not recommended for a particular reason

7.1 Recommendations for actions to be taken in case of minimal implementation of the core obligations

As indicated above, this section analyzes and evaluates a set of legal and non-legal instruments for the minimal implementation of the core obligations of the Protocol codified under Articles 5 to 9, Article 13 and Articles 15 to 18. This list is by no means exhaustive, but contains a set of recommendations resulting from the analysis in previous chapters and which supported the selection of the options of which the impact was analyzed in this study.

Priority of the measures

The below-mentionned action cards have been assigned a priority score according to the following scale:

★★★★	★★★	★★	★
highest priority, to be implemented at latest by the date of entry into force	**high priority**, essential component of implementation	**medium** priority, important element during implementation	**low priority**, less salient element for implementation (in Belgium), though potentially useful

7.1.1 Action card – Determine format of MAT

Description:	Under the NP, Belgian users are required to share benefits upon MAT. These MAT should hence be given binding effect under Belgian law. The NP, however, does not impose a format for MAT, which can be left to the discretion of stakeholders or flow from (mandatory) measures.
Related Article of the NP:	5, 18
Nature of the measure:	Legal
Priority for Belgium:	★★★
Relevant existing measures in Belgium	• BCCM's MOSAICC
Option 1 – Leave full discretion on how to execute the BS obligation to users and providers of genetic material	
Possible advantages:	• high flexibility for users and providers to agree on specific benefit-sharing • might be less of a burden for large company users, as they will choose to conclude MAT that generate the least cost • might represent a low-cost measure for public authorities as no additional resources are needed concerning MAT.
Possible disadvantages:	• does not allow the state to control the benefit-sharing procedure • does not allow to make sure benefits are shared in a fair and equitable way • does not allow to make sure that benefits contribute to the conservation of biological diversity and sustainable use of its

	components
Option 2 – Develop mandatory MAT terms and conditions and/or default MAT provisions	
Possible advantages:	• might provide stronger legal clarity to all stakeholders involved • allows the state to control the content of the MAT and can make sure benefits are shared according to principles of fairness and equity • might also smoothen the negotiation process between commercial users and providers
Possible disadvantages:	• might offer less flexibility to stakeholders
EVALUATION	The 2 options are potentially interesting and deserve further analysis.

7.1.2 Action card – Clarify access conditions

Description:	Holding sovereign rights over its genetic resources, Belgium can choose whether or not to require bioprospectors to obtain Prior Informed Consent for the competent authority for access to genetic resources under its jurisdiction
Related Article of the NP:	6, 7
Nature of the measure:	Legal
Priority for Belgium:	★★★
Examples of relevant existing measures in Belgium	• There are no existing legal measures on PIC to access GR in Belgium
Option 1 – Require PIC from the Belgian State as a Party to the Protocol	
Possible advantages:	• Contributes to the implementation of the Nagoya Protocol and its objective of promoting the conservation and sustainable use of genetic materials as well as their fair benefit-sharing • Allows to keep track of accessed Belgian GR • Allows for access statistics to be kept • Provides for legal certainty for users, through clarifying the legal state on access in Belgium and through the possibility of providing them with a PIC/international certificate of compliance
Possible disadvantages:	• Need to develop access rules and procedures • Depending on the implemented procedure, could create some additional administrative burden for users
Option 2 – Do not require PIC from the Belgian State as a Party to the Protocol	
Possible advantages:	• No additional legal measures needed, for establishing an access procedure • Lower administrative burden for users at time of access (as not

	needing to go through an access procedure)
Possible disadvantages:	• Does not allow to keep track of accessed Belgian GR • No information to base a potential policy review on; • Does not allow for access statistics to be kept • Would still need to take legal measures in order to clarify the current legal status for access to GR in Belgium • Would not provide legal certainty for users of Belgian GRs (*e.g.* use in third countries, subsequent use, etc.)
EVALUATION	Option 1: recommended measure ; contributes to the implementation of the Nagoya Protocol by assuring more legal certainty

7.1.3 Action card – Ensure ABS serves conservation and sustainable use of biodiversity

Description:	Alongside the aim to share benefits in a fair and equitable way, the implementation of the Nagoya Protocol should serve the broader goal of the CBD: conservation of biodiversity and sustainable use of its components
Related Article of the NP:	9
Nature of the measure:	Administrative and/or legal
Priority for Belgium:	★★
Examples of relevant existing measures in Belgium	• Article 16, Flemish Natuurdecreet: If a permit for access is delivered, the competent authority shall ensure that no avoidable damage to nature may arise by imposing reasonable conditions • Article 20, Flemish Soortenbesluit: Access to protected species can only be allowed if it does not affect the conservation of these species
Option 1 – Link access permit to mandatory conditions on the use of benefits	
Possible advantages:	• Could be a way to ensure at least a minimal part of benefits is directly flowing to conservation/sustainable use
Possible disadvantages:	• Difficult to impose on private sector legal owners
Option 2 – Require environmental impact assessment of collection, prior to access	
Possible advantages:	• Has already legal basis for certain types of access
Possible disadvantages:	• High administrative and financial burden/cost for users • May be ineffective, as collecting a sample probably does not have a major environmental impact

Option 3 – Establish a "benefit-sharing" fund or other mechanism which redirects the benefits	
Possible advantages:	• Allows for in-depth monitoring of distribution of benefits
Possible disadvantages:	• Institutional burden
Option 4 – Integrate ABS in biodiversity policies	
Possible advantages:	• Links the 3 objectives of the CBD together • ABS could benefit from more political attention through biodiversity policy • Could generate synergies between policies/actions/actors/administrations
Possible disadvantages:	• ?
EVALUATION	Option 1 and 4 recommended. The other options are only recommended if they do not lead to a disproportionately high institutional burden.

7.1.4 Action card – Facilitate access for biodiversity-related research

Description:	In order to foster biodiversity-related research, Belgium could develop additional measures to facilitate access to GR
Related Article of the NP:	8
Nature of the measure:	Administrative and/or legal
Priority for Belgium:	★★★
Examples of relevant existing measures in Belgium	• For example, in Flanders, Article 57bis of the Natuurdecreet allows access to real property for research conducted by public servants and related to nature conservation
Option 1 – Exempt biodiversity-related research by certain actors from any access requirements	
Possible advantages:	• Has already legal basis in (part of) Belgium (*cf.* example of existing measure)
Possible disadvantages:	• Does not allow for post-access monitoring
Option 2 – Facilitated access measures for non-commercial biodiversity related research (with a retun clause before entering in a commercial phase)	
Possible advantages:	• Allows to settle BS for the commercial phase at a later stage, based on clearer view of potential value of GR • Lowers administrative burden for non-commercial research at time of access
Possible disadvantages:	• Requires efficient monitoring of utilization

	• requires return clause to make sure users do come back when entering commercialization phase
EVALUATION	Option 1 and 2: both are recommended measures if they would lead to simplify the access procedure (the relevance of such an option would depend thus on the complexity of the proposed default procedures). They contribute to a core objective of the Nagoya Protocol and can build upon existing legal measures

7.1.5 Action card – Establish CNA

Description:	Each Party has to designate a CNA that grants access, issues written evidence that access requirements have been met and advises users on applicable procedures and requirements to get access to GR
Related Article of the NP:	Article 13
Nature of the measure:	Institutional
Priority for Belgium:	★★★★
Examples of relevant existing measures in Belgium	• Article 22, Flemish Soortenbesluit: access to protected species needs to be approved by the "Agentschap voor Natuur en Bos" of the Flemish government
Option 1 - Designate one existing institution as CNA	
Possible advantages:	• Low institutional cost, as institution(s) already exist • Low financial cost, as tasks would only be an addition to existing tasks
Possible disadvantages:	• Institutions could be reluctant to implement new tasks, as they might not be considered as 'core tasks' • Could be ineffective if the institution(s) does(do) not have sufficient know-how, related experience and resources • One centralized CNA is not in line with the actual division of competences for environmental issues, which are mainly situated at the level of the Regions (cf. chapter 2)
Option 2 – Establish and designate a new institution as CNA	
Possible advantages:	• Could establish very efficient procedures as it would be the 'core task' of the new institution. • Possibility to create synergies between CNA and NFP, providing more process certainty for users
Possible disadvantages:	• Could have a high financial and transaction cost, as new

	structure needs to be established • Some necessary information might be confidential and/or difficult to access • One centralized CNA is not in line with the actual division of competences for environmental issues, which are mainly situated at the level of the Regions (cf. chapter 2)
Option 3 – Designate more than one CNA	
Possible advantages:	• Would better fit the Belgian institutional framework, considering the actual division of competences
Possible disadvantages:	• Could create uncertainty for potential users on the competent CNA in certain specific cases of mixed competences (however in most cases access will be clearly granted in one of the regions). Coordination mechanisms (such as a web based centralized input system for access requests) might be required then
EVALUATION	If PIC is required, option 3 seems the most straightforward, as access is mostly clearly granted in one of the 3 regions and as the access requirements to indigenous species in the Regions are part of the regional competences.

7.1.6 Action card – Give binding effect to domestic legislation of provider country

Description:	Legal act establishing rules making it mandatory for user operating on the national territory to only use GR that has been accessed in accordance with the existing requirements of the provider country
Related Article of the NP:	15, 16, 18
Nature of the measure:	Legal
Priority for Belgium:	★★★★ *
Option 1 – Ensuring compliance with provider country legislation regarding PIC and MAT, with Belgian Law as fall-back	
Possible advantages:	• could serve as a strong measure to support compliance by Belgian users with the entire provider country ABS legislation
Possible disadvantages:	• might entail legal uncertainty and unpredictability for the users if legislation of the country of origin is improperly implemented and/or not clear enough (could be attenuated through the fall-back clause in Belgian code of private international law)

Option 2 – Self-standing obligation in the Belgian legislation to have PIC and MAT, if so required by the provider country.	
Possible advantages:	• could create less legal complexity for users and enforcement authorities in Belgium
Possible disadvantages:	• might be a less stringent measure for acting against potential illegal utilization of GR by Belgian users
EVALUATION	The 2 options are potentially interesting and deserve further analysis.

7.1.7 Action card - Designate checkpoints

Description:	At least one institution has to be designated by Belgium to function as a checkpoint to monitor and enhance transparency about the utilization of GR
Related Article of the NP:	17
Nature of the measure:	Administrative
Priority for Belgium:	★★★
Option 1 - Designate existing institution as checkpoints	
Possible advantages:	• Low institutional cost, as institutions already exist • Could have a relative low financial and transaction cost, as tasks would only be an addition to existing tasks (but depending on workload, institutional set-up, possible synergies, …)
Possible disadvantages:	• Institutions could be reluctant to implement checkpoint-tasks, as they are not considered as “core tasks” • Could be ineffective, if these institutions do not have sufficient relevant knowledge, know-how, related experience, etc. • Could represent high administrative burden, if these institutions have to create a whole new “section” for GR monitoring, with few synergies
Option 2 – Establish and designate new institution as general checkpoint	
Possible advantages:	• Could establish very efficient monitoring as it would be the “core task” of the new institution. • Possibility to create synergies with CNA and NFP, providing more process certainty for users
Possible disadvantages:	• Could have a high financial and transaction cost, as new structure needs to be established • Some necessary related information might be confidential and difficult to access by such a “monitoring” institution (compared to existing institutions that already have acquired data, the

	confidence from stakeholders and users, etc.)
Option 3 – Establish more than one checkpoint	
Possible advantages:	• Would better fit a monitoring system to support compliance if transparency is created and monitoring done at specific stages of the valorization chain • Could be better adapted to the institutional reality in Belgium • Could be more cost effective than one centralized institution • Allows to exploit existing institutional capacity to address the monitoring requirements • If based on existing institutions, these could benefit from more confidence of stakeholders and users
Possible disadvantages:	• Might need more time to install an effective set of checkpoints, and might incur a higher financial, legislative and administrative cost compared to option 1, but lower than option 2 • Might increase the complexity of the monitoring process • Might need additional coordination mechanisms amongst the checkpoints
EVALUATION	Recommended measure: Option 2: the necessary combination of technical, scientific and administrative competences will probably require a new structure to be effective. Could be combined with option 3, if needed.

7.2 Recommendations for actions to be taken in case of additional implementation

This section presents a list of recommendation for measures, which go beyond the minimal implementation of the core obligations and/or beyond the core obligations as explained above.

Priority of the measures

The below-mentioned action cards have been assigned a priority score according to the following scale:

★★★★	★★★	★★	★
highest priority, to be implemented at latest by the date of entry into force	**high priority**, essential component of implementation	**medium** priority, important element during implementation	**low priority**, less salient element for implementation (in Belgium), though potentially useful

7.2.1 Action card – Set additional specifications for benefit-sharing upon MAT

Description:	Alongside the basic mandatory conditions for access (PIC and MAT), Belgium can set additional specifications on BS upon MAT: as a mandatory access condition (in general terms (*e.g.* established in a legislative instrument/in standard PIC conditions/…) for all uses, for types of uses, or as specific terms (*e.g.* in the PIC) for the particular use(s) for which access is requested), as default access conditions (in case not provided for otherwise in the terms of the PIC), as a mandatory condition on the use in general terms (*e.g.* through a legislative instrument) for all uses, for certain uses, or in particular terms for the use envisaged (established in a particular terms for the use, probably through an approval….)
Related Article of the NP:	6, 8
Nature of the measure:	Legal
Priority for Belgium:	★★
Examples of relevant existing measures in Belgium	• In Flanders, Article 57bis of Natuurdecreet allows access to real property for research conducted by public servants and related to nature conservation • Besluit van de Vlaamse Regering betreffende de toegankelijkheid van de bossen en de natuurreservaten, 05/12/2008
Option 1 – 'One-size-fits-all' requirements for benefit-sharing	
Possible advantages:	• Easy to implement • High legal certainty
Possible disadvantages:	• Might be inefficient • Might be too constraining and inflexible for certain types of

	users
Option 2 – Differentiate benefit-sharing requirements depending on type of projected utilization, at the moment of access	
Possible advantages:	• Possibility to facilitate access for non-commercial/low-profit research, under the condition of clearly specifying additional conditions in the case of change in intent (from non-commercial to commercial)
Possible disadvantages:	• Might be difficult to establish efficient and effective conditions on down-stream use at time of access
Option 3 - Differentiate benefit-sharing requirements depending on type of actors, at the time of access	
Possible advantages:	• Possibility to foster domestic research • Could facilitate tracing of accessed GR
Possible disadvantages:	• Might foster reluctance of foreign prospectors • Might conflict with EU-rules, WTO MFN and national treatment • Might not advance the objectives of the CBD and NP • Might create loop holes in the benefit-sharing obligations, distinction domestic / non-domestic difficult to monitor
Option 4 - Utilize the actual trigger for establishing MAT/BS conditions, instead of access	
Possible advantages:	• Allows to settle BS agreement based on clearer view of potential value of GR • Lower administrative burden for users at time of access
Possible disadvantages:	• Requires efficient monitoring of utilization • Requires return clause to make sure users do come back when entering at different/certain phases of utilization (*e.g.* commercialization phase)
Option 5 - Specify types of benefits to be shared	
Possible advantages:	• Could include the (re)direction of (part of) the benefits towards conservation/sustainable use
Possible disadvantages:	• Might be difficult to establish a finite list
EVALUATION	Option 1 is not recommended because of a lack of flexibility; Option 3 is not recommended as it could be illegal. Options 2 and 4 are equally potentially interesting and are recommended for further analysis. Option 5 is also potentially interesting and recommended for further analysis and could be envisioned in combination with option 2 and 4.

7.2.2 Action card – Establish clear and transparent access procedure

Description:	The application and approval procedure should be made clear, including identifying required action to be taken, the consecutive steps of the application, setting time limits for decision-making process and provide a clear record of the final decision. Difficulties can arise when the

	application process is not clearly defined and/or stated in law or when the law leaves too much discretion to the competent access authority.
Related Article of the NP:	6, 7, 13
Nature of the measure:	Administrative and/or legal
Priority for Belgium:	★★
Option 1 – Enshrine procedure in legal act	
Possible advantages:	• High process certainty for user
Possible disadvantages:	• Lower flexibility • Higher legislative cost • Will require more time to set up
Option 2 – Develop administrative regulations, guidance for access procedure	
Possible advantages:	• Easily modifiable in case of changing circumstances • Could be quickly operational
Possible disadvantages:	• Would still need a legal basis, containing the essential elements of the procedure and the rights and obligations of individuals • Possibility of less legal certainty
EVALUATION	A combination of option 1 (legal basis with the essential elements of the procedure and setting out the rights and obligations of individuals) and 2 is recommended

7.2.3 Action card – Clarifying additional legal rights and duties of the CNA

Description:	Provide additional legal rights and duties to the CNA
Related Article of the NP:	13
Nature of the measure:	Legal
Priority for Belgium:	★★
Option 1 – CNA has full and sole responsibility for the entire access application (both ABS and ABS related permits)	
Possible advantages:	• Could create a more efficient process and follow-up • Less administrative burden for users • More process certainty for the user
Possible disadvantages:	• Could be difficult to implement, given division of ABS-related

	competences in Belgium
Option 2 – CNA is single point of contact for user on all ABS related permits, but serves as coordination/facilitation body between NFP, other ABS or non-ABS related access granting authorities	
Possible advantages:	• More suited for Belgium, given shared competences
Possible disadvantages:	• Could lead to lower process certainty for user • Probably longer application process • Would still need a degree of harmonization and integration of the different permits
EVALUATION	Option 2 is potentially interesting (especially for coordination between various permits/contracts if multiple permits/contracts are requested) and deserves further analysis.

7.2.4 Action card – Establish monitoring system

Description:	Measures should be taken to ensure an efficient monitoring
Related Article of the NP:	17
Nature of the measure:	Administrative
Priority for Belgium:	★★
Option 1 - voluntary monitoring system	
Possible advantages:	• Low-cost option • Easy to implement • Relatively flexible for users
Possible disadvantages:	• Requires a strong commitment and understanding of ABS by private users • Requires close collaboration between the monitoring authority and these users • Could be constraining for non-commercial research
Option 2 – 'Due-diligence' monitoring system	
Possible advantages:	• Relevant when GR is being transferred to third parties during the valorization process • Could have a lower legislative and administrative cost for authorities • Could be more flexible for users • Could build in a different type and level of standards according to users/use of GR • Could build in subsidiarity and responsibility for sectors

Possible disadvantages:	• requires a strong commitment and understanding of ABS by private users • requires close collaboration between the monitoring authority and these users • Could be constraining for non-commercial research • Depending on how it is implemented could still impose a considerable financial and administrative burden on users and administrations
Option 3 – Monitoring by checkpoints at specific stages of the valorization chain	
Possible advantages:	• Could be easily combined with the establishment of certain actions (*e.g.* patenting, commercialization) as triggers for BS, instead of access • Allow a more in-depth monitoring than voluntary based methods
Possible disadvantages:	• Depending on how it is implemented could be a high(er)-cost option for users and administrations • If existing institutions: institutions could be reluctant to implement new tasks, as they are not considered as 'core tasks'. • If existing institutions: could be ineffective if the institution does not have sufficient knowledge, knowhow
EVALUATION	These options should be assessed in combination with other action cards. If there is only 1 checkpoint, option 1 and 2, in combination with user incentives, is potentially interesting and deserves further analysis. If the option of more than one checkpoints is considered, option 3 is potentially interesting (seen the potential cost-effectiveness) and deserves further analysis.

7.2.5 Action card – Create incentives for users to comply

Description:	Incentives might be efficient complementary tools to enforcement mechanism.
Related Article of the NP:	15
Nature of the measure:	Administrative
Priority for Belgium:	★★
Option 1 – Set up financial incentives (tax reductions, rebates, …) for complying users	
Possible advantages:	• Could foster greater compliance motivation among (private) users
Possible disadvantages:	• Would have to transfer part of the extra cost arising out of BS to

	the state • Could favor important users who can more easily share benefits
Option 2 – Set up structural incentives (*e.g.*, special priority for other filings, permits or opportunities, (facilitated) access to special materials, programs, funds, …) for complying users	
Possible advantages:	• Could foster greater compliance motivation among (private) users • Lower financial cost than financial incentives
Possible disadvantages:	• Could favor important users who can more easily share benefits
Option 3 – Set up positive publicity measures (*e.g.* label) for complying user	
Possible advantages:	• Could foster greater compliance motivation among (private) users
Possible disadvantages:	• Labels need to be established and monitored • Could favor important users who can more easily share benefits
EVALUATION	The 3 options are potentially interesting and deserve further analysis.

7.2.6 Action card – Encourage the development of model clauses, codes of conducts and guidelines

Description:	Encourage the development of model clauses, codes of conducts and guidelines, to help stakeholders develop appropriate agreements when exchanging GR • Guidelines: Non-mandatory provisions aiming to facilitate the exchange of GR and generalize best practices • Code of conduct: Set of rules outlining the responsibilities of stakeholders when exchanging GR (*e.g.* IPEN) • Model contractual clauses: Specific clauses to be included in an ABS contract (*e.g.* ECCO core MTA)
Related Article of the NP:	19 and 20
Nature of the measure:	Administrative
Priority for Belgium:	★★
Examples of relevant existing measures in Belgium	• BCCM's MOSAICC • ECCO core MTA • IPEN Code of conduct
Option 1 – Rely upon current ABS practices of stakeholders	
Possible advantages:	• Low administrative burden • Gives responsibility to the sectors, taking into consideration

	sector specific aspects
Possible disadvantages:	• Effectiveness might be doubtful • Does not allow to address differences in bargaining power between stakeholders
Option 2 – Develop ABS guidelines	
Possible advantages:	• Could build on existing measures (MOSAICC) • Part of stakeholders already use it
Possible disadvantages:	• Difficult to impose on private sector users
Option 3 – Develop model contractual clauses or mandatory code of conduct	
Possible advantages:	• Increases control by the state on the content of ABS agreements • Could build on existing measures (IPEN, ECCO core MTA) • Could combine mandatory and non-mandatory provisions
Possible disadvantages:	• Provides less flexibility for users • Difficult to establish one model that fits all types of utilization • Could conflict with models of contracting Party • Higher administrative burden for authority
EVALUATION	Option 2 is recommended (can build upon existing practices and has proven its effectiveness). Option 3 might impose a higher burden on authorities. Option 1 gives more responsibility to the sectors, but might lack effectiveness.

8 DEFINING THE POLICY OPTIONS AND PRELIMINARY ANALYSIS OF THEIR EXPECTED IMPACTS

As for previous chapters, this chapter mainly focuses on the core measures specified in the terms of reference of this study as requiring special attention (see chapter 5.2).

Building upon chapter 6 and 7, this chapter presents policy options discussed at the first stakeholder meeting and, based on the discussion with stakeholders, selected by the Steering Committee of this study for the implementation of six core measures that are needed for the minimal implementation of the Nagoya Protocol in Belgium:

- Operationalizing Prior Informed Consent
- Specification of the Mutually Agreed Terms
- Establishment of the Competent National Authorities
- Setting up compliance measures
- Designation of one or more checkpoints
- Sharing of information through the ABS Clearing-House

It is important to remember that at least one of the legal provisions (designation of National Competent Authorities and the National Focal Point, Article 13.4) needs to be implemented no later than the entry into force of the Nagoya Protocol for each Party (that is the ninetieth day after the date of deposit of the 50th instrument of ratification if the Party ratified until the deposit of the 50th instrument, or on the ninetieth day after the date of deposit of the instrument of ratification if the Party ratifies after the deposit of the 50th instrument). Therefore, Article 13 and the core obligations directly related to that Article (such as Article 6 which has a direct impact on the tasks of the Competent National Authority) deserve a special urgent attention.

Further, in line with the EU guidelines, the general principle of the impact assessment is to assess the impact of policy options as *net changes* compared to the "no policy change" baseline. For this purpose, a general description of the "no policy baseline" is given and for each measure the particular expressions of this baseline are specified. For this purpose, a distinction is also made between a general default "no policy change over all the options" and a specific "0" option for each section, which considers a "no policy change" over a specific obligation, in a situation where nevertheless some other measures could have been taken.

The description of the options and the preliminary analysis regarding their expected impacts are based on the discussions held and the comments received during the first stakeholder meeting on 29th May 2012[174].

[174] Report of the stakeholder meeting is available here: http://www.biodiv.be/implementation/cross-cutting-issues/abs/workshop-np-20120529/20120529-nagoya-stakeholder-workshopreport-final.pdf

8.1 Description and discussion of the general “0” option

The general “0” option represents a situation where "no policy change" takes place for any of the items considered below; that is if none of the options discussed below are implemented. This would lead to a non-ratification of the Nagoya Protocol. However, in this situation, Belgium would still have to comply with the international obligations pertaining to GR and TK, mainly the CBD’s Articles 8(j) and 15 (for GR and TK associated to GR) and the ILO Convention No.107, Articles 7(1), 11 and 13 (for TK), which Belgium both ratified. In particular, Belgium would still have to take measures to clarify access to GR for their utilization, which may or may not be covered under existing legislation, and to take potential compliance measures with the aim of sharing benefits from the utilization of GR and TK in a fair and equitable way with the countries of origin of these resources. These measures related to existing international obligations would have to be taken in any of the specific “0” option measures discussed below as well. Moreover, after the entry into force of the Nagoya Protocol (in this case, without ratification by Belgium), there would be a need to clarify (reinterpret/amend) the current Belgian legal framework in the light of the adoption of the Nagoya Protocol. For example, clarify whether existing requirements on access also apply on access in the meaning of the Nagoya Protocol and for setting up a framework to enable dealing with transactions with GR from/to countries that have ratified the Nagoya Protocol.

An obvious disadvantage of the general “0” option is the failure to create the legal certainty and transparency, both prominent aspects of the implementation of the Nagoya Protocol, thereby potentially increasing transaction and litigation costs for users and providers. Moreover, as stated above, even in case of non-ratification, Belgium needs to take a set of legal measures on access and benefit-sharing. These would nevertheless be different than the set of measures required for implementing the Nagoya Protocol, creating a confusing situation for users and providers (*i.e.* existence of many different legal regimes for the same issue). Furthermore, non-ratification would lead to complex relations of Belgium as a non-Party with Parties to the Nagoya Protocol. It would also probably lead to a loss of Belgian credibility and trust on the international forum; with a risk of straining multilateral relations and also loss of exchanges (research, development, collections, industry, …) and hence opportunities for Belgian individuals and institutions (*e.g.* in relation with Parties to the Protocol).

8.2 Defining the policy options for the core measures and their expected impacts

8.2.1 Access to GR and Benefit-sharing

As a first preliminary finding of the study on the implementation in Belgium of the Nagoya Protocol, it is recommended to establish Prior Informed Consent (PIC) and Benefit-sharing (BS) as general legal principles in Belgium in order to implement Article 5 (on benefit-sharing) and Article 6 (on access) of the Nagoya Protocol. As a general principle, the operationalization of PIC and BS should be phased, flexible and based on the subsidiarity principle

This operationalization of PIC and BS can then be divided in two implementation components that are interrelated: the operationalization of PIC (first component) and the specification of the Mutually Agreed Terms (second component).

8.2.1.1 Description of the options

- **The specific "0" option: Benefit-sharing-component**
  The specific "0" option on BS would consider taking no measures on benefit-sharing in Belgium (such as establishing benefit-sharing as a general legal principle). This would lead to a non-ratification of the Nagoya Protocol, and would still require to take the measures specified in the general "0" option. Moreover, it is unclear if this would not amount to non-compliance by Belgium with Article 15 of the Convention on Biological Diversity.

- **The specific "0" option: Access-component**
  This specific "0" option on Access would consider no PIC requirement, with or without benefit-sharing as a horizontal principle. This would not necessary lead to a non-ratification of the Nagoya Protocol (if benefit-sharing is established as a horizontal principle). If it leads to a non-ratification, this "0" option would still require to take the measures specified in the general "0" option above. However in both cases (with or without benefit-sharing as a horizontal principle), this "0" option would create less legal certainty for users of Belgian GR, would not allow to deliver an international certificate of compliance for such users (which serves as evidence that GR, which it covers, has been accessed in accordance with PIC and that MAT have been established) and could lead to a lack of data on the use of Belgian GR for evaluating policy and promoting research and development.

- **General ABS option 1: No Prior Informed Consent required, but Benefit-sharing as horizontal principle**
  Under option 1, no PIC would be required, but BS would be established as a general legal principle in Belgium in order to implement Article 5 (on benefit-sharing) and Article 6 (on access) of the Nagoya Protocol (which specifies that a Party might determine not to require PIC). However, even if no PIC is established, the current legal framework on access will still need to be

clarified, in a way that allows complying with the obligations of the Nagoya Protocol and the options for implementing the core measures discussed in this report.

- **General ABS option 2: Prior Informed Consent and Benefit-sharing as horizontal principles**
  Under option 2, PIC and BS would be established as general legal principles in Belgium in order to implement Article 5 (on benefit-sharing) and Article 6 (on access) of the Nagoya Protocol. As a general principle, the subsequent operationalization of this general obligation through PIC and MAT should be phased, based on subsidiarity and flexible.

8.2.1.2 Expected impacts

- **General ABS option 1: No Prior Informed Consent (PIC) required, but benefit-sharing as a horizontal principle**
  This option might seem easily implementable as it would not require any additional legal measures to be taken and could imply a relatively low administrative burden, as the requirements for operationalizing PIC would be avoided (this possible advantage will only be important if the options chosen below imply a heavy administrative burden).

  However, this option would still require clarifying the current legal framework on access, in a way that would not only take into account the adoption of the Nagoya Protocol (see general baseline), but would also allow complying with the obligations of the Nagoya Protocol and the options for implementing the core measures discussed further in this section.

  Furthermore, it is unclear how this option could provide legal clarity for users after access, in particular since it does not allow the State to offer users a proof of legal access such as an international certificate. Nor will it allow post-access tracking and/or monitoring of the utilization of genetic resources and the collection of data, which could result in missing out important input of valuable data for research, innovation and conservation policy. In other words, under this option, the Belgian State would not give itself the means to get information on its GR accessed or to monitor/control the use of its own genetic resources. It could lose out on an important incentive to promote conservation and sustainable use of its own GR.

- **General ABS option 2: Prior Informed Consent (PIC) and Benefit-sharing as horizontal principles**
  The Nagoya Protocol contributed to turn the debates about PIC and BS around. Whereas previously, it was considered to be more interesting for users to access genetic resources in states having the least regulation in place, now users might prefer states with public and transparent access and benefit-sharing legislation in order to optimize the legal certainty for the subsequent utilization of these resources. A major advantage of the option 2 is that it paves the way for the delivery of an internationally recognized certificate of compliance to users by the Belgian State, hence increasing transparency and legal certainty. It could further allow more efficient and effective monitoring and tracking of the use of its GR. Keeping track of access to GR will also give a better view of the available genetic resources, and facilitate data and statistics collection which are useful for biodiversity policy in general and for further

implementation of the Nagoya Protocol in particular. To be functional, this option however needs additional legal access rules and a clearly defined access procedure. Depending on the further operationalization, it could create administrative burden, both for users as for public authorities involved in administrating PIC.

8.2.2 Further operationalizing general option 2 on PIC

If both Prior Informed Consent and Benefit-sharing are established as horizontal principles (general ABS option 2 above) two additional interrelated measures should be implemented: the operationalization of PIC (first component) and the specification(s) of the possible requirement of and conditions for the Mutually Agreed Terms (second component). The first implementation component could consider the operationalization of PIC through a notification/registration/approval requirement[175] to the Competent National Authority or authorities. In the second component, implementation measures related to the content of the mutually agreed terms of the access agreements, including as specified in the notification/registration/approval procedure, should be considered. In line with Articles 4 and 8 of the Nagoya Protocol, these measures should have due regard for the particular features of certain sectors, species or areas and, in line with Articles 1 and 9, they should contribute to the objectives of conservation and sustainable use of biodiversity.

8.2.2.1 Description of the options

The options to establish and operationalize PIC are built up in two parts:

1. **Starting point: limit administrative burdens by building on existing legislation**
   Two reasons make a preliminary analysis of the existing legislation necessary for the study of the different PIC "sub-options".

   First, situations should be avoided where different permits from different administrations would have to be obtained for accessing the same material: the superposition of different requirements and procedures for the same material would furthermore complicate the administrative follow-up and increase the administrative burden, in particular if the same data would have to be resubmitted to different, unrelated permit databases.

   Second, protected areas (PA) and protected species (PS) contain GR which are important for conservation and sustainable use of biodiversity and may be of actual/potential (high) value. The first step in the implementation of the PIC and BS requirements could

   (a) consider refining existing PA and PS relevant legislation in order to include more specific regulation for the access to GR for utilization, as defined under the Nagoya Protocol.
   (b) beyond refining PA and PS relevant legislation, potentially include other relevant categories of GR with *e.g.* actual or potential value, by also considering other existing

[175] "Notification" and "registration" refer to an easy and less burdensome permit requirement: the permit is automatically provided/generated if the applicant provides certain data and complies with certain general conditions. "Approval" refers to permit-requirement that demands an individual assessment of each individual application, that apart from general permit conditions, might also imply the imposition of permit specific conditions.

legislation relevant for the access to GR to build upon with the view to further operationalize PIC.

2. **Default option to complement the starting point (*cf. to build on existing legislation*)**

   Additionally, for all the GR which are not covered through PA or PS legislation, a default rule could be adopted. This could be done

   (c) by only allowing such access from/through Belgian collections, or

   (d) by allowing access from anywhere, providing the user has registered/notified the Competent National Authority (CNA).

When combining the above, the assessment of the impacts of the following three options seems to be the most relevant:

- **Option 1: The bottleneck model: only existing PS/PA relevant legislation & measures + only access to GR through ex-situ collections as default rule (a) + (c)**
  This option combines the refinement of existing PA and PS relevant legislation with the default rule for GR which are not in a protected area or which are not protected species that only Belgian collections can provide access to GR.
- **Option 2: The fishing net model: only existing PA/PS relevant legislation & measures + access to GR from everywhere but with registration as default rule (a) + (d)**
  This option combines the refinement of existing PA and PS relevant legislation, with the default rule that GR can be accessed from anywhere, providing the user has registered/notified the CNA.
- **Option3: potentially enlarged existing PA/PS relevant legislation & measures + other specific GR relevant legislation/measures + access to GR from everywhere but with registration as default rule (b) + (d)**
  This option combines an enlarged approach to refining existing legislation relevant for GR, with a default rule that GR, not covered by such modified legislation, can be accessed from anywhere, providing the user has registered/notified the Competent National Authority.

8.2.2.2 Expected impacts

- **Option 1: The bottleneck model: only existing PS/PA relevant legislation & measures + only access to GR through ex-situ collections as default rule**

  Possible Advantages: This option would allow the collections to keep a copy of each accessed GR in Belgium whenever this is feasible at a minor cost. The existing scientific and administrative infrastructure of the culture collections could foster ex-post follow up. Existing databases and standard information could be used. The newly encoded information could contribute to biodiversity research such as taxonomic research. Finally, and as a general remark, the cost for access to collections is very high and should be kept as low as

possible. To this end, it should take into account the high number of transactions by the collections.

In case part of the benefits arising from the utilization of GR would be directed to the conservation activities of the collections, benefit-sharing could generate additional financial support for the collections. This option would not necessarily lead to heavy transaction costs for the collections, as most collections already have standard Material Transfer Agreements (MTA) in place which could be easily adapted, on the condition that these are in line with CBD provisions, including the Bonn Guidelines.

Possible Disadvantages: A lot of the relevant GR might be situated outside the collections, such a configuration requiring thus additional resources for the handling of access requests. For these GR two situations can be distinguished.

(a) The collection decides to keep a copy of the GR (for example when it is feasible for the collection to keep the GR at a minor cost and whenever it is scientifically relevant). In that case there are no additional resources required for handling the access request, as it is part of the standard procedures of the collections (including encoding in databases, handling of MTAs, etc.). However additional financial resources might be needed to bear the cost of handling the access request and storing information or samples that would not have passed by the collections otherwise (*e.g.* depending on whether the access concerns physical samples or only information).
(b) The collection decides not to keep a copy of the GR (*e.g.* because it is expensive/beyond the capacity/scientifically not relevant/technically not possible). In that case, if information has to be kept on the access of the genetic resource, it would require the extension of the database infrastructure beyond the ex-situ holdings, to include documentation on access provided to in-situ resources through the collections. However, this might not represent an important additional cost, as it is possible to build upon the existing infrastructure. This second sub-option could also require the handling of MTA for the *in-situ* resources accessed through the collections, but not kept in the collection. .

Furthermore, the relation between the culture collections and the CNA and the specific access-related powers of the collections will need to be clarified, as the CNA is the final authority able to grant access for utilization in the context of the NP. This could lead to an additional step in the access procedure and could create additional administrative burden for users wishing to access GR. However this border is not necessarily higher than under the other options as it would be based on a division of labor in the PIC procedure over the different entities.

- **Option 2: The fishing net model: only existing PS/PA relevant legislation & measures + access from everywhere, but with registration as default rule**

Possible Advantages: For the default rule, this option could strongly encourage utilization, as the administrative burden for users would be low. Financial and transaction costs for the State could also be relatively low, as the notification obligation could be easily set up through

a standardized system. Moreover the notification/registration obligation would (1) provide data on the type of users of the genetic resource and (2) facilitate possible policy review.

Possible Disadvantages: Under this option the default rule could prove to be ineffective or even create a loophole in the basic rule, if cases where species are found only within protected areas prove to be rare, and/or if most species within protected areas can also be found outside of these areas. Furthermore, this option would not allow to obtain as easily a copy of accessed GR in Belgian collections (whenever feasible) and it might be harder to coordinate with the existing databases of the ex-situ collections which already contain information on previous accesses and utilization of Belgian GR. Moreover, the default rule under this option might need to be limited to non-commercial use only.

- **Option 3: Existing PA/PS relevant legislation & measures + other specific GR relevant legislation/measures + access from everywhere, but with registration as default rule**
  Possible Advantages: It can be expected that this option would mainly give the same positive impacts as under option 2(*PA/PS legislation +access from everywhere as default access to GR*).It will however have a bigger impact, as it would apply similar requirements as those for PA and PS to a broader set of GR and by integrating the new regulation with a broader set of related legislation. This option thus allows coping with cases where access to genetic resources is not limited to PA and PS. Microorganisms with potential value for research and development, for example, are generally found where natural selection has taken a different path *i.e.* in extreme environments that do not necessarily coincide with the PA/PS category. This option thus allows to extend the further operationalized PIC requirements to the broadest range of potentially interesting GR and reduces the amount of GR falling under the default category.

  Possible Disadvantages: Similar disadvantages as for the option 2. Furthermore, the amount of existing legislation relevant to GRs beyond the PS/PA related legislation, but also the amount of areas/material in Belgium beyond PA/PS, that are of particular importance for biodiversity, will determine whether or not this option has any added value beyond option 2.

8.2.3 Specification of the Mutually Agreed Terms

If PIC would be required in Belgium, it should also be clarified whether MAT is required and under what conditions (*e.g.* as a condition to obtain PIC). Given that a phased approach would allow to fine-tune the measures as more feedback is gathered, the initial MAT requirements could be further developed over timer after a rather limited first implementation phase.

This section therefore further describes the “sub-options” considered in the case where both Prior Informed Consent and Benefit-sharing are established as horizontal principles (general ABS option 2 above).

8.2.3.1 Description of the options

In order to develop an idea of possible impact, 3 types of MAT are proposed for further exploration:

- **Option 1: No specific BS requirements imposed for the MAT**
  A first type where, in the exercise of its sovereign rights over its GR, the Belgian State decides not to impose any specific benefit-sharing requirements from users in MAT (apart from the general legal obligation to share benefits and the structural benefits occurring from working of the future Belgian ABS system).
- **Option 2: Specific BS requirements imposed, through standard agreements, depending on finality of access**
  For the second type, specific benefit-sharing requirements are imposed through standard formats for the MAT (*e.g.* a limited number of standard MAT-agreements), depending on the finality of the access. This could imply that no specific BS requirements are imposed in the MAT if no commercial utilization of the GR is planned, while more specific BS requirements are imposed if commercial purposes are envisaged (*e.g.* the collection of revenues from that use or the sale of the GR itself). The related MAT for non-commercial utilization would include a re-negotiation requirement in case of change in intent to commercial use.
- **Option 3: Specific BS requirements imposed, but their implementation is negotiated on a case by case basis, depending on finality of access**
  Under option 3, specific benefit-sharing requirements are developed by the Belgian Authorities for each access request. These requirements can be of a different nature (*e.g.* a general regulatory obligation, a specific condition as a PIC-conditionality, etc.) and will be differentiated according to the finality of access.

8.2.3.2 Expected impacts

- **Option 1: No specific BS requirements imposed for the MAT**
  Possible Advantages: This option provides for high flexibility for users and providers to agree on specific benefit-sharing, depending on the specificities of the exchange of GR. It thus probably represents less of a burden for large company users, as they will choose to conclude MAT that generate the least costs, but it might be burdensome for non-commercial and small company users to negotiate individual MAT (*e.g.* if no standard MAT are available/applied in their sector). For the authorities, this option also represents a low-cost measure as no additional resources are needed concerning MAT.

  Possible Disadvantages: This option does not allow the Belgian State to control the benefit-sharing procedure and to make sure benefits are shared in a fair and equitable way, or that benefits contribute to the conservation of biological diversity and sustainable use of its components. According to paragraph 45 of the Bonn Guidelines, fair and equitable benefit-sharing varies “in light of the circumstances” and a third independent stakeholder (*i.e.* the state) might be needed to identify these circumstances.

- **Option 2: Standardized formats for BS requirements, depending on finality of access**
  Possible Advantages: This option provides strong legal clarity to all stakeholders involved. It also allows the Belgian State to control the content of the MAT and can make sure benefits are shared according to principles of fairness and equity. It might also smoothen the negotiation process between commercial users and providers, as it could offer standard formats containing guidelines/default rules/requirements to follow, while providing security to providers that changes of intent will need a renegotiation.

Possible Disadvantages: This option offers less flexibility to commercial users that already have their own systems or prefer a more flexible approach.

- **Option 3: Specific BS requirements, depending on finality of access**
  Possible Advantages: This option provides strong legal clarity to all stakeholders involved. It also allows the Belgian State to control the content of the MAT and make sure benefits are shared according to principles of fairness and equity. It furthermore provides much flexibility to fine tune the BS requirements to cover concerns of both users and providers, including the contribution to conservation and sustainable use.

  Possible Disadvantages: Non-commercial users and small commercial users might suffer from this option, as they might not necessarily possess the needed resources to negotiate and fulfill the specific BS requirements.

8.2.4 Establishing one or more Competent National Authorities

8.2.4.1 Description of the options

The designation of one or more Competent National Authorities needs to be implemented no later than the entry into force of the Protocol for each Party. Therefore this measure deserves special attention. Based on the options for the operationalization of PIC, the choice of the Competent National Authority would in the first place be based on the relevant competent authorities for the existing legislation and measures concerning in protected areas and/or protected species. This means four Competent National Authorities would be needed: one for each of the three Regions and a federal one, hence flowing from the actual division of competences in Belgium.

The difference between the proposed options lies in the way users might have to request access to GR.

- **Specific "0" option for the CNA**
  The specific "0" option on the Competent National Authority would consider not creating a Competent National Authority under the Nagoya Protocol. This would lead to a non-ratification of the Nagoya Protocol, and still require to take the measures specified in the general "0" option.

- **Option 1: Decentralized input**
  Each authority would have a separate entry-point, and users of genetic resources would need to request access through separate entry-points depending *e.g.* on the kind of GR or where they are found.

- **Option 2: Single entry-point**
  Under this option, the four responsible authorities could agree on a centralized input system. Users would request access through a single point of contact, independently of where/which types of GR are accessed.

8.2.4.2 Expected impacts

- **Option 1: Decentralized input**
  Possible Advantages: Flowing from the actual division of competences in Belgium, this option could provide more liberty to the federated entities to independently organize their biodiversity and/or genetic resources access policy.

  Possible Disadvantages: Having four different Competent National Authorities might strongly complicate the access procedure, not in the least for foreign users. Additional efforts will be needed in order to clarify the access procedure, *e.g.* providing users with a clear overview on which of the four Competent National Authorities is responsible for handling access requests, depending on where/which GR are accessed. This might result in a higher administrative

burden for both users and administrations. Moreover a decentralized input system for the data generated might lead to additional data coordination and exchange problems.

- **Option 2: Single entry-point**
  Possible Advantages: A uniform or harmonized process could increase the legal and procedural clarity for users. This might result in less administrative burdens related to the search for information on access procedures and requirements under the Nagoya Protocol in Belgium. Furthermore, some economies of scale could be possible here for the public authorities concerned. Depending on the scope of these economies of scale, it might be decided to opt for more or less coordination through the single entry-point.

  Possible Disadvantages: This option potentially has a higher initial administrative burden and transaction cost. A common system needs to be established and close coordination between the different authorities needs to be ensured.

8.2.5 Setting up compliance measures

8.2.5.1 Description of the options

The options for compliance in order to fulfill the obligations of articles 15, 16 and 18 of the Nagoya Protocol are dependent both on the sufficiency of the existing relevant dispositions contained, inter alia, in the existing criminal code, civil procedural code and on implementation of PIC in Belgium. A general criminal provision covering situations where PIC and MAT are required by the provider country is considered. In situations where a civil judge has to consider the contents of MAT, an extension of the field of application of art 15[176] of the Code of private international law is envisaged. The granting of PIC on the access to genetic resources within the context of the Nagoya Protocol pertains to the country of origin of the GR applying its sovereign rights. Therefore, compliance with PIC involves public law and administrative acts, which fall outside of the scope of private international law.

To contribute to the implementation of Articles 15, 16 and 18, the following options are proposed:

- **Specific "0" option for the compliance measures**
  The specific "0" option on compliance measures would consider not introducing any legal provision on compliance. This would lead to a non-ratification of the Nagoya Protocol, and still require to take the measures specified in the general "0" option. Moreover, even if these measures were be taken in order to comply with the obligations of the CBD and the ILO Convention No.107, users and providers would not be able to benefit from the clarified legal framework that the compliance measures envisioned under the Nagoya Protocol would

[176] The Belgian national law enacting the code of private international law states in its Article 15 that, if a foreign law needs to be applied to a case that is examined by a Belgian judge, the content of such applicable law should be identified by the judge, according to interpretations received in the "country of origin" (sic). Collaboration can be required if the content cannot be established clearly by the Belgian judge. If it is "impossible to determine the content of foreign law in due time, Belgian law should be applied" (art.15§2al2)"

entail. This might lead to increased litigation and transaction costs (for clarifying exactly what the compliance to the CBD implies in a situation of no additional measures).

- **Option 1: Ensuring compliance with provider country legislation regarding PIC and MAT, with Belgian Law as fall-back option**

Under this option, a general criminal provision is created that refers back to PIC and MAT obligations as specified in the legislation of the provider country while the private international law code would determine that provider country legislation is applicable to disputes regarding compliance with the PIC and MAT.

Sanctions would be provided for cases of non-compliance with PIC and MAT requirements set out by the provider country. When checking content of MAT, a provision in the code of international private law would provide for reference to provider country's legislation, with Belgian law as a fallback option. The state would enact a general prohibition to use GR/TK accessed in violation of the law of the providing country, by specifying that the reference to foreign law in the Belgian code of private international law also applies to the use of GR within the context of the Nagoya Protocol[177]. The sanctions for violation could in that case be a fine and a confiscation. The state could act *ex officio* to enforce this criminal provision, which is usually taken up on the basis of complaints by individuals. The fact that a violation of foreign law would be considered as a violation of national, Belgian law, and could be prosecuted and sanctioned as such, would also make it easier for providers to subsequently claim civil law damages.

A provision in the private international law code would determine that provider country legislation is applicable to disputes regarding compliance with PIC and MAT. If it is impossible to determine the content of the foreign law in due time, Belgian law should be applied[178].

Option 2: Self-standing obligation in the Belgian legislation to have PIC and MAT if so required by the provider country.

Under this option, a provision is created containing an obligation to have PIC from the provider country and MAT for the utilization in Belgium of foreign genetic resources, if the legislation of the provider country requires PIC and MAT for access to its GR. As such, Belgian legislation would not refer to the legislation of the provider country regarding PIC and MAT, but only to the specific obligation of requiring PIC and MAT for access to its GR.

8.2.5.2 Expected impacts

- **Option 1: Ensuring compliance with provider country legislation regarding PIC and MAT, with Belgian-law as fall-back**

[177] The Belgian national law enacting the code of private international law states in its Article 15 that, if a foreign law needs to be applied to a case that is examined by a Belgian judge, the content of such applicable law should be identified by the judge, according to interpretations received in the "country of origin" (sic). Collaboration can be required if the content cannot be established clearly by the Belgian judge. If it is "impossible to determine the content of foreign law in due time, Belgian law should be applied" (art.15§2al2)"

[178] *cf.* supra, previous footnote.

Possible Advantages: This option could serve as a strong measure to support compliance by Belgian users with the entire provider country ABS legislation.

Possible Disadvantages: The option relies upon the assumption that the legislation of the country of origin properly implements the Nagoya Protocol provisions and that it is clear enough and acceptable for enforcement. If not, the option might entail legal uncertainty and unpredictability for the users. This disadvantage is attenuated to a certain extent through the fall-back clause in the code of private international law (cf. description of the option above).

- **Option 2: Self-standing obligation in the Belgian legislation to have PIC and MAT if so required by the provider country.**
  Possible Advantages: It could create less legal complexity for users and enforcement authorities in Belgium
  Possible Disadvantages: It might be a less stringent measure for acting against potential illegal utilization of GR by Belgian users, although the criminal provision could later be extended to encompass other elements.

8.2.6 Designating one or more checkpoints

8.2.6.1 Description of the options

Belgium could consider not introducing checkpoints as envisioned under the Nagoya Protocol, within the general "0" option. If Belgium does decide to introduce checkpoints, their implementation could take place in several phases. In order to respect the political commitment to timely ratify the Nagoya Protocol, the first phase could look at a minimal implementation requiring the establishment of a single checkpoint. Two possible options seem relevant for the first phase, namely PIC ("Option 1") and an upgraded patent disclosure ("Option 2"). In subsequent phases, more effective checkpoints might need to be developed in order to monitor the utilization of GR. Possible checkpoints to be explored at a later stage could possibly include public research funding, *ex-situ* collections or intellectual property related checkpoints other than the patent authorities, such as authorities for assessing applications for geographical indications of origin.

Working with different phases could allow for a fast start with limited resources to prepare for an early ratification of the Nagoya Protocol. It also provides time to better identify concrete problems and to learn from the experience of others. However, it might take a longer time to arrive at the most effective and/or relevant checkpoints for the situation on the ground. Therefore caution should be taken not to delay addressing existing and known problem areas.

- **The specific "0" option on checkpoints**
  This option would consider not introducing checkpoints as envisioned under the Nagoya Protocol (whether through an integrated PIC requirement or upgrading the disclosure requirements in patent applications or through any other means). This would lead to a non-ratification of the Nagoya Protocol, but still require to take the measures specified in the general "0" option. Moreover, in the implementation of the CBD and ILO Convention No.107 obligations, it would lead to a lack of monitoring of the requirements under these

conventions (and therefore a lack of transparency and data), compared to a situation where the compliance provisions of the Nagoya Protocol would have been implemented. In particular this might create a lack of legal certainty through the lack of checkpoints (where they are supporting compliance)which, if established, would clarify the relevant obligations.

- **Option 1: Monitoring PIC in the ABS Clearing-House as a checkpoint**
  For this option, PIC might need to comply with more specific information collection and transfer obligations for checkpoints (irrespective of *e.g.* the obligation to make available permits to the ABS-CH (Article 14.2(c) of the NP), or the obligations linked to the obtaining of an internationally recognized certificate of compliance (Article 17.2-4 of the NP) which may to a certain extent overlap. Using the ABS CH as checkpoint will depend on further policy decisions taken regarding the CNA and the ABS CH.

- **Option 2: Using the patent office as a checkpoint**
  Legislation is already in place for the disclosure of origin in patent applications (whenever the information is available): a logical step in this first phase could thus be that the patent office would function as a checkpoint. This might be made possible by an upgrade of the disclosure requirement in the patent applications, including information related to both the country of origin (as under the current legislation) and information on PIC from the country of origin. However, as Article 17 of the NP talks about "relevant information related to PIC, to the source of GR, to the establishment of MAT, and/or to the utilization of GR, as appropriate", an upgrade might not even be necessary in order for the patent office to qualify as a checkpoint. Further clarification on the necessity to comply with the obligation to provide for "appropriate, effective and proportionate measures to address situations of non-compliance" is under negotiations in other multilateral *fora* (WTO).

8.2.6.2 Expected impacts

- **Option 1: Using the ABS Clearing-House as a checkpoint**
  Possible Advantages: This option could lead to very few additional obligations in the case that general ABS option 2 (PIC as a general legal principle) would be adopted, except for linking the PIC approval to the information obligations to the Clearing-House, and would therefore be sufficient to contribute to respect the political commitment to timely ratify the Nagoya Protocol. Moreover, if appropriately linked to the Clearing-House, the PIC could constitute an internationally recognized certificate of compliance under the Nagoya Protocol and thereby contribute to the objective of increasing overall legal certainty and transparency.

  Possible Disadvantages: Some extra administrative burden, as the PIC approval would need to be linked to the information obligations under the Clearing-House (which however will probably not be a heavy obligation).

- **Option 2: Using the patent office as a checkpoint**
  Possible Advantages: This option could lead to very few additional information exchange obligations and hence administrative burden for the patent authorities and users, as the

information on the country of origin of the GR has to be provided by the users in the patent application, is available. The microbial e*x-situ* collections that are recognized as international deposit authorities (IDA) also keep already records of such information in the current situation.

Possible Disadvantages: The Belgian patent office currently covers only a very small proportion of the transactions concerned by the Nagoya Protocol. A legal change could be required to upgrade the patent disclosure in order to be able to use it as a checkpoint within the framework of the Nagoya Protocol. In particular, the information on PIC should be included, wherever applicable, and a link with the information obligations under the Clearing-House should be made.

8.2.7 Sharing information through the Clearing-House

As the discussions on the exact modalities of the ABS CH are still ongoing internationally, it remains unclear if a separate Belgian ABS Clearing-House (ABS CH) component or only a Belgian entry-point will be required. The "0" option would therefore consist in not taking any steps regarding such a component or entry-point nor provide ABS specific information to the central ABS CH. This would lead to a non-ratification of the Nagoya Protocol, but still require to take the measures specified in the general "0" option. In particular, this "0" option would still need to comply with the obligations concerning the Belgian Clearing-House Mechanism to the Convention on Biological Diversity (CBD CHM), which also concerns information exchange on ABS as explained below.

8.2.7.1 Description of the options beyond the "0" option

A distinction needs to be made between two separate functions of a Clearing-House component for ABS:

1. Information exchange on ABS, including on the Nagoya Protocol, within the framework of the CBD

- This is ongoing and can be further strengthened by integrating more relevant material into the Belgian CBD CHM managed by the Royal Belgian Institute of Natural Sciences (RBINS). This obligation flows from the CBD and is therefore independent of the future ratification of the NP.

2. Support exchange of information on specific ABS measures within the framework of the Nagoya Protocol

- Measures are needed to organize the technical information to be provided according to the Nagoya Protocol (for example on PIC, checkpoints and the ABS CH) as well as other information to be decided upon at international level by the NP COP/MOP.

  The modalities of a separate Belgian ABS Clearing-House (ABS CH) component therefore still depend on the ongoing multilateral negotiations.

In this context, it remains unclear whether a Belgian CHM-component or only a Belgian information entry-point will be required. If such a component/entry-point is required, it is clear that the generated information will be useful for Belgian research and development, as well as for the objectives of conservation and sustainable use of biodiversity.

Depending on the decision regarding the exact ABS CH modalities, three options could be explored. Three institutions could be potential candidates to support a Belgian component/entry-point of the ABS Clearing-House, if required. The strengths of these different options can be summarized as follows:

- **Option 1: Royal Belgian Institute of Natural Sciences (RBINS) as ABS Clearing-House**
- **Option 2: Belgian Federal Science Policy Office (Belspo) as ABS Clearing-House**
- **Option 3: Scientific Institute for Public Health (WIV-ISP) as ABS Clearing-House**

8.2.7.2 Expected impacts

These will depend highly on the decisions taken on the exact role and technical specifications of the Clearing-House. However, in general the following points could be expected under these three options:

- **Option 1: Royal Belgian Institute of Natural Sciences (RBINS) as ABS Clearing-House**
  Possible Advantages: Interesting synergies could be created under this option. The RBINS already hosts the National Focal Point (NFP) to the CBD and ensures the Belgian component of the CBD Clearing-House Mechanism. The RBINS also runs several biodiversity-related research units which could directly benefit from the generated information. Additionally, the RBINS ensures an important awareness building mission towards the broader public through its Museum of Natural Sciences. It operates the Belgian Clearing-House Mechanism for the CBD, with a strong focus on awareness raising, education and communication. It has development projects running (in collaboration with DGD) on establishing CHM in partner countries. Through these capacity building activities with the partner countries, it could play an important role in supporting developing countries with their obligations under the Nagoya Protocol with regard to the ABS CH. Furthermore, the administrative burden for the RBINS could be relatively low if additional information obligations related to the ABS CH could build upon the experience of the RBINS with the general CBD CHM.

  Possible Disadvantages: Nevertheless, the CHM only has a general communication, information sharing approach and does not handle specific scientific or technical data, contrary to the WIV with the Biosafety Clearing-House (BCH) (see option 3). Its applicability will therefore heavily depend on the level of technical requirements for the ABS CH.

- **Option 2: Belgian Federal Science Policy Office (Belspo) as ABS Clearing-House**
  Possible Advantages: This option would be ideal for biodiversity research that contributes to sustainable development, as Belspo already hosts the Biodiversity Platform, which has as main task to foster such research. It has several collection databases that could support the working of PIC/checkpoints/ABS-CH. Belspo also hosts several other consultative bodies

linking scientific and policy analysis and is involved at international level with digitalization of collection databases.

Possible Disadvantages: Compared to the other options, the administrative burden might be heavier, as Belspo does not currently have any information obligations towards the secretariat of the CBD.

- **Option 3: Scientific Institute for Public Health (WIV-ISP) as ABS Clearing-House**
  Possible Advantages: As it hosts the Belgian component of the CBD's Biosafety Clearing-House (BCH), the WIV-ISP is used to exchanging scientific, technical data with the CBD Secretariat. It also runs several health-related research units which could directly benefit from the generated information. Furthermore, the administrative burden for the WIV-ISP could be relatively low if additional information obligations related to the ABS CH could build upon the experience of the WIV-ISP with the BCH.

  Possible Disadvantages: The current BCH is very disconnected from the CBD CHM which would be a disadvantage for the ABS CHM where the link between the three objectives is a prime requisite for any implementation option. It also might have little added value regarding awareness raising, capacity building etc. Its relevance will therefore strongly depend on how much the BCH is taken into account at international level as the example to develop the ABS CH.

8.3 Target Groups and Stakeholders for Which Potential Impact is Assessed

For the purpose of the impact assessment of the recommended options in chapter 10, a list with categories of target groups and stakeholders, that could be affected by the proposed measures, is established.

8.3.1 Users and providers of genetic resources

8.3.1.1 Land owners

- Protected areas: both public and private areas managed for conservation purposes (as providers (not necessarily in the meaning of the NP) of potentially valuable GR).
- Other land owners: any public/private land owner might become a provider of GR (not necessarily within the meaning of the NP) with potential interest for R&D.

8.3.1.2 Agriculture sector

The agricultural sector includes a variety of public and private organizations, working in the fields of crop and animal selection/improvement, horticulture, fisheries, forestry and biological control. It is an important sector, given the share of Belgium in the world's agricultural products export. Several types of genetic resources are used by the Belgian agricultural sector, including animal genetic resources for food and agriculture (AnGR), fisheries and aquatic genetic resources for food and agriculture (AqGR), forest genetic resources for food and agriculture (FGR), plant genetic resources for food and agriculture (PGR), microbial genetic resources for food and agriculture (MiGR) and genetic resources relevant for biological control and crop protection.

8.3.1.3 Healthcare sector

In the context of this study, the healthcare sector includes the pharmaceutical industries, the care and cosmetics industries, so-called 'soft' natural medicines and *in vitro* diagnostic companies/laboratories. In the healthcare sector, the industries from the private sector in general play a predominant role. This sector is made up of both major multinationals and small family-style firms. Belgium hosts around twenty multinational companies in this sector. The SME sector is much more developed, with almost one hundred companies in Belgium[179]. The country is the world's third largest importing country of biopharmaceutical products and the world's one-but-largest exporter[180]. The pharmaceutical sector is thus a major player in the Belgian economy. The sector claims to provide the country with more than 30,000 jobs and to account for up to 40% of private R&D funding[181].

[179] Frison C., Dedeurwaerdere T. (2006), *op. cit.*
[180] UN Comtrade (2010) Medicinal and pharmaceutical products (SITC 54) Available at http://comtrade.un.org/.
[181] Figures from Pharma.be, http://www.pharma.be/newsitem.aspx?nid=2174

8.3.1.4 Biotechnologies and processing industry sector

The sector is made up of the remaining stakeholders active in the field of biotechnologies, but not active in the healthcare sector. It covers, amongst other, the following fields: energy, materials, biocatalysts, and chemical industries. The processing industry sector in Belgium is mainly focused on food industries and animal feed industry.

8.3.1.5 *Ex-situ* collections of genetic resources

The *ex-situ* collections sector in Belgium includes over 300 organizations and covers botanical gardens, zoos, aquariums, museums, herbaria, gene banks, collections of micro-organisms/cells, collections of dead material, both in public and private collections.

Key players may include:

- The Belgian Co-ordinated Collections of Micro-organisms (BCCM) comprising seven Belgian biological resource centers;
- Royal Belgian Institute of Natural Sciences;
- Royal Museum for Central Africa;
- Vereniging van Botanische Tuinen en Arboreta (VBTA);
- National Botanic Garden of Belgium;
- Institute of Public Health;
- Veterinary and agrochemical research Center;
- The Walloon Agricultural Research Center;
- Zoos.

8.3.1.6 Governmental research institutions

Researchers in governmental institutions are accessing genetic resources, as well as traditional knowledge associated with genetic resources, on a regular basis for research purposes. In this category we only consider the specificities of public and academic research, while private research is dealt with under the other stakeholder categories.

Key players may include:

- The Royal Belgian Institute of Natural Sciences (RBINS);
- The Royal Museum for Central Africa (RMCA)
- The Walloon Agricultural Research Center (http://cra.wallon*i.e.*be)
- Veterinary and agrochemical Research Center (http://www.coda-cerva.be)

8.3.1.7 University research sector

Key players targeted are the departments of Belgian universities that deal in particular with life science, engineering, as well as chemical, agricultural, environmental, health research, etc.

8.3.2 Other possible stakeholders

8.3.2.1 Civil society

Civil society organizations (advocacy NGOs, interest groups, etc.) do not seem to be directly impacted by the Nagoya Protocol as such. However, they might be consulted if they have gathered relevant information on the provision and/or use of genetic resources that can contribute to the impact assessment (if they developed a certain expertise, or have a privileged contact to information from a main user/provider of GR for example).

8.3.2.2 Citizens and consumers

Same comment as for civil society.

9 IMPLEMENTATION OF THE OPTIONS WITHIN THE EXISTING LEGAL SITUATION IN BELGIUM

This chapter analyzes the implementation modalities of the policy options described in chapter 8, taking into account the existing legal and institutional situation in Belgium described in chapters 2 to 5. The structure of the chapter is based on the six core measures used in chapter 8.

9.1 Operationalizing PIC

Summary of the selected options for the operationalization of PIC

8. **Specific "0" option** (access component): the specific "0" option on access would consider no PIC requirement, with benefit-sharing as a horizontal principle
9. **Option 1** – The bottleneck model: refining existing PS/PA relevant legislation & measures + only access to GR through *ex-situ* collections as default rule
10. **Option 2** – The baseline fishing net model: refining existing PA/PS relevant legislation & measures + access to GR from everywhere but with registration as default rule
11. **Option 3** – Modified fishing net model: potentially enlarged refinement of existing PA/PS relevant legislation & measures + refinement of other specific GR relevant legislation/measures+ access to GR from everywhere but with registration as default rule

For a detailed description of the options please refer to chapter 8.2.

Two different components of these options need to be compared in the assessment of the options for operationalizing PIC:

- First, for the GR which are not PS/PA, comparing the bottleneck option to the fishing net option (access through *ex-situ* collections, compared to access from everywhere).
- Second, comparing the "baseline" fishing net model, which envisions the refinement of existing PA/PS relevant legislation to the "modified" fishing net model, where, in addition, other existing GR relevant legislation would be refined.

The impacts identified below are an aggregate of the impacts likely to occur along these two components that are present in options 1, 2 and 3.

Under the specific "0" option for access, only the situation where BS as a horizontal principle has been adopted is considered, as the situation, where BS is not addressed as a horizontal principle will be assessed under measures for BS as the specific "0" option for MAT (chapter 9.3). As such the specific "0" option for PIC considered here is equivalent to the general ABS option 1 (BS, but no PIC).

9.1.1 IMP 1.0 – Implementation of the specific "0" option for operationalizing PIC

Under the "0" option, benefit-sharing would still be established as a general legal principle in Belgium, which is not currently the case (*cf.* chapter 5). In addition, the European Commission's

proposal for a Regulation on ABS[182], which is currently under discussion, encourages benefit-sharing but in its current form, does not establish benefit-sharing as a general legal principle.

Seen the division of competences in Belgium, this general legal principle should be firmly anchored in the environmental competences of the Regions and the Federal Government. Indeed, as argued in section 3.2 of chapter 3, any legal measure that would consider introducing Prior Informed Consent could benefit from building upon existing legislation on physical access to and use of genetic material. Under the current regulations, the rules regulating physical access depend upon the type of ownership (private, public or *res nullius*), the existence of restrictions to the ownership, such as specific protection (protected species, protected areas, forests or marine environments) and the location (all four authorities apply their own rules) of the genetic material. As these regulations currently are part of the environmental competences of the Regions and the Federal Government such anchorage seems the most logical way forward.

The implementation and the subsequent operationalization of this general principle would be phased, based on subsidiarity and flexible. Moreover, as for the implementation of other multilateral environmental agreements such as the Kyoto Protocol[183] and the Cartagena Protocol[184], considering the need for a minimum level of harmonization of the implementation procedure in Belgium, a cooperation agreement between the Regions and the Federal Government may be necessary.

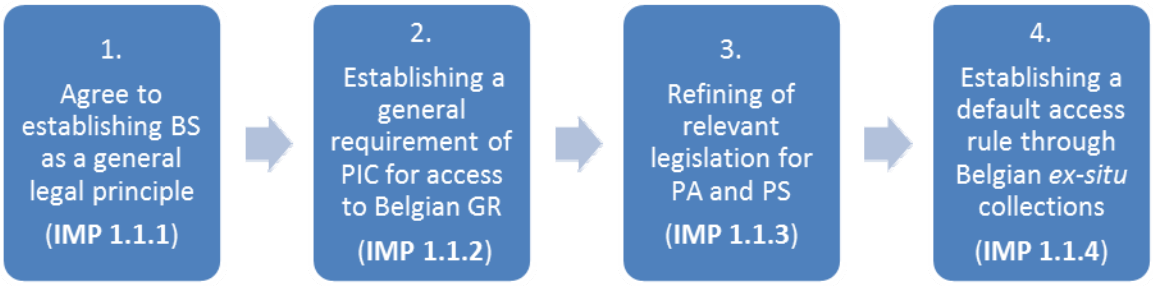
On this basis, the implementation of option "0" could be based on three components:

(1) A political agreement from the competent governments to establish benefit-sharing as a general legal principle, to be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations, such as the basic environmental code of the three Regions and at the federal level.
(2) The subsequent or parallel implementation of this general principle through a cooperation agreement and/or analogous provisions in relevant legislations, such as the basic environmental code of the three Regions and at the federal level[185].
(3) The subsequent operationalization of the general principle by the respective governments at the regional (through executive orders) and federal level (through royal orders), establishing rules and procedures for further implementation of the benefit-sharing provision as envisioned in the other options considered below.

[182] EC (2012b), *op. cit.*
[183] 19th February 2007 - Accord de coopération entre l'Autorité fédérale, la Région flamande, la Région wallonne et la Région de Bruxelles-Capitale relatif à la mise en œuvre de certaines dispositions du Protocole de Kyoto
[184] 25th April 1997 - Accord de coopération entre l'Etat fédéral et les Régions relatif à la coordination administrative et scientifique en matière de biosécurité (M.B. 14.07.1998)
[185] The provisions IMP 1.0 (2); IMP 1.1.1 (2); IMP 2.2 ; IMP 2.3 would require a Federal Law and Decrees of the Federated Entities, to amend the basic environmental codes of the Regions and the Federal State : Natuurdecreet, 21st of October 1997 (Vlaams Gewest) ; Loi sur la Conservation de la Nature, 12th of July 1973 (Région Wallonne) ; Ordonnance sur la conservation de la nature, 1st of March 2012 (Région Bruxelloise) ; Law on the protection of the Marine Environment, 20th January 1999. For a detailed description of these laws, *cf.* above section 3.1 of the study on the "Access and use of genetic resources under national jurisdiction in Belgium".

9.1.2 IMP 1.1 – Implementation of option 1 for operationalizing PIC

The implementation of option 1 for operationalizing PIC can be broken down in four subsequent components:



IMP 1.1.1 – The establishment of BS as a general legal principle

Option 1 also includes (as option 2 and 3) the establishment of BS as a general legal principle in Belgium. For this implementation part, the same components are considered as for IMP1.0:

(1) A political agreement from the competent governments to establish benefit-sharing as a general legal principle to be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the basic environmental code of the three Regions and at the federal level.
(2) Subsequent or parallel implementation of this general principle through a cooperation agreement and/or analogous provisions in relevant legislation such as the basic environmental code of the three Regions and at the federal level.
(3) Subsequent operationalization of the general principle by the respective governments at the regional (through executive orders) and federal level (through royal orders), establishing rules and procedures for further implementation of the benefit-sharing provision as envisioned in the other options considered below.

IMP 1.1.2 – Establishing a general legal principle to require PIC for access to Belgian GR

In addition, option 1 would require establishing as a general legal principle that access to Belgian GR requires PIC. For the implementation of this principle, the same considerations as those considered for IMP 1.0 apply. Therefore, the same three phased components are considered as for IMP1.0:

(1) A political agreement from the competent governments to establish PIC as a general legal principle for access to Belgian GR, with the specifications that this would be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the basic environmental code of the three Regions and at the Federal level.
(2) Subsequent or parallel implementation of this general principle through a cooperation agreement and/or analogous provisions in relevant legislations such as the basic environmental code of the three Regions and at the federal level.
(3) Subsequent operationalization of the general principle by the respective governments at the regional (through executive orders) and federal level (through royal orders), establishing

rules and procedures for further implementation of the general PIC provision as envisioned in the other options considered below.

IMP 1.1.3 – Refinement of relevant legislation for Protected Areas (PA) and Protected Species (PS)

Option 1 could be implemented by refining existing PA/PS relevant legislation to establish that access provisions to PA/PS not only concern physical access but also access within the meaning of the Nagoya Protocol and that such access would also amount to prior informed consent from the Belgian State. Once more information becomes available over time regarding experience with the implementation of that general provision and taking into account ongoing discussions and/or practices at international and Party level, the modalities for executing this general principle/provision could be further refined. In addition, IMP 1.1.3 is a further operationalization of IMP 1.1.2, which in itself already provides a sufficient legal basis for establishing PIC as a general principle in the context of the ratification of the Nagoya Protocol.

Therefore, any further specification can be made in a later stage after IMP 1.1.1 and IMP 1.1.2, as soon as more experience is available, and for the implementation of this aspect of option 1, the assessment only considers the following component:

(1) Amendment of existing legislation relevant for PA/PS to establish that access provisions to PA/PS not only concern physical access but also access within the meaning of the Nagoya Protocol and that such access also automatically amounts to PIC under the implementation of the principle established under IMP 1.1.2. (through a Decree/Ordinance of the Regions)[186]

IMP 1.1.4 – Establishing the default access rule (from qualified Belgian collections only)

Option 1 would specify that, for GR outside PA/PS, access to Belgian GR would need to be sought and processed as much as possible through qualified Belgian collections (which are equipped for deposit of data and/or samples). Once IMP 1.1.2 is established, IMP 1.1.4 is a further operationalization that is part of the specification of the procedures for processing access requests by the Competent National Authorities, including the designation of the qualified collections by the Regions and the Federal Government. Therefore, under IMP 1.1.4, only the establishment of the general principle is considered, while the detailed operationalization will be considered under IMP 3.1 below.

(1) A political agreement from the competent governments to establish a default access rule from qualified Belgian collections between the Regions and the Federal Government which

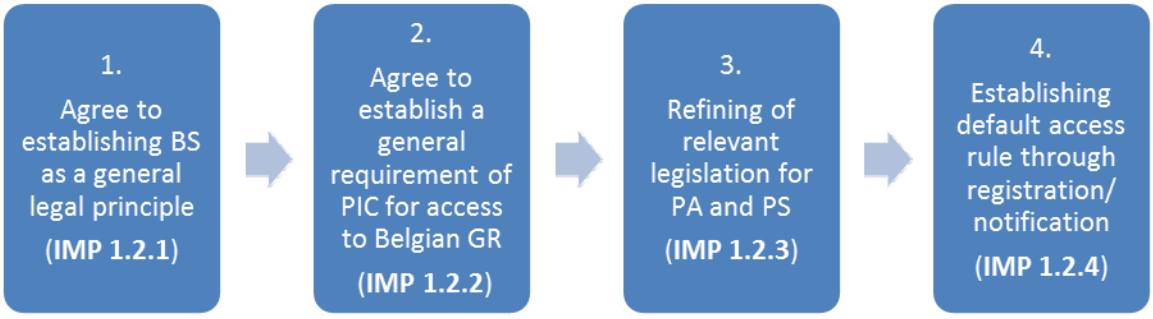
[186] As explained in the detailed analysis in section 3.2., the current access provisions are regulated by various legal measures, depending on the nature of the material, the region and the environmental competence. Therefore, it would be probably most effective (and efficient) to implement this first through a general provision in the basic environmental code and second make specific amendements in the other applicable codes as discussed in ch 3.2.2. to 3.2.5.. The first step would require a Federal Law and Decrees of the Federated Entities, to amend the basic environmental codes of the Regions and the Federal State : Natuurdecreet, 21st October 1997 (Vlaams Gewest) ; Loi sur la Conservation de la Nature, 12th July 1973 (Région Wallonne) ; Ordonnance sur la conservation de la nature, 1st March 2012 (Région Bruxelloise) ; Law on the protection of the Marine Environment, 20th January 1999. The second step could build upon several specific existing access regulations (for example whenever access is given for research), see explanations on existing PA/PS relevant legislation (chapters 3.2.2 - 3.2.5).

would be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the basic environmental code of the three Regions and at the Federal level (which would not be necessarily part of the first implementation step, *cf.* considerations in chapter 11). This access rule would specify that access to Belgian GR, that are not covered by PA/PS relevant legislation, would need to be sought and processed through qualified Belgian collections (which are equipped for deposit of data and/or samples).

(2) Subsequent or parallel implementation of this general principle for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the basic environmental code of the three Regions and at the federal level, which deal with the establishment of the Competent National Authorities and the rules and procedures for processing access requests by these Authorities (*cf.* IMP 3.1. below).

9.1.3 IMP 1.2 – Implementation of option 2 for operationalizing PIC

Similarly to option 1, the implementation of option 2 for operationalizing PIC can be broken down in four subsequent steps:



The first three implementation steps are identical to the first three implementation steps of option 1 (IMP 1.1.1; IMP 1.1.2; IMP 1.1.3)

The fourth implementation step of option 2 (**IMP 1.2.4**) is similar to the fourth step of option 1 (IMP 1.1.4), with the exception that the default access rule would specify that PIC would require minimally a registration/notification to the Competent National Authority. As also discussed below, a combination of IMP 1.2.4 and IMP 1.1.4, as a general principle in a cooperation agreement, can also be envisioned. However, for the purposes of the assessment under this section, at this stage these options are considered separately.

9.1.4 IMP 1.3 – Implementation of option 3 for operationalizing PIC

The implementation components of IMP 1.3 are the same as under IMP 1.2, except that it would also include the refinement of other existing legislation relevant to access to GR[187] in an analogous way as the refinement of the access provisions under the PA/PS relevant legislation.

[187] The refined fishing net would consider any other legislation where notification/registration/permit exist and specify that such notification/registration/permit is also considered as a PIC under the Nagoya Protocol. The case of the conservation varieties, cited for illustration only, shows such a legislation that is different from the PA/PS legislation and where the current legislation on the "admission to use" could be considered also as a PIC under the Nagoya Protocol, in further

IMP 1.3.1 – Further refinement of GR legislation

(1) Amendment of other existing legislation relevant for access to GR, establishing that any access in that context not only concerns physical access but also access within the meaning of the Nagoya Protocol and that such access also automatically amounts to PIC under the implementation of the principle established under IMP 1.1.2. (through a Decree/Ordinance of the Regions).

refinement of the legislation. The matter of conservation varieties do not fall under Annex 1 of the ITPGRFA Treaty and are currently regulated by the following legislations : Ministerieel besluit van 2 juni 2009 tot vaststelling van bepaalde afwijkingen voor de toelating van landrassen en rassen in de landbouw die zich op natuurlijke wijze hebben aangepast aan de lokale en regionale omstandigheden en die door genetische erosie worden bedreigd (Vlaams Gewest); Arrêté du Gouvernement wallon introduisant certaines dérogations pour l'admission des variétés de légumes traditionnellement cultivées dans des régions spécifiques ou sans valeur commerciale (Région Wallonne) ; Arrêté ministériel du 10 décembre 2010 introduisant certaines dérogations pour l'admission des races primitives et variétés de légumes traditionnellement cultivées dans des localités et régions spécifiques et menacées d'érosion génétique (Région Bruxelloise).

9.2 Specification of MAT

Summary of the selected options for the specification of MAT

0. **Specific "0" option**: No benefit-sharing
1. **Option 1**: No specific benefit-sharing requirements imposed for the MAT
2. **Option 2**: Standard agreements with specific benefit-sharing requirements, depending on finality of access
3. **Option 3**: Specific benefit-sharing requirements, negotiated on a case by case basis, depending on finality of access

For a detailed description of the options please refer to chapter 8.2.

Given that a phased approach would allow fine-tuning the measures as more feedback is gathered, the initial MAT requirements analyzed hereunder could be further developed over time after a rather limited first implementation phase.

9.2.1 IMP 2.0 – Implementation of the specific "0" option for the specification of MAT

The specific "0" option under MAT would lead to a non-ratification of the Nagoya Protocol. However, as discussed in the preliminary assessment above, it is unclear how the specific "0" option would still allow the Belgian State to comply with the BS obligations of the CBD and the obligations under ILO 107, and what implementation steps would result from this alternative scenario.

9.2.2 IMP 2.1 – Implementation of option 1 for the specification of MAT

The implementation of option 1 would require establishing the general principle of benefit-sharing (*cf.* IMP 1.0. above). However, as option 1 considers no specific regulation in addition to the general BS principle, no additional implementation steps are needed.

9.2.3 IMP 2.2 – Implementation of option 2 for the specification of MAT

As under IMP 2.1 the implementation of option 2 is part of the subsequent operationalization of the general principle of benefit-sharing under IMP 1.0., as envisioned in step 3 of IMP 1.0. However, in this case, specific requirements on MAT are considered. Therefore, to assess this option, we will consider the following implementation component:

- The subsequent operationalization of the general principle formulated under IMP 1.0. by the respective governments at the regional (through executive orders) and federal level (through royal orders), establishing specific requirements on MAT, including the use of standard agreements, depending on the finality of use.

9.2.4 IMP 2.3 – Implementation of option 3 for the specification of MAT

Idem as IMP 2.2., but the specification of the BS requirements in the general rules does not impose the use of standard agreements. In this option, the implementation of the specific BS requirements would always be negotiated on a case by case basis. Therefore, to assess this option, we will consider the following implementation component:

- The subsequent operationalization of the general principle formulated under IMP 1.0. by the respective governments at the regional (through executive orders) and federal level (through royal orders), establishing specific benefit-sharing requirements, negotiated on a case by case basis.

9.3 Establishing one or more Competent National Authorities

Summary of the selected options on the Competent National Authority

6. **Specific 0 option**: non-establishment of the CNAs
7. **Option 1**: Decentralized input to the CNAs
8. **Option 2**: Single entry-point to the CNAs

For a detailed description of the options please refer to chapter 8.2.

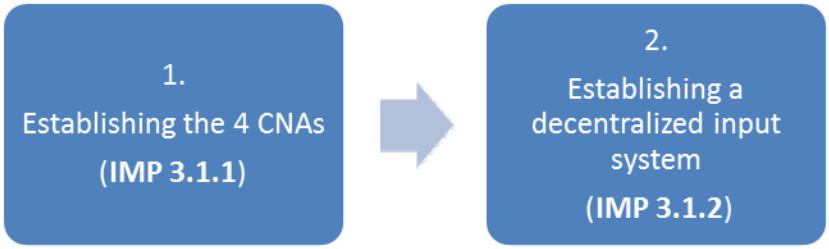
The choice of the Competent National Authority would in the first place be based on the relevant competent authorities for the existing legislation and measures related to GR (that is PA/PS and possibly other existing legislation on GR). This means four Competent National Authorities would be needed: one for each of the three regions and a federal one, flowing from the actual division of competences in Belgium. These CNAs would thereby build upon existing institutions and be responsible for granting the access permits. Given this institutional context, the options do not reflect the amount of CNAs to be established but rather the ways in which users can request access (*i.e.* directly through one of the CNAs *vs.* through a centralized entry-point). In particular, under a centralized access system, the CNAs would coordinate through channeling, facilitating and/or advising the access requests. This has consequences for the level of comparability of the proposed options. Whereas options 1 and 2 focus on different scenarios to organize the ways in which a user requests access, option 0 focuses on the non-establishment of the CNA. The latter would lead to a non-implementation of the Nagoya Protocol, but still require from the Belgian State to clarify the access procedures to Belgian GR, as discussed in chapter 8.

9.3.1 IMP 3.0 – Implementation of the specific "0" option on the Competent National Authorities

Idem to IMP 2.0

9.3.2 IMP 3.1 – Implementation of option 1 on the Competent National Authorities

The implementation of option 1 on the CNA implies two distinct steps:



IMP 3.1.1 – Establishing the four Competent National Authorities

The choice of the Competent National Authorities should take into consideration the division of competences in Belgium on environmental issues, and the objective of the Nagoya Protocol to contribute to conservation of biological diversity and the sustainable use of its components. The choice of the four authorities competent for the existing legislations and measures related to protected areas and protected species, or for other existing legislation on access to GR, would seem logical. Therefore, option 1 and option 2 consider the logical situation where the CNAs would be established in the respective authorities (*cf.* section 3 of this report), that is the "Agentschap voor Natuur en Bos" in the Flemish Region, the "Division de la nature et des forêts" in the Walloon Region, the "Institut Bruxellois pour la gestion de l'environnement" in the Brussels-Capital Region and one authority to be established at the federal level, probably at the Directorate-General for the Environment of the Federal Public Service "Health, Food Chain Safety and Environment" (for GR that are not under competences of the federated entities, such as Marine GR and ex-situ GR held at federal institutions).

Considering that both option 1 and 2 would benefit from the additional legal clarity that will be provided through a timely ratification of the Nagoya Protocol (in particular through the decisions at the first COP/MOP to the NP), two phased implementation components for this option are considered in this assessment:

(1) A political agreement from the competent governments to establish four Competent National Authorities to be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the environmental codes of the three Regions and at the Federal level.
(2) Subsequent or parallel implementation for example through a cooperation agreement and/or the analogous provisions of relevant legislations such as the basic environmental code of the three Regions and at the federal level. The specification of the rules and procedures for processing access requests by these Authorities would be done to the maximum possible extent through executive orders of the governments of the Federated Entities.
(3) Administrative arrangements could be established between designated ex-situ collections and the CNAs for processing access requests (under option 1 for PIC)or for the management of the notification/registration procedures by the four CNAs (as envisioned under option 2 and 3 for PIC). Such administrative arrangements would not require any additional legal measures (legislative or executive), but could be supported by policy guidance (advice, provision of technical information).

IMP 3.1.2 – Decentralized input system

A decentralized input would not require any additional implementation measures to the measures under IMP 3.1.1.

9.3.3 IMP 3.2 – Implementation of option 2 on the Competent National Authorities

The implementation of option 2 would be very similar to the implementation of option 1 (IMP 3.1). The choice of the Competent National Authority would in the first place be based on the relevant competent authorities and the division of competences (**IMP 3.2.1**). The main difference is that option 2 would provide for a centralized input system to access requests, which are then referred to one of the 4 CNAs and their respective rules and procedures. This would require the establishment of a single entry-point (such as a webportal) and the specification of rules and procedures for the single entry-point (**IMP 3.2.2**). Therefore this assessment will consider the following implementation of option 2

- A political agreement from the competent governments to establish a single entry-point for access requests (including the specification of its rules and procedures) through a cooperation agreement between the Regions and the federal level
- Subsequent or parallel implementation through a cooperation agreement which would include the rules and procedures for requesting access through a single entry-point as this would avoid differences between the Regions and the federal level

9.4 Setting up compliance measures

Summary of the selected options on compliance

0. **Specific "0" option**: not introducing any legal provision on compliance
1. **Option 1**: Ensuring compliance with provider country legislation regarding PIC and MAT, with Belgian law as a fall-back
2. **Option 2**: Self-standing obligation in the Belgian legislation to have PIC and MAT if so required by the provider country.

For a detailed description of the options please refer to chapter 8.2.

As highlighted in chapter 8.2, the Belgian national law enacting the code of private international law states in its Article 15 that, if a foreign law needs to be applied to a case that is examined by a Belgian judge, the content of such applicable law should be identified by the judge, according to interpretations received in the "country of origin" (sic). Collaboration can be required if the content cannot be established clearly by the Belgian judge. If it is "impossible to determine the content of foreign law in due time, Belgian law should be applied" (art.15§2al2)". Therefore, the implementation of option 1 would only entail a minimal amendment to this code by including explicit reference to the use of GR within the context of the Nagoya Protocol as being part of the scope of this code.

At the same time, private international law gives to the legislator the possibility to enact “mandatory laws”, that rule out the application of the foreign law even though it would have been applicable according to the usual rules of private international law (for instance in cases when the foreign applicable law is inexistent). The “mandatory law” is applied – with a large interpretation – if the

State reckons that a national application is necessary. The criteria defining a "mandatory law" are not clearly cut by the jurisprudence and the doctrine, and thus provide the legislator with a certain political margin: that is the ground upon which this report envisages the option 2.

Finally, and independently of the options chosen, the effectiveness of the ABS compliance regime will largely depend on the effectiveness of both the national focal points and the Clearing-Houses[188]. This is particularly true when referring back to provider country legislation, as these two institutions are responsible for the channelling of information. Some of the assumptions made in the following part could differ in light of the disparity between provider countries. The amount of legal certainty under option 1 for instance, could greatly differ when dealing with a provider country effectively relaying information to the Clearing-House or when dealing with a provider country which is not.

9.4.1 IMP 4.0 – Implementation of the specific "0" option on compliance

Idem as under IMP 2.0

9.4.2 IMP 4.1 – Implementation of option 1 on compliance

The implementation of the compliance provisions of the Nagoya Protocol is explicitly addressed in the EC's proposal for a Regulation on ABS[189]. Therefore, seen the important effort of harmonization at the EU level concerning compliance, and the ongoing discussions on the proposal, a phased approach to the implementation of the compliance obligations is indicated. Moreover, at the present state, it is unclear to what extent the proposed Regulation will be sufficient to implement the core obligations on compliance and/or what additional compliance measure will be needed in case the Regulation is not sufficient.

On the basis of these considerations, the assessment of option 1 on compliance will consider the following implementation components:

(1) A political agreement from the competent governments to express the commitment that legislative measures will be taken to provide that GR utilized within Belgian jurisdiction have been accessed by PIC and MAT as required by provider country legislation and to address situations of non-compliance. This political agreement would be executed in a later stage of the implementation, as soon as sufficient clarity is provided at the EU level.

(2) Implementation of this general principle for MAT through the referring back to the provider country legislation, with Belgian law as a fall-back. As these two elements are currently already part of the Belgian code of International Private Law, such implementation would minimally only entail to amend this code by including explicit reference to the use of GR within the context of the Nagoya Protocol as being part of the scope of this code.

(3) Implementation of a criminal provision on complying with provider country legislation regarding PIC and MAT. Due to the ongoing EU negotiations it is premature at this stage to provide for a detailed analysis of criminal sanctions. This will be evaluated once relative certainty on type of behaviors concerned and level of sanctions are available.

[188] Tveldt, Fauchald, (2011), *op.cit.,* p.398
[189] EC (2012b), *op. cit.*

9.4.3 IMP 4.2 – Implementation of option 2 on compliance

Idem as IMP 4.1, except that the implementation of the general principle of compliance would be based on a self-standing obligation, which requires Belgian users to have PIC and MAT from the provider country (as part of Belgian Law), as far as the legislation of the provider country requires PIC and MAT for access to its GR.

9.5 Designating one or more checkpoints

Summary of the selected options on checkpoints

0. **Specific "0"Option** : No checkpoints would be introduced as envisioned under the Nagoya Protocol
1. **Option 1**: Monitor PIC in the ABS Clearing-House
2. **Option 2**: Using the patent office as a checkpoint

For a detailed description of the options please refer to chapter 8.2.

The provision of Article 17 of the NP is of binding nature. Therefore, as discussed in chapter 8, option 0 (introducing no checkpoints) would lead to a non-ratification of the Nagoya Protocol.

Option 1 envisions using the ABS Clearing-House, which monitors the PIC established in the implementation of the Nagoya Protocol, as checkpoint. However, the choice of the ABS CH as checkpoint depends among others on the options chosen for the operationalization of PIC and the ABS CH (*cf.* discussion on operationalizing PIC above and the ABS CH below). Under option 2, it is the patent office that would function as such a checkpoint.

In any case, the tasks of the institution handling the checkpoint should also be further specified, so that it can address, as appropriate, the monitoring of GR and TKaGR used in Belgium, both for Belgian GR and GR or and TKaGR acquired from other countries. The further specification of these tasks can be done gradually, as part of the phased implementation of the Nagoya Protocol, but would include in the first stance the collection and transfer of relevant information on prior informed consent. “PIC as checkpoint” thus can be understood as the collection/reception (by a yet to be defined authority) of the proof of PIC from the provider country (whether that is Belgium or not) as a condition for the utilization of GR in Belgium. Options 1 and 2 are not mutually exclusive and, in a phased implementation approach, it can be envisioned to implement both options together.

Checkpoints are monitoring services collecting or receiving information at different stages of the development chain: before utilization (activities such as collecting, identifying and storing GR), during utilization (basic and applied research, and research for product development) or after utilization stages of the development chain (*e.g.* commercial sale). Options 1 and 2 respectively represent early and later stages of this development chain. The difference is therefore less regarding what is monitored, than when the monitoring takes place. With its focus on the early steps of the development chain, it is assumed that monitoring under option 1 will cover the broadest possible amount of GR and its users in order to be effective. Option 2, on the contrary, would only focus on the specific situations where the utilization of GR is part of a patent application procedure.

9.5.1 IMP 5.0 – Implementation of the specific “0” option on checkpoints

Idem as under IMP 2.0

9.5.2 IMP 5.1 – Implementation of option 1 on checkpoints

The implementation of the monitoring obligations under option 1 is closely related to the establishment of the ABS Clearing-House considered below in section 2.6. Indeed, information regarding uses of GR in Belgium, as obtained from the CNAs of the provider countries, will be made available through the Clearing-House Mechanism of the Nagoya Protocol. If PIC is provided within this information, it will be considered as an international certificate of compliance and be acceptable as a checkpoint. The use of PIC as checkpoint therefore could be organized through ensuring that PIC for GRs accessed and or used in Belgium is available in the Belgian node of the Clearing-House Mechanism. No other implementation components therefore are currently required for the timely ratification of the protocol, in addition to the implementation components considered under the establishment of the Clearing-House (see chapter 9.6 below).

9.5.3 IMP 5.2 – Implementation of option 2 on checkpoints

The Belgian legislation, while implementing recital 27 of the Directive 98/44/EC of 6th July 1998 on the legal protection of biotechnological inventions, which has due regard to the obligations stemming from the CBD with specific regards to its Articles 8(j), 15 and 16 has included a (qualified) origin indication requirement (if the origin of the material is known) in its Article 15§1(6). In order for the patent application to be admissible, the filing must contain a statement regarding the geographical origin of the biological material that has been used as a basis for the invention, if known. This provision would need to be amended to allow its use as checkpoint under the Nagoya Protocol, specifying that patent application should contain relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate (NP Art 17.1) in the patent applications. The implementation of the monitoring obligations under option 2 would require an amendment of the federal law transposing the Directive 98/44/EC on the legal protection of biotechnological inventions to include such a new provision. It would also imply a change in the tasks of the patent office to ensure the monitoring of the checkpoint.

9.6 Sharing information through the clearing-house

Summary of the selected options on the ABS clearing-house

8. **Specific "0" option** : not creating a Belgian entry-point to/component of the clearing-house
9. **Option 1**: Royal Belgian Institute of Natural Sciences as ABS Clearing-House (RBINS)
10. **Option 2**: Belgian Federal Science Policy Office (BELSPO) as ABS Clearing-House
11. **Option 3**: Scientific Institute for Public Health (ISP/WIV) as ABS Clearing-House

For a detailed description of the options please refer to chapter 8.2.

The discussions on the exact modalities of the ABS Clearing-House (CH) are still on-going internationally and decisions will only be taken at the NP COP/MOP1 (earliest: October 2014). In the meantime, it remains unclear if a separate Belgian ABS CH component or only a Belgian entry-point will be required. Moreover, the impact of the CH will highly depend on the decisions taken on the exact role and technical specifications of the Clearing-House. Therefore, the impact assessment of this implementation provision is still tentative and will need to be refined in the future.

9.6.1 IMP 6.0 – Implementation of the specific “0” option for the CH

Idem as IMP 2.0

9.6.2 IMP 6.1 – Implementation of option 1 for the CH

Seen the still ongoing discussions on the international level and the uncertainty regarding the obligations of Belgium under the Nagoya Protocol, the implementation of this option will benefit from a phased approach. As it is likely that the information tasks under the ABS CH will need to be implemented in Belgium in any case, in a first phase, a CH could be established that specifically deals with the information tasks. In a second phase, collaboration between this CH and other institutions/databases could be established if required to implement the more technical tasks of an ABS CH.

Given the existing CBD CHM at the RBINS and the strong Belgian preference to ensure coherence between the different Clearing-Houses under the CBD, it seems logical to start this exercise at the RBINS by extending the current ABS part of the CBD CHM.

Therefore, two implementation components will be considered in the assessment of this option:

(1) Specify in the cooperation agreement that the RBINS will be appointed as the ABS CH, for dealing with the information exchange on ABS under the Nagoya Protocol and indicate that further development of the ABS CH in terms of more technical or specific tasks related to the implementation of the NP will be undertaken after the first COP/MOP of the NP).

(2) Subsequent implementation by establishing cooperation between this CH and other institutions, through appropriate administrative arrangements between all the players involved.

Importantly, in this assessment, for comparative purposes, we consider option 1, 2 and 3 separately. However, in practice it is likely that, based on the assessment of the respective strengths and weaknesses of the players, the first step will only involve the RBINS while a combination of the options might be considered for the full implementation of the CH obligations.

9.6.3 IMP 6.2 – Implementation of option 2 for the CH

Idem as under IMP 6.1 except that BELSPO would be appointed in the first phase for contributing to the information tasks of the CH.

9.6.4 IMP 6.3 – Implementation of option 3 for the CH

Idem as under IMP 6.1 except that WIV-ISP would be appointed in the first phase for contributing to the information tasks of the CH.

10 IMPACT ANALYSIS

10.1 Methodology of the impact analysis

The evaluation of the possible consequences of the implementation of the NP is conducted through a detailed comparative impact analysis (IA) related to the options described in chapters 8 and 9. The IA has three main objectives:

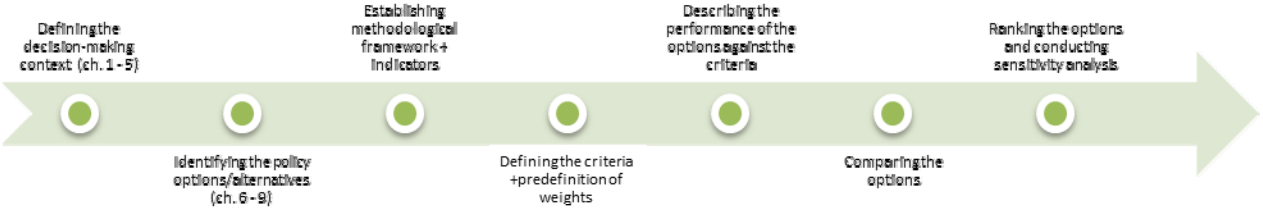
1. Identifying the possible effects of the options
2. Identifying the affected stakeholders
3. Comparing the different options

In this framework, the IA is conducted through a multi-criteria analysis (MCA). MCA has been developed as an alternative to the conventional cost-benefit analysis (CBA). CBA assumes value commensurability between the different objectives (*i.e.* the possibility to measure them through a common monetary metric, which supposes that it makes sense to construct monetized proxies of all criteria and that information is available to do so) and compensability (*i.e.* the assumption that a loss observed in one attribute or good can be compensated in quantitative terms by a gain in another, which supposes, for example, that one can quantitatively compare through a common metric such as the loss of biodiversity conservation benefits, profits for industry relating to facilitated access to resources or administrative costs). However, there is a wide literature showing that, from an environmental, social and economic perspective, these assumptions are clearly not substantiated for sustainability impact assessments[190]. Nevertheless quantitative monetary values are not to be dismissed completely from the evaluation in a MCA: wherever possible, quantification of certain advantages and disadvantages are a crucial input component the MCA, as shown below, even if there is no commensurability or equivalent compensation across all the criteria. But unlike CBA, MCA allows to compare impacts represented both qualitatively and quantitatively. The goal of the IA is thus to identify the existence of qualitative elements in addition to the quantitative elements that can build the basis for a comparison amongst the options for the implementation of the Nagoya Protocol, rather than the calculus of a specific quantitative threshold of aggregated monetary benefits in a common metric, able to justify the expected aggregated costs.

The evaluation of the impact is conducted against a set of evaluation criteria described below, which leads to a performance score per criteria for each of the options. Using the performance scores, a dominance analysis and an outranking analysis are performed to compare and rank the alternatives, based on pre-defined weighting (*cf.* description below). A sensitivity analysis is then conducted to describe the "behavior" of the outcome when changing the weighting (*cf.* sensitivity analysis paragraph 10.1.3, Step 4). **Figure 1** gives an overview of the different steps of the MCA.

[190] For an overview see Vatn A. (2005), *Institutions and the Environment*. Edward Elgar Pub

Figure 1 - Steps of the MCA



10.1.1 Defining the criteria and weights

The formulation of the set of evaluation criteria has been obtained through two overarching questions:

1. To what objectives is the implementation of the Nagoya Protocol seeking to contribute?
2. How would a good option be distinguished from a bad option, given the decision-making context?

Although no clear rules exist on the definition of criteria and their number, it is generally considered that it should be kept as low as is operationally desirable (*i.e.* the model should be as simple as possible). Different economic, social, environmental and procedural criteria were considered, checking them against the preferences of stakeholders and against quality requirements.

- **Stakeholder-preferences**: Analysis of the preferences of stakeholders, expressed both during the first stakeholder workshop as during the interviews, helped to refine a first set of criteria derived from the above questions. Examples of these preferences include flexibility, continuity, knowledge-improvement, legal certainty, non-redundancy and cost-effectiveness in the establishment of the regulatory framework of the Nagoya Protocol.
- **Quality requirements**: the criteria were then checked against a range of qualities such as value relevance (relation with the overall objective), cognitive relevance (shared understanding of concepts), measurability (some form of measurement or judgment, objective or subjective[191]) and non-redundancy (several indicators measuring the same factor).

This selection process allowed identifying four criteria to assess the impacts of the proposed options, which are described below. The assessment of the environmental and social impacts is based on two individual sub-criteria (S1 and M1), while the assessment of the economic impact is composed of three sub-criteria (E1, E2, E3). Four procedural (G1 to G4) sub-criteria have also been added to reflect the overall policy process. The different sub-criteria for the economic and the procedural impact have been created for analytical ease, as the assessment would have been too complex if grouped

[191] Due to the scarcity of quantitative data, most performances of criteria in this report reflect a subjective assessment and evaluation based on the various available input and data. Nevertheless, quantitative figures have been included and detailed whenever possible and reliable.

into one single criterion. Having more sub-criteria does not confer more importance to a particular impact.

For this report, the social and economic impact are considered to have the same weight (*i.e.* they are considered of equal importance), while the environmental impact is slightly more important, given the objectives of the Protocol and the CBD to contribute to conservation and sustainable use of biodiversity. The procedural impact has the lowest importance and serves mainly to help refine the preference for an option in case the difference is not clear enough when using the substantive criteria. If the total weight of the impacts represents 100%, the weighting is distributed based on the following basic allocation key: environmental impact (37,5%), social impact (25%), economic impact (25%) and procedural impact (12,5%) (see also sensitivity analysis below).

Economic impact

E1	**Legal certainty and effectiveness for users and providers of GR, at low cost** Four indicators are taken into account to evaluate this criterion. *Legal certainty* refers to the consistency and predictability of the rules and the process in place. *Effectiveness* of the legal framework refers to a set of indicators including: • *Enforceability*: the level with which an option allows the ABS regulation to be enforced. • *Redundancy* relates to existing legislation regulating related obligations. • *Proximity with other international agreements*. When combining these indicators, an option will be preferred when it increases, at an equivalent cost, legal certainty, allows better enforceability, reduces redundancy and does not conflict with obligations under other existing international treatments. In addition, an option with similar level of legal certainty and effectiveness, compared to another option, will be considered preferable if it leads to less legal costs (such as the cost for drafting new legislation and the cost for asking legal advice.)
E2	**Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs** Extensive research on private sector return from public and private investment in research infrastructures involving genetic resources shows a clear correlation between improved conditions for R&D and an increase in likelihood of the development of innovative products and services. Options that maximize research and development opportunities for users and providers of GR are therefore considered preferable. These benefits will be assessed while taking into account the changes in research costs that stakeholders incur for the necessary steps they need to take in order to allow for research that complies with the NP to take place. Such costs include, among others, costs involved in the negotiation of the ABS agreement, the acquisition of genetic resources and transaction costs related to the transferring of the GR.
E3	**Minimizing implementation costs** Implementation costs are costs related to obligations flowing from the implementation of

	the Nagoya Protocol. They include, for example, the administrative costs related to keeping track of the ABS agreements, the financial costs for the creation of new institutions (if needed), the costs for asking for legal advice in the course of the implementation or the cost of monitoring utilization. An option having a lower cost is considered preferable over another with a higher cost for an equivalent level of produced benefits. In addition, an option leading to a one-time expense is preferred over an option which generates recurring expenses.

Social impact

S	**Achievement of social objectives** Innovation resulting from R&D with GR is expected to contribute to the achievement of important social objectives, be it health, nutrition, food security, or else. Options that maximize opportunities for the users in socially relevant fields are therefore considered preferable over options that create less such opportunities. Options contributing to the transfer of knowledge and technologies to developing countries and to job creation/preservation in the sectors utilizing genetic resources, both in developing and developed countries, are also considered preferable. A particular social aspect is the contribution to the effective protection of the rights of indigenous and local communities over their traditional knowledge associated with GR. Options that effectively protect or advance indigenous rights are preferable over options that do not achieve this aim.

Environmental impact

M	**Promotion of conservation and sustainable use of biodiversity** Options that enhance conservation and sustainable use of biodiversity, inter alia through improving its knowledge base (*e.g.* by enhancing taxonomic research), enhance capacity building and technology transfer, through channeling benefit-sharing to conservation and sustainable use, improving protected areas and protected species management and raising awareness are preferable.

Procedural impact

G1	**Flexibility to accommodating sectorial differences** The implementation of the Nagoya Protocol will impact different types of actors, using GR under different conditions, in many different ways and at varying moments in the development process. Therefore it seems important that implementing measures offer some flexibility to accommodate for differences between diverse sectors utilizing genetic resources. An option will be considered preferable if it better balances the need for clear and certain rules with flexibility to accommodate for sectorial differences. An inflexible "one-size-fits-all" regime might have negative effects and might contradict the objectives of the CBD[192].

[192] See C. Correa (2000*),* Implications of national access legislation for germplasm flows, *In Strengthening partnerships in agricultural research for development in the context of globalization, proceedings of the GFAR Conference, 21-23 May 2000,* Dresden, Germany. FAO/Global forum on agricultural research; K.D. Prathapan, R. Dharma, T.C. Priyadarsanan and Narendran, C.A. Viraktamath, N.A. Aravind, J. Poorani, J. (2008) Death sentence on taxonomy in India. *Current Science*, 94 (2). pp. 170-171.

G2	**Temporal flexibility to allow for future policy and adjustments** The boundaries and needs of the utilization of GR evolve continuously, with new resources being discovered every day. The political and socio-economic context of the NP also changes rapidly, as ABS is a relatively new field. This evolving reality creates the need for a flexible and adaptable implementation over time, in particular in light of implementation measures taken by other Parties of the Protocol and in light of future sectorial initiatives. An option is considered as advantageous if it leaves space for adaptation of the implementation and future policy and adjustments over time. In addition, an option providing such a temporal flexibility at lower costs will be considered preferable over another option.
G3	**Improving knowledge on the exchange of GR and existing ABS agreements for future policy development and evaluation** Currently, little data exists on the exchange of GR and existing ABS agreements. Increasing this knowledge is primordial to design efficient rules addressing the needs of the different stakeholders involved. Furthermore, ABS has a clear link with the conservation and sustainable use of biodiversity. Improving the understanding and knowledge of their inter-linkage is an important part of the efforts to halt the erosion of biodiversity. An option is preferred when it allows increasing the knowledge in these two fields.
G4	**Correspondence with existing practices** Previous research stresses the importance of relying upon previously established relationships and existing practices of genetic resource use for the success of ABS agreements. For example, Täuber *et al.* show that strengthening existing research capacities and existing relationships fosters understanding and mutual trust, attracts users and lowers transaction costs[193]. Options building upon existing practices will therefore be generally considered preferable. An option that would require a significant change in practice or which would run against the basic economic model of a practice will be considered less preferable.

10.1.2 Data collection for the indicators

Due to the scarcity of data and knowledge on the flows of GR and on the current practices of the ABS in Belgium, three types of sources needed to be triangulated.

1. **Primary sources** such as internal documents, activity reports and policy documents/reports, inasmuch as these were available and shared, have been collected and analyzed. The list of documents can be found in the bibliography of this report.
2. **Existing literature** on the economics of genetic resource use has been consulted and integrated whenever possible. For a complete list of reference see footnote references and bibliography.

[193] S. Täuber, K. Holm-Müller, T. Jacob, U. Feit (2011), *An Economic Analysis of new Instruments for Access and Benefit-sharing under the CBD – Standardisation options for ABS Transactions*. Research project of the Federal Agency for Nature Conservation, Germany.

3. **In-depth interviews** have been conducted to collect information and data specific to the Belgian situation. These are discussed below.

It should be noted that relevant data for the measurement of indicators was not always existent, available or shared. Especially quantitative data was very scarce. An evaluation of the most relevant quantitative costs has nevertheless been attempted and applied towards the fine-tuning of choices amongst closely ranked options (*cf.* also tables in annex 2 and annex 3).

For the data gathering, based on these three sources, a list of general indicators was used, as indicated in Table 6.

Table 6 - List of indicators

Criteria	Selected indicators for assessment
E1 Legal certainty and effectiveness for users and providers of GR, at low cost	*Legal certainty* • IE1: consistency and predictability of the rules and the process in place. *Effectiveness of the legal framework* • IE2: enforceability (the level with which an option allows the ABS regulation to be enforced) • IE3: limiting redundancy (if existing legislations regulate related obligations). • IE4: proximity with other international agreements.
E2 Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs	• IE5: maximize research and development opportunities for users and providers of GR • IE6: allow economic and research stakeholders to compliance with the NP at reasonable costs (negotiation costs, costs related to acquisition/transfer of GR, etc.)
E3 Minimizing implementation costs	• IE7: minimize administrative costs related to keeping track of the ABS agreements (including monitoring costs) • IE8: minimize financial costs for the creation of / changes in institutions (including costs for asking for legal advice)
S Achievement of social objectives	• IS1: job creation/preservation in the sectors utilizing genetic resources (including through management support, collaboration programs amongst companies, educational programs, etc.) • IS2: maximize research and innovation opportunities in socially relevant fields such as health, nutrition and food security • IS3: support to small and medium enterprises • IS4: transfer of knowledge and technologies to developing countries • IS5: effective protection of the rights of indigenous and local communities over their traditional knowledge associated with GR
M Promotion of conservation and sustainable use of biodiversity, including biodiversity research	• IM1: helping ensure fair and equitable benefit-sharing • IM2: more predictable conditions for access (including through creating greater legal certainty for users/providers of GR) • IM3: encouraging advancement of research on GR and biodiversity • IM4: creating incentives to conservation and sustainable use of GR (for ex. through recognizing their value and through benefit-sharing, through capacity building and technology transfer) • IM5: enhancing the contribution of biodiversity to development

	and human well-being • IM6: raising awareness on conservation and sustainable use of biodiversity
G1 Flexibility to accommodating sectorial differences	• IG1: balancing need for clear rules with sectorial flexibility
G2 Temporal flexibility to allow for future policy and adjustments	• IG2: leaving space for adaptation of the implementation • IG3: leaving space for future policy
G3 Improving knowledge on the exchange of GR and existing ABS agreements for future policy development and evaluation	• IG4: Increasing knowledge on exchange of GR • IG5: Increasing knowledge on existing ABS agreements
G4 Correspondence with existing practices	• IG6: Change in existing practices (including behavioral changes, change in cost models)

Interviews

29 interviewees, pertaining to groups of potentially impacted stakeholders, were selected in a non-random way based on their proven relevant experience and knowledge of the subject. 17 out of 29 accepted the request for an interview, which were conducted between 23rd July and 20th August 2012. A complete list of interviewees can be found at the end of this report (annex 5). 12 others declined or did not reply to the requests for an interview. However this did not result in an overall unbalanced representation of certain sectors, as stakeholders from all sectors were interviewed. The decline by some contacted persons could point to a lack of knowledge, understanding and/or interest for the NP by certain persons within the Belgian stakeholder groups. Any form of future implementation will need to address this by setting up targeted capacity-building activities. A full list of the contacted persons has been sent to the accompanying committee of the study.

Most interviews were conducted face to face. Interviewees were briefly introduced to the objectives and progression of the study, if needed. Two sets of structured questionnaires were used for the interviews: one for users of genetic resources and one for providers. Some specific additional questions were also prepared for specific profiles of interviewees which were neither users nor providers. These sets addressed both the quantitative and qualitative evaluation of the options through two distinct parts. Questions related to quantitative data aimed at collecting **objective figures** related to the access, the distribution and the sharing of benefits related to genetic resources in order to try to map the flows of GR in Belgium. Questions included, *inter alia*, the amount of access made/received and their related costs, the patenting and commercialization rates of acquired GR or the costs of managing collections. Questions related to qualitative data were used to further elucidate **stakeholder preferences** observed during the first stakeholder workshop and were mostly open-ended and behavior-based questions (*e.g.* "If you have the choice between options 1 and 2, which one would you chose and why?"). The questionnaires can be found in annexes 2 and 4. As can be seen in the correspondence table between the criteria and the indicators in annex 3, the majority of the indicators are related to the economic and the environmental criteria. As can be seen in the table, the indicators for the environmental criteria refer both to the quantitative aspects (gaps in biodiversity research, incentive for conservation by potential increased use of Belgian GR, *etc*.) and with more qualitative aspects of the environmental criterion (as these are more difficult to capture in a quantitative indicator). These qualitative aspects, such as increased awareness of biodiversity issues and education for example, were also discussed during the interviews, and the results of the discussion on these qualitative elements have also been included in our discussion below. The same comment applies to the social aspects, such as promotion of indigenous and local communities and

social impact through capacity building, which were also discussed both in a quantitative and qualitative manner with the interviewees.

10.1.3 Comparing the alternatives

The general principle of the impact analysis is to assess the impact of several policy options as net changes compared to a no-policy-change baseline (“0” options) and to compare the impacts of the options amongst each other. The overall goal is to establish a ranking amongst the options. To this purpose, under each section the proposed options were contrasted with each other and with the specific "0" options. In this exercise, it is important to state from the outset that the evaluations do not give any absolute figures/values for each of the criteria, but give a set of values that allow seeing which option would, comparatively, score higher or lower on each of the criteria.

As for the comparison with the general “0” option ("no policy change" over PIC, BS, CNA, compliance, etc.), this can be done through an indirect method, based on the aggregated effects of specific “0” options. If all the specific “0” options rank lower than the list of proposed options under the several measures, then the general “0" option (which is the sum of all the specific “0” options, which is no policy change at all) will *a fortiori* rank lower than the list of the proposed options under these several measures. Therefore this issue is addressed after having assessed the impacts of all the specific “0” options and seen what consequences can be drawn from an aggregation of all the specific decisions not to act on a certain measure.

Step 1: Performance of the options

Each option is thus analyzed in relation to the others and described in an accompanying text divided per individual criterion. The impact on stakeholders is described for each individual group of stakeholders (land owners, agriculture sector, healthcare sector, biotechnology and processing industry sector, governmental research institutions, collections, university research sector, and other; as described in chapter 8.3, the agriculture, healthcare and biotechnology sectors are evaluated jointly, except when there are major differences in impact that justify to treat them separately). The economic, social and environmental assessments are then represented in a separate impact grid, indicating whether the impact is positive or negative, the likelihood of the occurrence, the magnitude of the impact as well as a general score. The score ranges from [- - -] (most negative) to [+ + +] (most positive). Neutral and unimportant impacts are indicated with a "0". Table 6 offers an overview of the scoring system. Reading and interpretation of the impact grids is to be done with caution, as some assessments are based on assumptions that are justified in the text. Also, some options have a different subject-matter (see the IA of the establishment of the CNA for example), or represent an aggregate of different possible scenarios (see the IA of the operationalization of PIC for example). The procedural sub-criteria (G1 to G4), which were outside of the Terms of Reference of the study[194], are not represented in an impact grid. They are submitted to an assessment of their contribution to overall quality and effectiveness of the policy process in the following steps of the MCA, instead of a likelihood/magnitude analysis which is less appropriate for these criteria.

[194] Terms of reference No. DG5/AMSZ/11008

Table 7 – Scoring system of the impact grid

Likelihood	Magnitude	If positive effect	If negative effect
High	Strong	+ + +	- - -
Medium High	Strong Medium	+ +	- -
Medium High Low	Medium Weak Strong	+	-
Medium Low Low	Weak Medium Weak	0	0

Step 2: Visual dominance analysis

Options and (sub-)criteria are then compared on the basis of a performance chart. The performance chart visually represents the differences between the options and allows for a dominance analysis to be made. The goal here is to identify if there exists an *ideal point*: the option that dominates all others. An option dominates another if it scores at least as well on all criteria and is strictly better at least on one. However, having an ideal point is rare: only three of our cases present such an ideal point. To allow for this dominance analysis to be based on all criteria, the procedural sub-criteria are included in this visual analysis[195].

Step 3: Ranking the alternatives

If no ideal point can be identified, a ranking the alternatives can nonetheless be made based on their performance. As the scores are the result of comparisons between the options within the criteria, and not of comparisons amongst the criteria (*cf.* introduction), the results for one criterion cannot simply be added up to the results for another. Therefore, the "Preference Ranking Organization Method for Enrichment of Evaluations" (PROMETHEE) was applied, which allows building an *outranking relation* on the set of alternatives (called "options" in this report). An outranking relation allows building an ordering of the alternatives through a series of pairwise comparisons of these same alternatives[196]. The basic principle of this method is that an option outranks another if that option outweighs all the other options over a larger number of (sub-)criteria than any other option.

[195] Procedural sub-criteria have been dichotomized through a Boolean expression, as these criteria were not attributed performance in the previous particle. Options positively addressing the issues raised by a general criterion were assigned a true (1) status, whereas others were considered as false (0). This Boolean expression has been broadened a little in the course of the analysis, as it quickly became apparent that some options could be both true and false. Therefore, a third category was created (0,5) in some cases.

[196] In order to allow for software-based comparison scores have been quantified on a scale from 1 to 7: the "- - -" score corresponds to value 1 and the "+++" to value 7. The software used for the PROMETHEE calculus is Visual Promethee, version 1.0.10.1.

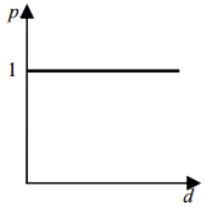
PROMETHEE uses a preference function for each of the alternatives, which allows identifying the *intensity of preference*. The intensity of preference represents the importance of the difference between two alternatives when comparing them. The values of the preference function (*i.e.* the different levels of intensities) lie in an interval from zero to one, within which higher value of the preference function corresponds to a better alternative. In other words, when option 1 outranks option 2 for a certain criterion, the amount of the difference between option 1 and option 2 determines the intensity of the preference of option 1 for that criterion: the higher the difference, the higher the intensity of the preference[197]. A *preference index* can then be set up for one option over the other. The preference index is the weighted average of preferences on the individual criteria:

$$P(option1,\ option2) = \frac{\sum_{k=1}^{n} P_k(option1,\ option2) w_k}{\sum_{k=1}^{n} w_k}$$

Where P_k (*option1, option2)* represents the intensity of the preference of option 1 over option 2 for criterion k, and W_k represents the weight of criterion k.

In this analysis, a *Usual preference function* is used (Figure 2) for all the alternatives, which is best suited for qualitative criteria with a small number of levels on the criteria scale[198]. With this function, it is considered that values of the intensity of the preference can only be 0 or 1. In other words, the importance of the difference (*d* in Figure 2) does not matter. Preference is given to the alternative which has a higher value of criterion.

Figure 2 - Usual preference function



$$p(d) = \begin{cases} 0 \text{ when } d \leq 0 \\ 1 \text{ when } d > 0 \end{cases}$$

The preference index of each comparison between two alternatives is then summed up to create two indices: the *positive outranking flow* and the *negative outranking flow*. The positive outranking flow represents the strength of an alternative when compared to all others (*i.e.* when it outranks all others). The negative outranking flow represents the weakness of an alternative when compared to all others (*i.e.* when it outranks all others). These flows are defined as follows:

- Positive outranking flow for option 1: $Q^{+}(option1) = \sum P(option1, option n)$

[197] Belton V., Stewart T.J. (2002), *Multiple criteria decision analysis: an integrated approach*. Kluwer Academic Publishers; Podvezko V., Podviezko A. (2010), Use and choice of preference functions for evaluation of characteristics of socio-economical processes. *6th International Scientific Conference*, 13th-14th May 2010, Vilnius, Lithuania; Brans J.P., Marechal B. (2002), *Prométhée-Gaia. Une méthodologie d'aide à la décision en présence de critères multiples*. Editions de l'Universite Libre de Bruxelles..

[198] The PROMETHEE-GAIA FAQ "How to choose the right preference function?"; http://www.promethee-gaia.net/faq-pro/?action=Article&cat_id=003002&id=4&lang=; Another preference function can however be applied easily if needed.

- Negative outranking flow for option 1: $Q^{-}(option1) = \sum P(option\,n, option1)$

Positive and negative flows allow calculating the *net flow* of each alternative, by which a complete pre-order of the alternatives can be established:

$$Q(option1) = Q^{+}(option1) - Q^{-}(option1)$$

Option 1 then outranks option n if the net flow of option 1 is higher than the net flow of option n – $Q(option1) > Q(option\,n)$.

For each subset of proposed policy options, the performance of the options will be evaluated and presented in the impact grid along with the explanatory text. A visual dominance analysis is then performed followed by a first ranking of the alternatives. In this first approximation, as indicated earlier, the environmental impact is considered more important than both the social and economic impacts, which in turn are weighted more than the procedural impact (used for fine-tuning the choice amongst closely ranked options). If the total weight of the impacts represents 100%, the weighting is distributed based on the following basic allocation key:

- environmental impact: 37,5%
- social impact: 25%
- economic impact: 25%
- procedural impact: 12,5 %

Step 4: Sensitivity analysis

In addition to the analysis based on the predefined weight distribution of the criteria, a sensitivity analysis has been performed by changing the weighting amongst the criteria and analyzing the impact on the ranking of the options. The sensitivity analysis is used to test the robustness of the outcome of the ranking. It allows assessing how sensitive the outcome is to changes in the problem definition. To perform the sensitivity analysis, two additional weighting scenarios are compared with the basic allocation scenario, to see if there is a reasonable low threshold of change in these criteria that leads to a change in choice amongst the options:

1. The *equalized weighting scenario* equalizes the importance of the impacts: an equal weighting (25%) is applied to all the four groups of criteria (environmental, social, economic and procedural).
2. The *economic weighting scenario* puts a stronger focus on the economic impact, which becomes the most important one (37.5%), while social and environmental impacts are considered of equal importance and procedural impact remains unchanged.

Wherever a change in ranking occurs, a ranking of the alternatives based on these new weights has been presented in addition to the environmental weighting scenario, in order to be able to compare the weighting choices amongst each other.

The interpretation of this analysis, especially the results of the outranking flow calculus of the PROMETHEE method, is to be done with care and in light of both the context described in the evaluation of the performance of the options (step 1 of the IA, as described above) and the analysis of the relationship between the options as presented in the visual dominance analysis (step 2 of the IA).

10.2 Operationalizing PIC

Summary of the selected options for the operationalization of PIC

0. **Specific "0" option** (access component): the specific "0" option on access would consider no PIC requirement, with benefit-sharing as a horizontal principle
1. **Option 1** – The bottleneck model: refining existing PS/PA relevant legislation & measures + only access to GR through *ex-situ* collections as default rule
2. **Option 2** – The baseline fishing net model: refining existing PA/PS relevant legislation & measures + access to GR from everywhere but with registration as default rule
3. **Option 3** – Modified fishing net model: potentially enlarged refinement of existing PA/PS relevant legislation & measures + refinement of other specific GR relevant legislation/measures+ access to GR from everywhere but with registration as default rule

For a detailed description of the options please refer to chapter 8.2 and chapter 9.

10.2.1 Performance of the options

Economic impact

E1 – Legal certainty and effectiveness for users and providers of GR, at low cost

Option 0 is the least preferred option for this criterion: it does not provide any legal certainty to the user, due to the fact that it does not establish proof of legal access; nor is it enforceable as it does not allow any post-access tracking and monitoring to take place; and it makes responsibility so diffuse that no Party can be held accountable. Moreover, it would not allow issuing an internationally recognized certificate of compliance, which is one of the main contributions of the Nagoya Protocol for increasing legal certainty and transparency of exchanges of GR.

Under the fishing net model, PIC is operationalized through a simple notification obligation upon the point of access. Therefore, this model provides users with a high level of process certainty and legal certainty, at an early stage of the ABS application process (before identification and storage procedures in the public *ex-situ* collections or in research laboratories). The simplified nature of the model also allows for a good overview regarding this process (compared to the sometimes lengthy and complex laboratory operations required before a GR can enter an *ex-situ* collection). However,

this option might be problematic in the cases where the GR is not yet accurately known at the point of access, as it will be very hard to control the accuracy of the provided notification and its adequacy for later monitoring if the GR is of uncertain nature.

On the other hand, *ex-situ* culture collections dispose of all the necessary technical and scientific expertise for the appropriate identification (*e.g.* genetic profiling) of the accessed GR, providing additional information on the GR to the information available with the PIC (compared to a PIC issued for example for an *in-situ* resource of uncertain nature). Also, if utilized in combination with a post-access self-monitoring system (*e.g.* a due diligence system), the bottleneck option will guarantee that only well identified GR enters the value chain of "legally acquired GR", creating strong legal certainty and easing the auto-monitoring by users[199].

The modified fishing net model would lead to some increase in legal certainty, compared to the baseline fishing model, as it considers also to refine legislation pertaining to GR that are outside PA/PS[200]. However, such an additional refinement would imply an additional legislative cost compared to the two other options. As shown in chapter 9.1 (IMP 1.3), while the implementation of all three options implies the same legislative cost for the amendment of PA/PS relevant legislation, option 3 also includes the identification and refinement of other relevant legislation.. The latter additional cost that is specific to option 3 would only be worthwhile if the GR covered by that legislation would be of potential or actual value not found elsewhere. However, in spite of this uncertainty and the cost, the impact of increase in legal certainty for users of GR can still be rated of medium magnitude.

- **Impact on stakeholders**:
  - Coll.: impacted under option 0, 1, 2 and 3, depending on level of legal certainty
  - Gov. Res.: impacted under option 0, 1, 2 and 3, depending on level of legal certainty
  - Ag., health and Biotech : impacted under option 0, 1, 2 and 3, depending on level of legal certainty
  - Univ.: impacted under option 0, 1, 2 and 3, depending on level of legal certainty
  - Land: impacted under option 0, 1, 2 and 3, depending on level of legal certainty
  - Other: None

E2 – Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs

[199] EC (2012) Impact Assessment accompanying the document "Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, European Commission Staff Working Document, COM(2012) 576 final

[200] As mentioned under IMP 1.3, the refined fishing net would consider any other legislation where notification/registration/permit exist and specify that such notification/registration/permit is also considered as a PIC under the Nagoya Protocol. This option is part of the later implementation steps (step 3 of the implementation, *cf.* chapter 11) and at this stage it seems difficult to go beyond an illustration of what the "refined fishing net" option could entail. The case of the conservation varieties, cited in chapter 9.1 however provides a plausible illustration of such a legislation that is different from the PA/PS legislation and where the current legislation on the "admission to use" could be considered also as a PIC under the Nagoya Protocol, in further refinement of the legislation (*cf.* references provided in the footnote in that section).

By establishing both PIC and BS as legal principles and by refining existing legislation (see chapter 9.1, IMP 1.1, 1.2 and 1.3), it can be argued that options 1, 2 and 3 increase legal certainty, which is likely to consolidate or increase the use of Belgian GR and therefore is expected to lead to more economic innovation and product development, in particular through higher R&D benefits, compared to the situation of the specific "0" option. Conversely, under the specific "0" option, the absence of legal certainty generated by the obligations to share benefits but the absence of any proof of PIC (see chapter 9.1, IMP 1.0) is likely to lead to less use of Belgian GR and could therefore be an obstacle to innovation and development.

Giving *ex-situ* collections a central role in the PIC process, might strongly foster an increase of deposits, as collections are used to deposit a physical copy of GR they work with[201]. This could imply an important financial cost for the collection providing those resources that are accessed for utilization outside PA/PS and that are usually not deposited in an *ex-situ* collection. If it is assumed that both access situations (through fishing net and through bottleneck) lead to an equivalent increase in economic benefits, then the fishing net is to be preferred over the bottleneck under this criterion, as resources are not deposited under the fishing net model. Measuring this cost is difficult, as it strongly differs depending on the type of resource being deposited. The costs of storing GR ranges from a few Euros for herbaria, between 100 and 250€ for plant collections and microbes and up to 40 000€ for animal breeds[202]. Moreover, users and providers could decide to deposit only the information, only the physical resource, or both, which would lead to different price tags. These costs can also be nuanced in light of the positive effects the storing of GR can have for other research users (not intended by the users accessing the GR), such as further taxonomic research in the case the deposited GR is of a yet unknown taxonomic nature.

The additional cost for organizing the access to materials for research under the bottleneck and the fishing net model, compared to the specific "0" option is likely to be low in both cases. It would be limited to the working hours for administrative requirements such as the establishment of the agreement, including settling the specifications of use of the material, the scope of the agreement and the drafting. Under the bottleneck option, this effort will be shared between users and providers. Under the fishing net, these costs do not take place, as the sole obligation is that users notify the CNA of the access to a GR. Some time investment will nevertheless be required for this notification obligation, but if a centralized notification system is established, whether digitally or physically (*cf.* E3 below), the working-time is expected to be low. These additional costs are estimated to be ranging from 70 to 140€ per transaction, with the fishing net model having the least additional costs (between 1 and 54€)[203].

[201] For some sectors, the rate of deposits of material used for research outside of the collections is very low. According to one interviewee, for the microbial GR, for instance, less than 1% of the GR serving for research outside of the collections is currently being deposited in an *ex-situ* collection.

[202] M.M. Watanabe, K. Suzuki, T. Seki (2004), *Innovative Roles of Biological Resource Centers*. Proceedings of the Tenth International Congress for Culture Collections, Japan Society for Culture Collections ; World Federation for the Culture Collections p. 435-438; K B. Koo, P.G. Pardey, B.D. Wright and others (2004), *Saving Seeds; The economics of conserving crop genetic resources ex situ in the future harvest centre of CGIAR*, CABI Publishing, p.45.; Interviews.

[203] These figures are based on a quantitative evaluation, by the study team, of the additional costs for accessing materials under the options for the operationalization of PIC. This evaluation is based on the data generated in the interviews (especially indicators IND 3.1 and 3.2, data collected for the various stakeholder groups, and IND 8.1 to 8.5 for the collections) and existing models from the literature for assessing the implementation costs (in particular Täuber *et al.* (2007); Eaton and Visser (2007); CBD Bonn Guidelines (2002); Visser B, Eaton D, Louwaars N, Engels J, (2000), *op. cit.*).

The baseline and the modified fishing net model do not show any difference according to this criterion (they both equally promote economic innovation and there is no expected difference in research costs).

- **Impact on stakeholders**:
  - Coll.: financial impact if increase of deposits under option 1 (but magnitude of impact is unclear). Bear part of the costs for accessing material under option 1. No impact under option 2 and 3.
  - Gov. Res.: Impact in terms of working hours for complying with the administrative requirements under options 1, 2 and 3. Indirect positive impact from possible additional storage under option 1.
  - Ag., health and biotech: Impact in terms of working hours for complying with the administrative requirements under options 1, 2 and 3. Indirect positive impact from possible additional storage under option 1.
  - Univ.: Impact in terms of working hours for complying with the administrative requirements under options 1, 2 and 3. Indirect positive impact from possible additional storage under option 1.
  - Land: No impact
  - Other: No impact

E3 – Minimizing implementation costs

Implementation costs for the access procedure are mostly administrative costs for the later follow-up of the process, such as drafting the PIC notification/registration/approval and handling the ABS agreements, the genetic profiling and the storage of a track-record of the exchange in a centralized database (*e.g.* the ABS Clearing-House). These costs are shared between users and providers, but they are small (between 1 and 24€ per transaction) and, on the exception of the costs for drafting, occur equally in options 1, 2 and 3 (except for the genetic profiling, not applicable for option 2)[204].

Implementation costs for the public administration will occur under all options, related to the structure of notification that will be set up for the PIC. Notification could be done through a digital access portal where these notifications will be made directly by users or a physical access point for input by an administrative agent. Such a structure could also build synergies with existing services in the collections. However, as Belgium counts around 150 different collections[205], the need for operability and transparency could necessitate the centralization of access requests in a few qualified collections[206]. The expected increase of the access requests could then possibly lead to some increase in administrative costs for these collections, even though this could be shared between the collections and the users requesting access (*e.g.* through a fee). Under option 3, the public administration for PA/PS could also incur some additional costs, as it will have to handle more access

[204] *Ibid*.
[205] Data from address database from Belgian users of GR, acquired for the 2006 awareness study on access and benefit-sharing (Frison and Dedeurwaerdere, 2006).
[206] This does not imply that these key collections acquire the authority to decide whether or not to grant access, as this task is reserved to the CNA.

requests due to the inclusion of GR in a refined legislation relevant to PA/PS. Overall, in the various structures that could be set up, the additional administrative costs for implementation of the PIC can be considered to be equivalent between the three options, but potentially incurred by different stakeholders. It should also be noted that, as indicated in chapter 9.1, the impact generated by a growing number of access requests will depend upon the relationship with other institutions created for the implementation of the NP, such as the CNA and the ABS CH.

The impact of the specific "0" option is unclear as this option still implies to organize BS, which is highly likely to also lead to implementation costs for the users and providers of the GR. However, probably the costs would be lower than under a systematic PIC requirement.

- **Impact on stakeholders**:
  - Coll.: Limited administrative costs per transaction under option 1 (as providers) and under options 2 and 3 (as users). If centralization of access in qualified collections (without prejudice to CNAs), possible increase of costs.
  - Gov. Res.: Limited administrative costs per transaction under option 1, 2 and 3.
  - Ag., health and biotech: Limited administrative costs per transaction under option 1, 2 and 3
  - Univ.: Limited administrative costs per transaction under option 1, 2 and 3
  - Land: Limited administrative costs per transaction under option 1, 2 and 3 (as providers).
  - Other: No impact

Table 8 - Economic impact of the options for the operationalization of PIC

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
E1	Option 0	Negative	High	Strong	- - -
	Option 1	Positive	High	Strong	+++
	Option 2	Positive	Medium	Medium	+
	Option 3	Positive	High	Medium	++
E2	Option 0	Negative	Medium	Medium	-
	Option 1	/	Medium	Weak (*)	0
	Option 2	Positive	Medium	Medium	+
	Option 3	Positive	Medium	Medium	+
E3	Option 0	Negative	High	Weak	-
	Option 1	Negative	High	Medium	- -
	Option 2	Negative	High	Medium	- -
	Option 3	Negative	High	Medium	- -

(*)The main reason of ranking « weak » instead of « medium » for this option is the possible financial cost of storage (*cf.* discussion under E2)

Social impact

S – Achievement of social objectives

It is likely that the overall contribution to economic innovation and product development of options 1, 2 and 3 (*cf.* criterion E2 above) will also have (at least indirect) positive effects on socially important sectors such as food security, health and nutrition, albeit with a difference between option 1 and option 2/3 as discussed above. This contribution to the R&D sector is also expected to contribute to job creation in the overall economy, and in public and private research institutions in particular. Requiring PIC for Belgian genetic resources might improve the knowledge base on ABS in Belgium and could therefore contribute to education activities and help to build capacity. However, making a causal link between the requirement of PIC in Belgium and the fulfillment of specific social objectives, especially concerning the impact on transfer of technology or on the ILCs and TK in developing countries, would require more in-depth and long-term data on the effects of the PIC requirement, which will only be available once the implementation is in place.

- **Impact on stakeholders**:
  - Coll.: Increasing R&D could trigger job creation
  - Gov. Res.: Increasing R&D could trigger job creation
  - Ag., health and biotech: Increasing R&D could trigger job creation
  - Univ.: Increasing R&D could trigger job creation
  - Land: Could help to build institutional capacity with small land owners, in particular on ABS issues related to use of biodiversity for R&D
  - Other: Indirect positive effects for society as a whole through innovation and new available products in the field of food security, health and nutrition

Table 9 - Social impact of the options for the operationalization of PIC

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
S	Option 0	Negative	Unclear		
	Option 1	Positive	Unclear		
	Option 2	Positive	Unclear		
	Option 3	Positive	Unclear		

Environmental impact

M - Promotion of conservation and sustainable use of biodiversity

In spite of the higher costs of the bottleneck option, environmental benefits can be expected to be higher than under the fishing net model. Indeed, by obliging users to come back to the *ex-situ* collections for each new acquisition, the quality and the accurate documentation of the exchanged resources can be guaranteed. Furthermore, as stressed earlier, giving the *ex-situ* collections a central role in the PIC process will increase deposits, which will eventually support further biodiversity research and improve the knowledge base of conservation and sustainable use of biodiversity. Even though all the options will lead to an increased awareness on biodiversity conservation, sustainable use and access and benefit-sharing, option 1 is expected to have a larger impact in terms of increased

awareness, in particular through increased attention to the use of biodiversity and increased availability of resources for research.

If the bottleneck model allows for a more efficient follow-up of the accessed resources (see E1), the benefit-sharing is likely to be more easily monitored and channeled to conservation and sustainable use activities. As argued here, these benefits are likely to be important (generating increase awareness, knowledge and documentation amongst others). However, the importance of expected benefits for biodiversity conservation can be considered quite similar under options 1, 2, and 3, with some advantage of option 1 over options 2 and 3. In any case these benefits are much broader then the specific category of agreed upon monetary benefits from possible returns on commercial profits from the utilization of GR, which would be low over all the options[207].

The modified fishing net model offers another form of environmental benefit over options 1 and 2, in that, alongside the amendments to PA/PS relevant legislation, it also refines other legislation and thus allows covering a broader range of genetic resources (see also chapter 9.1, IMP 1.3). Furthermore, it could remedy situations where the default rule of option 1 proves to be ineffective or even creates a loophole. This could happen in cases where species found exclusively within protected areas prove to be rare, and/or if most species within protected areas can also be found outside of these areas.

As the overall contribution to economic innovation and product development is positive, the research benefits for knowledge on biodiversity can also be expected to be positive, but this applies equally under the three options.

- **Impact on stakeholders**:
    - Coll.: More opportunities for own (taxonomic) research due to increased deposits under option 1
    - Gov. Res.: No impact
    - Ag., health and biotech: No impact
    - Univ.: No impact
    - Land: Could increase awareness on ABS related to use of biodiversity for R&D
    - Other: Indirect positive effects for society through increase of knowledge base and closer monitoring of benefits under option 1 and through refined PA/PS under option 3

Table 10 - Environmental impact of the options for the operationalization of PIC

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
M	Option 0	Negative	Medium	Medium	-

[207] Yun M. (2005), *Economic Valuation of Biodiversity*, Final Report for the MOSAICS Project. Korea Institute for International Economic Policy; Rausser G.C., Small A. (2000), Valuing Research Leads: Bioprospecting and the Conservation of Genetic Resources. *Journal of Political Economy*. 108(1), pp. 173-206; Biber-Klemm S., Martinez S.I., Jacob A. (2010), *Access to Genetic Resources and Sharing of Benefits – ABS Program 2003–2010*, Swiss Academy of Sciences, Bern, Switzerland; Martin B.R. and Tang P. (2007), *The benefits from publicly funded research*. SPRU Working Paper: 161.

	Option 1	Positive	High	Medium	++
	Option 2	Positive	Medium	Weak	0
	Option 3	Positive	Medium	Medium	+

Procedural impact

G1 – Flexibility to accommodating sectorial differences

As indicated in chapter 9.1, the assessment only applies to the establishment of the principle of PIC for access to Belgian GR, which is a necessary condition for the implementation of all three options. As this will be done through for example a cooperation agreement or provisions in relevant legislation, flexibility to accommodate sectorial differences will fully be preserved. The choice of the default access procedure (whether through ex-situ collections or through a notification requirement) is not a crucial step for the implementation of the NP and could be taken at a later stage of the implementation. Therefore, all 3 options can be implemented once sectorial specificities have clearly been identified and adapt accordingly. The same goes for the refinement of the existing legislation relevant to PA/PS, which applies to all three options. The specific "0" option does not lead to sector specific differences.

G2 – Temporal flexibility to allow for future policy and adjustments

As the assessment only applies to the establishment of the general legal principle of PIC for access to Belgian GR (see chapter 9.1), all options allow for temporal flexibility and can be adjusted to integrate future developments, in particular by integrating elements from the other options.

G3 – Improving knowledge for future policy development and evaluation

The possible increase in deposits under the bottleneck option, if feasible at reasonable cost (*cf.* criteria E2), will strongly foster overall understanding and knowledge of the type of GR that is being exchanged and valued. Furthermore, *ex-situ* collections host an important part of the Belgian biodiversity heritage, which is currently underexploited or unknown. Allowing the collections to play a more important role will help to increase knowledge on currently unknown specimen. The bottleneck component is thus preferable under this criterion.

The baseline and modified fishing net would both generate information from all type of use sectors and uses (according to the content of the registration), so there is no difference over this criterion.

The specific "0" option scores very badly over this criterion. Indeed, in contrast to all the other options, it will not generate systematic data on notification/registration, on user requests for information on PIC when accessing GR or other knowledge generated in the operationalization of the PIC.

G4 – Correspondence with existing practices

For the reasons discussed under G1, the bottleneck model might require some changes in practices from those sectors that acquire their GR from outside PA/PS and who do not rely on the public culture collections (so acquisition from in situ outside PA/PS and acquisition from informal exchanges with in house collections, often without systematic track record and documentation). However, as explained above, these practices only concern some sectors and some uses.

Indeed, in Belgium, as several interviewees have pointed out, most utilized GR come from *ex-situ* collections, while the use of *in-situ* GR presents a diminishing trend. Consequently, *ex-situ* facilities act as important agents in the production chain: studies show that the use of *ex-situ* collections for new material is larger than both in situ and induced mutation[208]. The requested changes would essentially re-enforce this existing practice and growing trend of relying upon *ex-situ* collections for the exchange of GR. Moreover, the *ex-situ* collections already have a practice of documenting GR and dealing with CBD requirements.

So overall one can say that the discordance with existing practices is not very likely to occur in the bottleneck model and that for most access situations the correspondence is very high.

Under the fishing net component, the GR can be accessed from everywhere, but the introduction of the notification/registration requirement for the GR outside PA/PS would require a change in practices, although with an expected minor impact on these practices as the intent is to have a light notification/registration requirement.

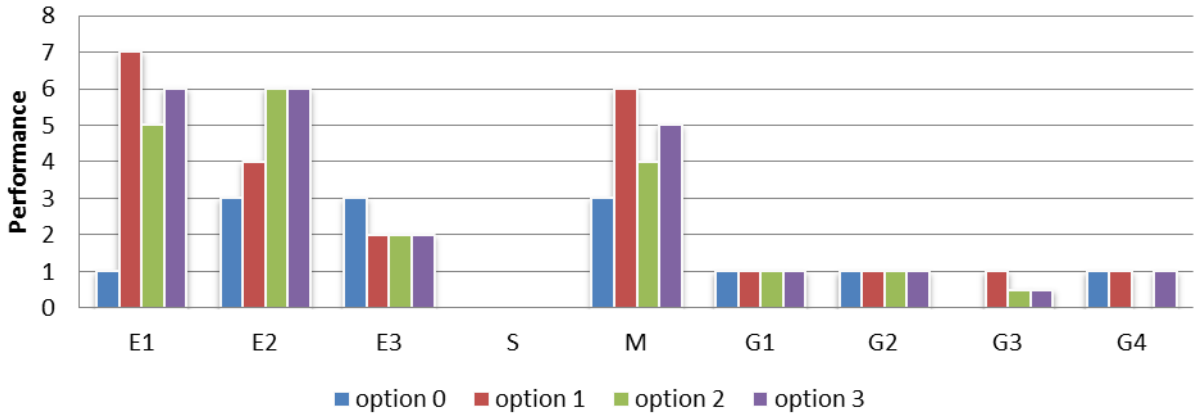
Comparing the baseline fishing net to the modified fishing net model, one can conclude that the modified fishing net model has a slight advantage over this criterion, as it relies on additional pieces of existing legislation covering GR. In particular, and although counter-intuitive, there is no evidence that only protected areas contain interesting genetic material. Refining GR legislation beyond the focus on PA and PS only could therefore increase the correspondence with the existing practices of utilization of GR.

10.2.2 Visual dominance analysis

No ideal point can be identified in the performance chart (**Figure 3**).

[208] Stromberg P., Dedeurwaerdere T., Pascual U. (2007), *An empirical analysis of ex-situ conservation of microbial diversity*. Presentation at the 9th International BIOECON Conference, Kings College Cambridge, 19th -20th September 2007; Täuber *et al.,* (2011), *op.cit.*

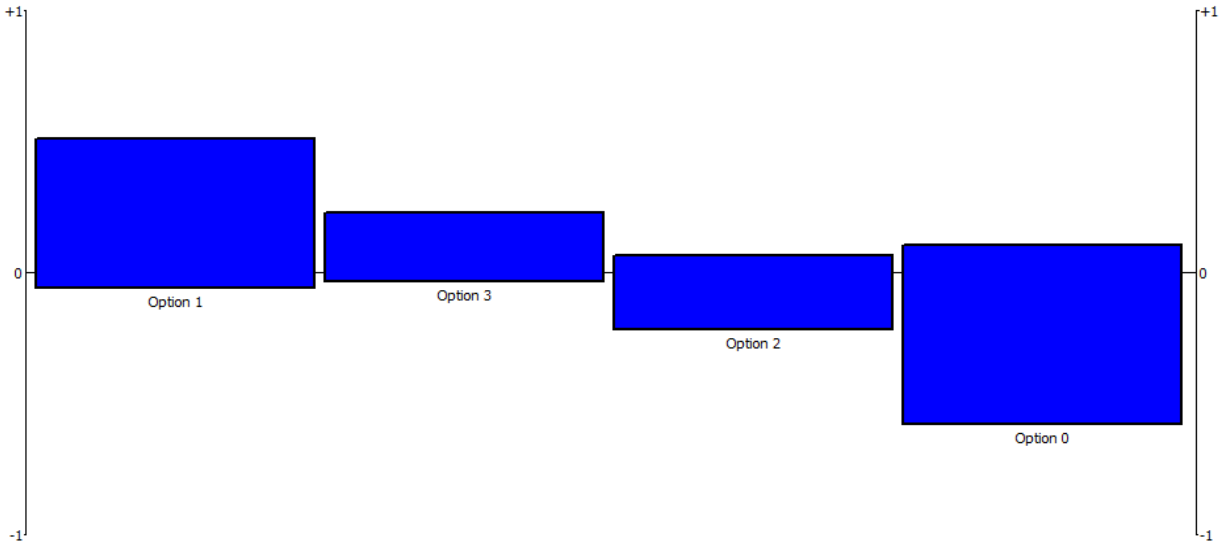
Figure 3 - Performance chart of the options for the operationalization of PIC



10.2.3 Ranking the alternatives

A preference can be observed for options 1 and 3. This can be explained by the fact that option 2 is dominated by both option 1 and 3 for legal certainty (E1), for the environmental impact (M) and for correspondence to current practice (G4). A reasonable change in the weighting amongst the options does not allow changing this result. It should be noted that the social impact is not accounted for in this analysis, as the performance of the options is unclear (see description of performances above). Additional data could alter the outcome of the ranking, given that the social criterion is of substantial importance in all three weighting scenarios.

Figure 4 - Net flows of the alternatives for operationalizing PIC (basic weighting scenario)



As for the difference between option 1 and 3, a further analysis by changing the weighting can refine the analysis, as this difference is not very high. Option 3 scores comparatively better over the economic innovation criterion (E2). Option 1 has advantages over option 3 due to gain in legal certainty (E1), overall environmental benefits (M), and knowledge gathering for future policy making

(G3). In the scenario with the basic allocation key (see chapter 1), this leads to option 1 to be preferred.

Based on the sensitivity analysis, this outcome appears to be a solid one. None of the alternative weighting scenarios leads to a change in the leading position of option 1 or in the classification of the options. However, both scenario 2 and 3 tend to attenuate the differences between option 1, on the one hand, and options 2 and 3, on the other. Again, the social impact is not accounted for in this analysis, as the performance of the options is unclear (see description of performances above).

10.3 Specification of MAT

Summary of the selected options for the specification of MAT

0. **Specific "0" option**: No benefit-sharing
1. **Option 1**: No specific benefit-sharing requirements imposed for the MAT
2. **Option 2**: Standard agreements with specific benefit-sharing requirements, depending on finality of access
3. **Option 3**: Specific benefit-sharing requirements, negotiated on a case by case basis, depending on finality of access

For a detailed description of the options please refer to chapter 8.2 and chapter 9.

10.3.1 Performance of the options

Economic impact

E1 – Legal certainty and effectiveness for users and providers of GR, at low cost

The sharing of benefits for the exchange or the utilization of GR in Belgium is currently self-regulated by the sector, each provider institution proposing its own rules and standard agreements. In this context, option 1 does not impose important legal costs, as it would simply rely on the same model. However, this option does not allow the Belgian State to specify the circumstances of the benefit-sharing procedure and to make sure benefits are shared in a fair and equitable way. In addition, both option 1 and the specific "0" option would not allow the users to benefit from the advantages on legal certainty and effectively provided by options 2 and 3.

Indeed, from a perspective of legal effectiveness and legal certainty, working with model contractual clauses (option 2) or tailoring the BS agreements to the specificities of each new transaction (option 3) encompass various advantages for users, providers and public authorities. *First* the development of standard agreements could eliminate variations between ABS regimes, hence providing legal certainty, facilitating transaction initiation, and suppressing information gaps created by extraneity factors[209]. *Second,* it could give more incentives to respect the rules already in place, insofar as the actors of the private sector currently prefer to trade with informal private collections that do not follow BS standards[210]. *Third*, using contracts will facilitate the enforcement of contracts between providers and users: "a contract would be binding as long as it is not found to be void, and could,

[209] Tauber *et al.* (2011), *op.cit*. The term of « extraneity » is used when a legal issue confronts two or more different national legal systems and requires thus to rule a conflicts of laws or jurisdictions. It is envisaged here that the situation where the identity of the physical provider of a genetic resource (*e.g.* a public collection) differs from the identity of the owner or the original provider of this resource.

[210] Laird S., Wynberg R. (2012), *Bioscience at a crossroads: Implementing the Nagoya Protocol on Access and Benefit-sharing in a Time of Scientific, Technological and Industry Change,* CBD.

depending on the dispute settlement clause included in the contract, be brought to arbitration" [211]. *Fourth*, standardizing the negotiation and/or the agreement allows overcoming unbalanced bargaining power resulting from asymmetries in information, knowledge, negotiation, skills and capacity[212], which is a barrier to fair and equitable benefit-sharing. *Fifth* – and related to the fourth point – it allows the state to control if benefits arising from potentially high-value resources are being shared accordingly to their value and being used accordingly with the objectives of the Protocol and the Convention.

Option 2 might smoothen the negotiation process between users and providers, as it offers guidelines while providing security to providers that changes of intent will be renegotiated. Nonetheless, the legal setup of option 2 and option 3 (*i.e.* the inclusion of specific BS requirements in the provisions of the environmental code, *cf.* chapter 9.2) has yet to overcome the difficulty of delineating practically how divergent finalities of access can be distinguished from each other. Failing to specify the nature of different types of utilization, especially commercial utilization, and the correlated adequate BS, is likely to deprive the Belgian State from possible benefit-sharing which might contribute to conservation and sustainable use of biodiversity. However, this report has identified examples of how to deal with this distinction (*cf.* chapter 6.1 and 6.2). Hence, these practical difficulties do not seem to outweigh the benefits offered by options 2 and 3 through legal certainty and effectiveness. In particular, in the case of option 3, even if the legal costs are likely to be substantially higher, the benefits for effectiveness discussed above could be higher as well.

Impact on stakeholders:

- Coll.: Benefit from higher legal certainty under options 2 and 3.
- Gov. Res.: Benefit from higher legal certainty under options 2 and 3.
- Ag., health and biotech: Benefit from higher legal certainty under options 2 and 3.
- Univ.: Benefit from higher legal certainty under options 2 and 3.
- Land: Benefit from higher legal certainty under options 2 and 3..
- Other: No impact

E2 – Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs

Option "0" would also lead to a non-ratification of the Nagoya Protocol as well as to non-compliance with the BS obligations of Belgium in the framework of the CBD. The resulting legal uncertainty (see also E1) is likely to lead to less utilization of Belgian GR in research and development and thus potentially hamper economic innovation and product development substantially[213].

[211] M.W. Tvedt, O.K. Fauchald, O. K. (2011), Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit-sharing in Norway. *The Journal of World Intellectual Property*, 14: p. 392

[212] Tauber *et al.*, (2011), *op.cit.*

[213] This expected impact of this hypothetical situation for the Belgium providers and users can be illustrated with the historical example of the legal vacuum, between 1992 and 1994, of the international network of the CGIAR collections (Consortium for International Agricultural Research). As documented in the literature, this legal vacuum led to a temporary, but spectacular, decrease by over 50% of the use of the GR of these collections, see Byerlee, D. and Dubin, J. 2010. Crop improvement in the CGIAR as a global success story of open access and international collaboration. *International Journal of the Commons* (4) 1.

Conversely, the adoption of BS as a horizontal principle envisioned in options 1, 2 and 3 is likely to maximize economic innovation in the future. In general, if BS is adopted, then the increase in legal certainly under options 2 and 3 will spur the utilization of Belgian GR while leading to the lowest level of transaction costs for the different categories of users of GR. Option 1 could also prove to serve economic innovation and product development, as it offers the advantage to agree upon benefits that generate the least costs. But this advantage mainly applies to users, with providers risk to invest a lot of resources to make sure the benefits shared with them reflect a fair and equitable share of the benefits. Under option 3 this flexibility for users (for instance by encompassing an *ex-post* renegotiation process once the "non-commercial" utilization of the resource finds a commercial application) can be conserved, while offering a basis of negotiation for providers through specific requirements. Option 3 thus has the advantage of both providing a certain level of certainty for providers and small users (through a predefined set of requirements adapted for this sector) and leaving a certain level of flexibility for bigger commercial users (through the case-by-case negotiation). Furthermore, options 2 and 3 will streamline the utilization of GR for both formally and informally organized providers (such as research laboratories that distribute GR that they collected from *in situ* or official *ex-situ* collections that work in the context of public-private partnerships). These advantages seem strongest in option 3 as compared to option 2, where both public and private sector research might feel hindered from the lack of flexibility in a fully standardized set of BS requirements. This could rebalance the role of public collections which sometimes lack the resources/bargaining power to impose the appropriate rules.

- **Impact on stakeholders**:
    - Coll.: As user, might be disadvantaged under option 3, as resources are generally limited to negotiate specific BS requirements.
    - Gov. Res.: Might be disadvantaged under option 3, as resources could be limited to negotiate specific BS requirements.
    - Ag., health and biotech: Bigger users might prefer option 1 or 3, due to the flexibility to accommodate to existing functioning. Small commercial users might be disadvantaged under option 2, as resources could be limited to negotiate specific BS requirements.
    - Univ.: Might be disadvantaged under option 3, as resources are generally limited to negotiate specific BS requirements.
    - Land: No impact on economic innovation and product development of land owners
    - Other: Economic innovation more likely if benefit-sharing is adopted as a general principle.

E3 – Minimizing implementation costs

The impact of the specific "0" option for minimizing implementation costs is unclear as it is unclear how the specific "0" option would still allow the Belgian State to comply with the BS obligations of the CBD (*cf.* chapter 8) and what implementation costs would result from this alternative scenario.

The implementation costs of the options 1, 2 and 3 will be different for stakeholders on the one hand and for the public administration on the other. Stakeholders will be impacted by the negotiation costs they incur to agree upon the sharing of benefits. The level of these costs is inversely proportional to the standardization of (the process to establish) MAT[214]. When BS is not specified, negotiations can include agreeing on the types of benefits to share, the time-frame of the benefit-sharing, the distribution of the benefits between the different stakeholders involved, etc. The less the process is standardized and/or is facilitated by pre-existing requirements, the more time stakeholders will spend on the negotiation of terms they both agree upon. This cost is also likely to differ depending on the moment negotiations are taking place. They can take place before the exchange (*ex-ante* negotiation), most likely at the moment of access, or after the negotiations (*ex-post* negotiation) when the agreement specifies that benefit-sharing terms are to be settled at a later stage of the development chain (*e.g.* the patent stage, the commercialization stage, etc.) or when terms of a project need to be renegotiated. It is assumed that the cost of *ex-post* negotiation is substantially larger than the costs of agreeing on BS *ex-ante*, because of the relationship-specific investment related to an already pre-developed product[215]. This is also voiced by some interviewees, who fear that deciding on the amount of benefits to share at a later stage than the moment of access will create higher expectations, resulting in difficult negotiations between users and providers. Taking the above into account, the negotiation cost could range from no costs at all for a fully standardized procedure to more than 1000€ per transaction for ex-post negotiation in a fully flexible context[216].

For the public administration, option 1 leads to the least implementation costs, while option 2 might lead to high set-up and follow-up costs for implementation and option 3 might lead to high implementation costs due to the recurring need to adapt the BS requirements to every new transaction (including legal advice). At the same time, the legislative costs for the drafting of the different options are not necessarily very high, depending on how the standardized mutually agreed terms are specified in the implementation provisions of the Nagoya Protocol in Belgium. In particular, such implementation provisions can draw some lessons from the practices with existing standardized MTA clauses (Material Transfer Agreements) already put into practice by the collections, which shows the benefits from using standardized material acquisition and transfer arrangements.

[214] Täuber *et al.*, (2011), *op.cit.*

[215] O.E. Williamson (1985), *The Economic Institutions of Capitalism*, New York: Free Press; relationship-specific investment are investments whose return depends on the duration on the relationships continuation (See V.P. Crawford (1990), "Relationship-Specific Investment", *The Quarterly Journal of Economics*, 105(2), pp. 561-574). In other words, the return on the investment made by users of GR in developing a product depends upon the continuation of the relationship (the ABS agreement) they have with the provider.

[216] These figures are based on a quantitative evaluation, by the study team, of the negotiation costs related to the MAT under the various options. This evaluation is based on the data generated in the interviews (especially indicators IND 3.1 and 3.2, data collected for the various stakeholder groups).

Combining these two contrasted impacts for comparing options 2 and 3, it can be considered that one time set up costs lead to fewer impacts, compared to recurrent costs such as transaction and negotiation costs (*cf.* E1 and E2). Under options 2 and 3, negotiation and transaction costs are born on a regular basis by the users and providers of GR. However, the setting-up costs of standardized formats for option 2 are costs incurred only once and lead to less recurrent negotiation costs. As a result, it might be said that the overall impact of option 2 on minimizing implementation costs is better than option 3 which leads to higher recurrent costs for all stakeholders. Option 1 is hard to evaluate as it could both be minimalistic or very extensive, even though it has less set-up costs for the State compared to options 2 and 3.

- **Impact on stakeholders**:
  - Coll.: Incurring less implementation costs under option 2 and, to a lesser extent, option 3, both as users and providers.
  - Gov. Res.: Incurring less implementation costs under option 2 and, to a lesser extent, option 3.
  - Ag., health and biotech: Incurring less implementation costs under option 2 and, to a lesser extent, option 3. More flexibility under option 3
  - Univ.: Incurring less implementation costs under option 2 and, to a lesser extent, option 3.
  - Land: Incurring less implementation costs under option 2 and, to a lesser extent, option 3
  - Other: No impact

Table 11 - Economic impacts of the options for the specification of MAT

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
E1	Option 0	Negative	High	Strong	- - -
	Option 1	/	Medium	Weak	0
	Option 2	Positive	Medium	Medium	+
	Option 3	Positive	Medium	Medium	+
E2	Option 0	Negative	High	Medium	-
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+
	Option 3	Positive	High	Medium	+ +
E3	Option 0	Unclear			
	Option 1	Positive	Medium	Weak	0
	Option 2	Positive	Medium	Medium	+
	Option 3	/	Medium	Weak	0

Social impact

S – Achievement of social objectives

It is likely that the overall contribution to economic innovation and product development of the adoption of BS as a horizontal principle might also have (at least indirect) positive effects on socially important sectors such as food security, health and nutrition. The sharing of (monetary and/or non-monetary) benefits could take the form of management support, educational programs, technology transfer, institutional capacity building, collaboration among companies, etc. which are expected to support social objectives. A concurrent contribution to the R&D sector is also expected to contribute to job creation in the overall economy, and in public and private research institutions in particular. Conversely contribution for socially important sectors under option 0 can be considered negative.

However, the different options might have contrasted effects on various sectors of use, impacting their capacity to innovate, create jobs and contribute to social objectives. Option 2, and to a lesser extent option 3, could at least partially contribute to overcome problems of unbalanced bargaining power between the actors. Small commercial users and the non-commercial users might suffer from option 3 if they do not have sufficient capacity to negotiate the case by case agreements, while at the same time this option could potentially better take into account the specificities of the small commercial and non-commercial users and providers. Option 1 is hard to evaluate as it could both be minimalistic or very extensive.

Overall, options 3 and 2, compared to option 1, offer a better opportunity for the Belgian authorities to control the types of benefits being shared and monitor whether use made of them by stakeholders serves social objectives.

Combining these effects (specific BS requirements and public control over benefits), it seems that option 2, and to a lesser extent option 3, offer an advantage for this criterion over option 1.

- **Impact on stakeholders**:
    - Coll.: As provider, more opportunity to contribute to social objectives with BS as horizontal principle.
    - Gov. Res.: Contribution to the R&D can lead to job creation and contribute to social objectives
    - Ag., health and biotech: Contribution to the R&D can lead to job creation and contribute to social objectives
    - Univ.: Contribution to the R&D can lead to job creation and contribute to social objectives
    - Land: As provider, more opportunity to contribute to social objectives with BS as horizontal principle
    - Other: the adoption of BS as a horizontal principle might also have (at least indirect) positive effects on socially important sectors

Table 12 - Social impacts of the options for the specification of MAT

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
S	Option 0	Negative	Medium	Medium	-
	Option 1	/	Medium	Weak	0
	Option 2	Positive	High	Medium	++
	Option 3	Positive	High	Weak	+

Environmental impact

M - Promotion of conservation and sustainable use of biodiversity

It is likely that BS, as a horizontal principle would have positive effects on conservation of sustainable use of biodiversity, in particular when non-monetary and monetary benefits, as included in the MAT, are directed towards the objectives of conservation and sustainable use of biodiversity. Conversely, contribution of the option 0 can be considered negative.

Like for social objectives, options 3 and 2 offer a better opportunity for the Belgian authorities to control the types of benefits being shared and monitor whether they contribute to conservation and sustainable use of biodiversity.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: Option 1 offers less possibility to channel benefits towards conservation and sustainable use
  - Other: BS as a horizontal principle is expected to offer positive environmental effects for society as a whole

Table 13 - Environmental impacts of the options for the specification of MAT

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
M	Option 0	Negative	Medium	Medium	-
	Option 1	Positive	Medium	Weak	0
	Option 2	Positive	Medium	Medium	+
	Option 3	Positive	Medium	Medium	+

Procedural impact

G1 – Flexibility to accommodating sectorial differences

The utilization of genetic resources is very heterogeneous, ranging across different sectors of the biotechnology industry and including different types of users. BS agreements could reflect heterogeneous uses of genetic resources, in different sectors and different production chains.

The possibility to accommodate sectorial differences will clearly be highest in option 1 and to a lesser extent in option 3. At first glance, options 1 and 3 will provide some advantage as the BS conditions will be specified upon case by case transaction. In the case of option 1 this will be without having to follow specific BS requirements, in the case of option 3 there will be specific BS requirements but these will leave a large degree of flexibility to accommodate sector specificities. However, option 1 might have some hidden costs of accommodating flexibility, for the public authorities implementing the Nagoya Protocol, as they have to specify the circumstances under which a certain type of benefit-sharing can be considered fair and equitable. Therefore, an option such as option 3, leaving sufficient room for flexibility while providing such indications of “appropriate circumstances” by some standardization, might have a lower cost for organizing flexibility. Overall, for the authorities, both option 2 and option 3 represent a low-cost measure for organizing flexibility with sectorial differences, while providing clear and certain rules for benefit-sharing.

Comparing the impact on various stakeholders, it can be said that the lack of flexibility regarding sectorial differences in option 2 might be disadvantageous for larger commercial users while it could benefit non-commercial and small commercial users who do not have the same amount of resources for detailed negotiations under option 3 as larger commercial users.

The impact of the specific "0" option for accommodating sectorial differences is unclear as it is unclear how the specific "0" option would still allow the Belgian State to comply with the CBD BS obligations (*cf.* chapter 8 and 9) and how flexibility would be built in this alternative scenario.

G2 – Temporal flexibility to allow for future policy and adjustments

Overall, the options 1, 2 and 3 allow for some temporal flexibility as they could provide for gradual fine-tuning, or possibly even for a gradual increase of the level of requirements (1->2->3), for example when more knowledge about the use of GR would become available. However, options requiring a substantial investment in order to put into place (such as options 2 and 3 where substantial effort is needed to define the specific requirements) will be more difficult (and there will be more resistance) to change at a later stage.

The specific "0" option is likely to have a contrasted effect on temporal flexibility. On one hand, it would lead to non-ratification of the Nagoya Protocol and also to a default on the implementation of the CBD BS obligations. This would still require, in a later stage, to move towards better implementation of the CBD and could lead towards the ratification of the Nagoya Protocol in a

second step by adopting option 1, 2 or 3 in a later stage. However, postponing the implementation of the BS obligations to the future is likely to create comparatively higher costs in the future, than the costs that are envisioned now (for example in option 1). Indeed, not ratifying the Nagoya Protocol would still require legal action, as a non-party, to clarify the relationship with Parties to the Protocol and to deal with implementation measures in other countries when distributing GR to these countries (for example if these countries would put a due diligence system in place, requiring clarification of legal provenance for the GR from Belgium). Changing legal actions that would have been taken place outside the system of the Protocol, in a later stage, and revert back to the implementation of the BS sharing under the Nagoya Protocol at a later stage, in a way which is consistent with the legal developments in other countries, would probably lead to additional costs which outweigh the temporal flexibility gained by postponing the implementation.

G3 – Improving knowledge for future policy development and evaluation

The absence of a horizontal BS requirement (specific "0" option) comparatively would generate less information than the options requiring BS. Indeed these options would generate information on the way actors deal with benefit-sharing obligations (both under options 1, 2 and 3) that could prove relevant for future policy making.

G4 – Correspondence with existing practices

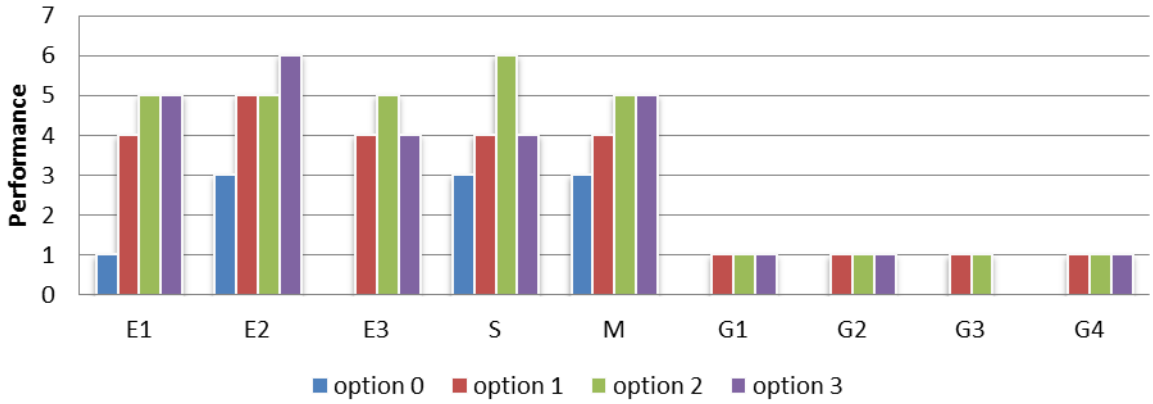
The exchange of GR in Belgium is currently self-regulated and most current exchanges of GR already include a benefit-sharing clause based on semi-standardized or standardized BS used between user and provider, many of which make a difference between commercial and non-commercial use purposes. Option 1 could therefore easily build upon existing practice, but there would be no decisive difficulty for those providers to adapt themselves to the options 2 or 3, if the specific conditions imposed by the state would be sufficiently flexible. As for the private actors, the small companies could prefer a certain use of standard models given their possible lack of direct legal expertise and/or resources for extensive negotiations.

In contrast, the specific "0" option would move away from the existing trends and practices of the Belgian stakeholders.

10.3.2 Visual dominance analysis

No ideal point can be identified in the performance chart (**Figure 5**).

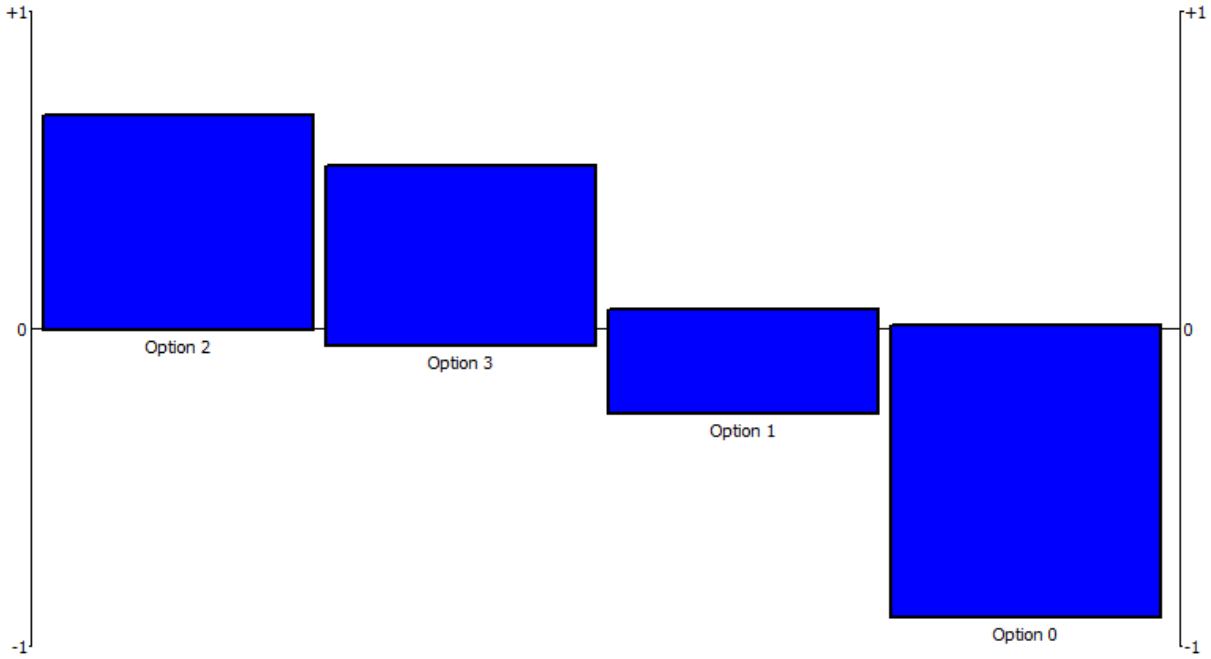
Figure 5 - Performance chart of the options for the specification of MAT



10.3.3 Ranking the alternatives

With our basic allocation key, option 2 stands out as the preferred solution (Figure 6): it performs better or at least as good as other options on all the criteria except on criterion E2. However, the differences with option 3, which comes second, are rather small, as option 3 scores well on economic (E1 and E2), environmental (M) and most procedural criteria. The leading position of option 2 is maintained throughout the sensitivity analysis but is slightly attenuated. In light of this analysis, option 1 and option 0 are not valuable alternatives.

Figure 6 - Net flows of the alternatives for specification of MAT (basic weighting scenario)



10.4 Establishing one or more Competent National Authorities

Summary of the selected options on the Competent National Authority

0. **Specific "0" option**: non-establishment of CNAs
1. **Option 1**: Decentralized input to the CNAs
2. **Option 2**: Single entry-point to the CNAs

For a detailed description of the options please refer to chapter 8.2 and chapter 9.

10.4.1 Performance of the options

Economic impact

E1 – Legal certainty and effectiveness for users and providers of GR, at low cost

Option 2 has, compared to option 1, a set of advantages pertaining to legal certainty and effectiveness. Indeed, this option is likely to increase legal clarity, as it would lead to a more standardized input system of access requests, and reduce the redundancy in information provision on access procedures. In addition, it can reduce costs related to the search of the adequate information for users, as only one input system will be in place. The set-up costs of a single entry-point to the CNAs is to be born only once (and might benefit from some economies of scale), while the operating costs are likely to remain low once implemented (for example through a single digital portal as entry-point to the CNAs).

These effects would probably be different for foreign users and for Belgian users. If accessed resources are to be used mainly by Belgian users, the impact on users has to be nuanced, as Belgian users are accustomed to the decentralized Belgian system. In contrast, for foreign users, the choice between 4 different entry-points could indeed create confusion and thereby lead to higher legal uncertainty and/or ineffectiveness.

Option 0 clearly represents the least favored option as the non-implementation will create high process as well as legal uncertainty for users. It will also make it impossible to keep track of legally accessed resources and hence prevent the public authority to enforce any obligations at a later stage of the utilization.

- **Impact on stakeholders**:
    - Coll.: As users, no impact. As providers, no impact.
    - Gov. Res.: No impact
    - Ag., health and biotech: Foreign users can benefit from increased legal certainty and effectiveness under option 2

- Univ.: Foreign universities can benefit from increased legal certainty and effectiveness under option 2
- Land: No impact.
- Other: No impact

E2 – Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs

Option 2 will generate lower transaction costs in accessing GR, due to a simplified one stop access procedure for users, but the difference in costs with option 1 is unlikely to have a major impact on economic innovation and product development. Moreover, this effect will be stronger for foreign users of GR, and will be more nuanced for Belgian users. Most Belgian actors already function in the strongly decentralized Belgian system. Therefore, option 1 and option 2 cannot clearly be differentiated along this sub-criterion.

With its high process as well as legal uncertainty (due to the non-ratification of the Nagoya Protocol), option 0 represents the least favored option for this sub-criterion.

- **Impact on stakeholders**:
  - Coll.: Little to no impact
  - Gov. Res.: Little to no impact
  - Ag., health and biotech: Little to no impact
  - Univ.: Little to no impact
  - Land: No impact
  - Other: No impact

E3 – Minimizing implementation costs

Under option 1, both users and public administrations will be faced with higher implementation costs. For public administrations, the cost of establishing the entry-point is fourfold higher under option 1, as four separate entry-points will have to be created and manned. As indicated earlier, for users (especially foreign users), identifying the competent entry-point is likely to require more working time than under option 2. Option 2 will have a higher coordination cost, at least in the initial phase of the implementation, as internal mechanisms and procedures will have to be established to deal with the different CNA's in line with their internal legislations and procedures. However, an initial higher set-up cost is to be preferred over continuing higher operating costs.

The impact of the specific 0 option along this criterion is unclear as this option would lead to non-ratification of the Nagoya Protocol and therefore depend on the alternative measures taken to clarify the access requests.

- **Impact on stakeholders**: public administrations (for setting-up and operating costs), users (for search and input costs).

- Coll.: No impact
- Gov. Res.: No impact
- Ag., health and biotech: Foreign users can benefit from lower implementation costs under option 2
- Univ.: Foreign universities can benefit from lower implementation costs under option 2
- Land: No impact
- Other: No impact

Table 14 - Economic impacts of the establishment of the CNA

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
E1	Option 0	Negative	High	Strong	- - -
	Option 1	/	Medium	Weak	0
	Option 2	Positive	Medium	Medium	+
E2	Option 0	Negative	High	Strong	- - -
	Option 1	/	Low	Medium	0
	Option 2	/	Low	Medium	0
E3	Option 0	Unclear			
	Option 1	Negative	High	Medium	- -
	Option 2	Negative	High	Medium	- -

Social impact

S - Achievement of social objectives

Choosing between a single entry-point and four different entry-points to the CNAs is unlikely to have any significant impacts on any social objective.

With its high process as well as legal uncertainty (due to the non-ratification of the Nagoya Protocol), option 0 clearly does not benefit any social objective and therefore represents the least favored option for this criterion.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: No impact
  - Other: No impact

Table 15 - Social impacts of the establishment of the CNA

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
S	Option 0	Negative	High	Strong	- - -
	Option 1	/	Low	Weak	0
	Option 2	/	Low	Weak	0

Environmental impact

M - Promotion of conservation and sustainable use of biodiversity, including biodiversity research

Option 0 would not allow keeping track of the access requests and analyzing the ways in which the resources are accessed, missing a major opportunity to enhance knowledge which could be used for the improvement of conservation and sustainable use. Options 1 and 2 do not lead to a different impact on the environment.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: No impact
  - Other: No impact

Table 16 - Environmental impacts of the establishment of the CNA

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
M	Option 0	Negative	High	Strong	- - -
	Option 1	/	Low	Weak	0
	Option 2	/	Low	Weak	0

Procedural impact

G1 – Flexibility to accommodating sectorial differences

As indicated in chapter 9.3, the choice of the entry-point, as dealt with in this analysis, is independent from the establishment of the four CNAs (one for each of the regional + federal authorities). The latter applies in any situation, hence this analysis is only concerned with the entry-points to the CNA. In this context, both options 1 and 2 potentially offer the same level of sectorial flexibility in the implementation of the NP. The impact of this criterion on the specific 0 option is unclear as it would lead to non-ratification of the Nagoya Protocol and depend on the alternative measures taken to clarify the access procedures to Belgian GR.

G2 – Temporal flexibility to allow future policy and adjustment

The specific 0 option would lead to non-ratification of the Nagoya Protocol. This could lead to keep more flexibility at present, but is likely to lead to less flexibility later on as explained above (*cf.* analysis under criterion G2 for specifying MAT).

The higher set-up costs of a centralized entry-point would partially lead to less flexibility to allow future changes (due to higher resistance to change, lower willingness to renegotiate) or to change modalities that are inherent to the institutional set-up. However, it is important to note that this partial difference in flexibility for change in modalities only concerns the difference in the entry-point to the CNAs and so can be considered asminor (the establishment of the CNA by each relevant authority applies in any situation, see chapter 9.3)

G3 – Improving knowledge for future policy development and evaluation

Option 0 would strongly inhibit the gathering of information, as no PIC would be granted and no information would be kept about previous access requests in case of the non-establishment of the CNA. It is unclear which of the options 1 or 2 would provide better opportunities to improve the knowledge base, but it might be argued that a centralized system will avoid redundant knowledge acquisition, improve the consistency of the generated data on the various access requests, and hence be more efficient.

G4 – Correspondence with existing practices

Both option 1 and option 2 build upon existing practices to a certain extent. On the one hand, the decentralized input of access requirements proposed under option 1 clearly corresponds to the current exercise of competences over GR, where there is no coordination between authorities in charge for dealing with access to GR in PA/PS. From this perspective, establishing an increased coordination would introduce a change to the existing practices, albeit at a low cost as it can be implemented through a one-stop digital portal. A notable exception to this is the longstanding coordination within the BCCM consortium for the culture collections, where information on GR and access procedures is available through a common portal which redirects users to the decentralized member collections.

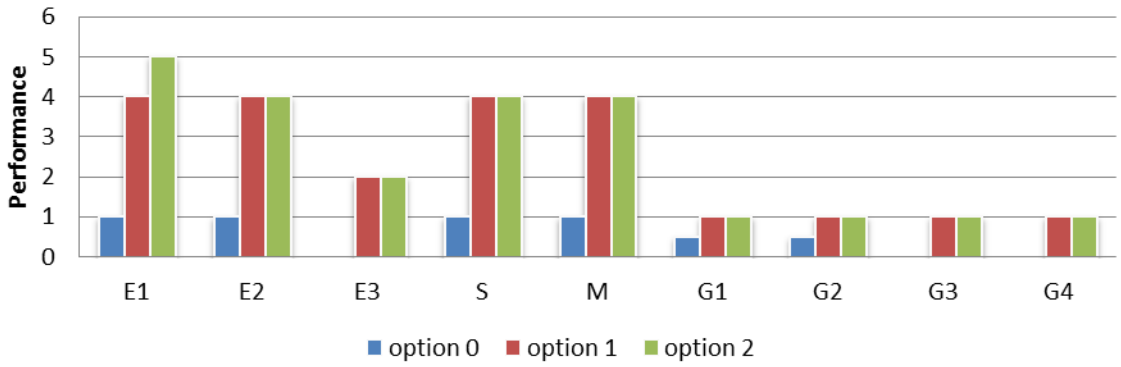
On the other hand, there is already an established practice of coordination amongst the federated entities and the Federal Government on matters pertaining to ABS policy. For example, issues related to the CBD and the NP are coordinated through the Biodiversity Steering Committee of the CCIEP, for which the secretariat is provided by the Federal Public Sevice for Environment. The Belgian Clearing-House Mechanism, managed by the focal point to the CBD is a central access point for information and awareness-raising pertaining to the CBD. Hence, establishing a single entry-point for facilitation/channeling of requests/advice (option 2) would also to a certain extent correspond with existing practices.

The impact of the specific 0 option under this criterion is unclear, as this option would lead to a non-ratification of the Nagoya Protocol and the impact would therefore depend on the alternative measures taken to clarify the access requirements.

10.4.2 Visual dominance analysis

Option 2 is the dominant alternative: compared to options 0 and 1, it scores at least as well on all criteria and is strictly better on one economic sub-criteria (legal certainty). However, this dominance has little relative value. In light of the preceding analysis of the performance and the impact on the stakeholders, this chart shows that little difference can be observed between the impact of establishing a single entry-point and the impact of establishing four separate entry points.

Figure 7 - Performance chart for the establishment of the CNA



10.5 Setting up compliance measures

Summary of the selected options on compliance

0. **Specific "0" option**: not introducing any legal provision on compliance
1. **Option 1**: Ensuring compliance with provider country legislation regarding PIC and MAT, with Belgian law as a fall-back option
2. **Option 2**: Self-standing obligation in the Belgian legislation to have PIC and MAT if so required by the provider country.

For a detailed description of the options please refer to chapter 8.2 and chapter 9.

10.5.1 Performance of the options

Economic impact

E1 – Legal certainty and effectiveness for users and providers of GR, at low cost

Even if the measures under the general "0" option were taken in order to comply with the obligations of the CBD and the ILO 107, users and providers would not be able to benefit from the clarified legal framework that the compliance measures envisioned under the NP. This would not create a sufficient level playing field for stakeholders. Therefore both options 1 and 2 are preferable over option 0 under this criterion.

Option 1 refers back to the legislation of the provider country while the private international law code would determine that provider country legislation is applicable to disputes regarding compliance with the MAT. If it is impossible to determine the content of the foreign law in due time, Belgian law should be applied.

This option therefore relies on the assumption that the legislation of the country of origin properly implements the NP provisions and is clear enough and acceptable for enforcement based on the provider country legislation. Instructing courts and authorities to directly apply the terms set by the provider country could create a level of uncertainty for Belgian users and public authorities, "given that access legislation will vary among countries, creating legal uncertainty as to whether and how each country's provider-side law will affect rights and obligations of users"[217]. However, the latter disadvantage is attenuated by the fall-back clause of the Belgian code of private international law, which specifies that if it is "impossible to determine the content of foreign law in due time, Belgian law should be applied" (art.15§2al2). In addition, now that Belgium has a national code of private

[217] Tvedt, Fauchald, (2011), *op.cit*.p.386.

international law, the application and control of foreign law is quite common[218]. There are today more than 300 judgments on the most-used database (Jura) with the keyword "applicable law to contracts in situations of international private law"; and at least 50 cases regarding "the application of foreign law by a Belgian judge". This is therefore absolutely not a new phenomenon, and would not create an additional burden to the judiciary system.

Nevertheless, in this perspective, the passing of a self-standing obligation as envisioned under option 2 could instead create less complexity for users, courts and enforcement authorities in Belgium. However, the obvious disadvantage is that it would respect to a lesser degree the political options and the legal requirements of the provider country pertaining to its national ABS legislation.

- **Impact on stakeholders**:
  - Coll.: As users, less complexity under option 1
  - Gov. Res.: Less complexity under option 1
  - Ag., health and biotech: Less complexity under option 1
  - Univ.: Less complexity under option 1
  - Land: No impact as providers.
  - Other: No impact

E2 – Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs

The 0 option would lead to non-implementation of the Nagoya Protocol, which would likely lead to an increased difficulty for Belgian users to acquire foreign GR for research and development and result in a barrier for economic innovation. As stated in chapter 3, there are already various substantial (material rules) and formal (private international law) provisions that could be applied to the contractual and extra contractual conflicts related to GR benefit-sharing. However, these are not fully adapted to the NP playing field (*e.g.* absence of notion of "informational component"). In the field of research and development, collaborations with users in foreign countries which are Parties to the Protocol might be hampered, which will also hinder obtaining internationally recognized standards for proof of good legal provenance of GR. In comparison, options 1 and 2 would allow implementing the Nagoya Protocol and thereby safeguard, or even extend, the level of trust in the research sector.

The expected positive impact from the implementation of the Nagoya Protocol will however differ between option 1 and 2. Indeed, under option 1, giving the priority to the law of the provider country within the Belgian legal system could entail significant transaction costs. The extent of these transaction costs will of course largely depend on the effectiveness of the ABS Clearing-House in providing detailed and up to date information. On the other hand, option 2 would be less complex for users to comply with the provider country requirement regarding the existence of PIC and MAT, which would promote the use of GR for economic innovation and product development.

[218] Marchal, P. (2008) Le droit comparé dans la Jurisprudence de la Cour de Cassation. *Revue de Droit International et de Droit Comparé*, liv.2-3, 2008 - p. 418.

- **Impact on stakeholders**:
    - Coll.: As users, incurring higher costs under option 1
    - Gov. Res.: Incurring higher costs under option 1
    - Ag., health and biotech: Incurring higher costs under option 1
    - Univ.: Incurring higher costs under option 1
    - Land: No impact as providers
    - Other: No impact

E3 – Minimizing implementation costs

The impact of the 0 option under this criterion is unclear. The 0 option would lead to non-ratification of the Nagoya Protocol and therefore the impact on implementation costs will depend on the alternative measures that are taken to comply with the obligations of CBD and ILO Convention 107, which are both ratified by Belgium.

ABS disputes would relate to disagreement about implementation of provisions included in the MAT. In this context, the absence of related jurisprudence will create a challenge for the initial cases in all the considered options, which might be reduced only by a legislative draft that is as precise as possible. This remark applies equally to options 1 and 2.

- **Impact on stakeholders**:
    - Coll.: As users, possible additional costs
    - Gov. Res.: Possible additional costs
    - Ag., health and biotech: Possible additional costs
    - Univ.: Possible additional costs
    - Land: No impact as providers
    - Other: No impact

Table 17 - Economic impacts of the compliance measures

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
E1	Option 0	Negative	High	Strong	- - -
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+
E2	Option 0	Negative	High	Medium	- -
	Option 1	Positive	Medium	Weak	0
	Option 2	Positive	Low	Weak	0
E3	Option 0	Unclear	/	/	/
	Option 1	Unclear	/	/	/
	Option 2	Unclear	/	/	/

Social impact

S – Achievement of social objectives

The envisioned implementation of both option 1 and 2 would contain a firm commitment under Belgian law to the compliance with PIC and MAT of the provider countries, both for GR and TK associated to GR (IMP 4.1 (1)). However, contrary to option 2, in option 1, the actual provisions for the PIC and MAT and the compliance with those provisions, would also be considered by the courts in the context of the relevant legislations of the provider country. If this legislation covers social objectives, and these are included in the MAT, then option 1 could have a better performance.

The 0 option is likely to have negative effects on the social objectives. As discussed earlier, option 0 could hinder access, due to lack of trust and level-playing field, and thus the social objectives of possible BS provisions. Furthermore, it would impede R&D in Belgium, which could be a barrier for innovation in the health, nutrition or food security sectors.

- **Impact on stakeholders**:
  - Coll.: Capacity for social innovation is limited.
  - Gov. Res.: Capacity for social innovation is limited.
  - Ag., health and biotech: Capacity for social innovation is limited.
  - Univ.: Capacity for social innovation is limited.
  - Land: No impact.
  - Other: Option 1 and 2 both offer opportunities for increasing protection of ILCs and TK in provider countries

Table 18 - Social impacts of the compliance measures

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
S	Option 0	Negative	High	Medium	- -
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+

Environmental impact

M - Promotion of conservation and sustainable use of biodiversity, including biodiversity research

The implementation of the Nagoya Protocol is expected to have a positive impact on conservation activities and biodiversity research. Therefore, options 1 and 2 are to be preferred over option 0 on this criterion.

The difference between option 1 and option 2 are difficult to assess, as the environmental benefits would depend in both cases on the Mutually Agreed Terms specified in the provider country legislations and/or the clauses negotiated on a case by case basis upon the access of the GR.

However, contrary to option 2, in option 1, the actual provisions for the PIC and MAT and the compliance with those provisions, would also be subject to revision by the courts in the context of the relevant legislations of the provider country. If this legislation includes provisions on conservation

and sustainable use of biodiversity, and these are included within the MAT, then option 1 would better address conservation and sustainable use of biodiversity.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: Better level playing field, within an effective regime, would benefit awareness raising on biodiversity issues more generally, and in *in situ* environments in particular.
  - Other: capacity building and technology transfer to third countries for conservation and sustainable use easier if NP is implemented

Table 19 - Environmental impacts of the compliance measures

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
M	Option 0	Negative	High	Medium	- -
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+

Procedural impact

G1 – Flexibility to accommodating sectorial differences

N/a (the three options are neutral as regards the specificities of various user sectors). All options can be adapted to sectorial and utilization differences.

G2 – Temporal flexibility to allow for future policy and adjustments

The impact of options 1 and 2 on temporal flexibility is probably quite similar, as all options would still leave room for further adjustments. Shifting from one option to another, or combining the options, still seems possible at further points in time, even though it would always imply a legislative cost.

The specific 0 option would lead to the non-implementation of the Nagoya Protocol. This could lead to keep more flexibility at present, but is likely to lead to less flexibility later on as explained above (cf. analysis under criterion G2 for specifying MAT).

G3 – Improving knowledge for future policy development and evaluation

Both options could generate knowledge through court decisions. Under option 1, this information could also serve provider countries.

G4 – Correspondence with existing practices

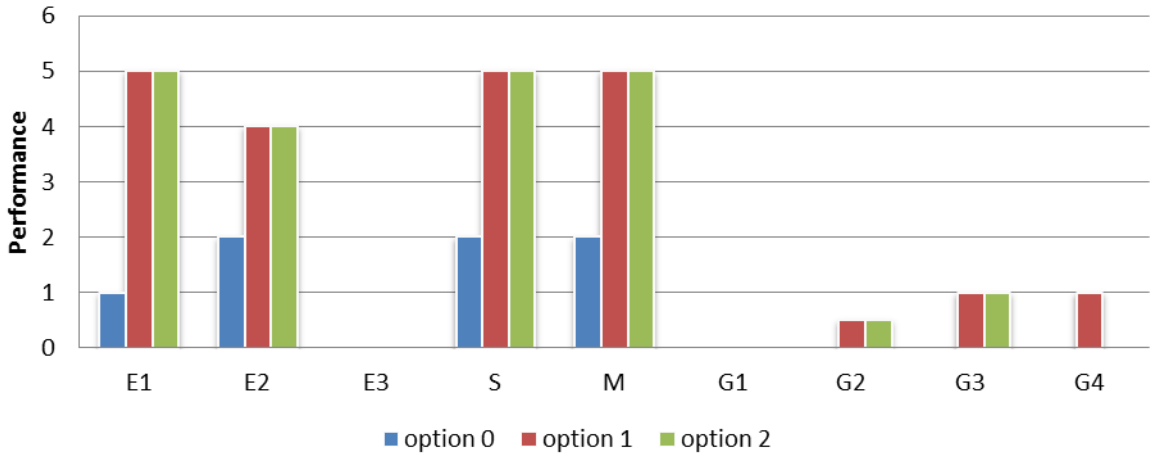
As indicated in the introduction to this section on compliance, currently there is no reference to GR in the scope of the Belgian code on private international law. Both option 1 and 2 would therefore require a change compared to current practices (including the specific 0 option, because of the obligations under CBD and ILO 107 that still need to be implemented). However, option 1 clearly is closer to the existing practices, as it basically extends the existing code of private international law, in order to explicitly address situations of disputes on the content of MAT.

The impact of option 0 is unclear as it depends on the way that the obligations under CBD and ILO 107 would be implemented in a situation of non-ratification of the Nagoya Protocol.

10.5.2 Visual dominance analysis

No ideal point can be identified in the performance chart (Figure 8).

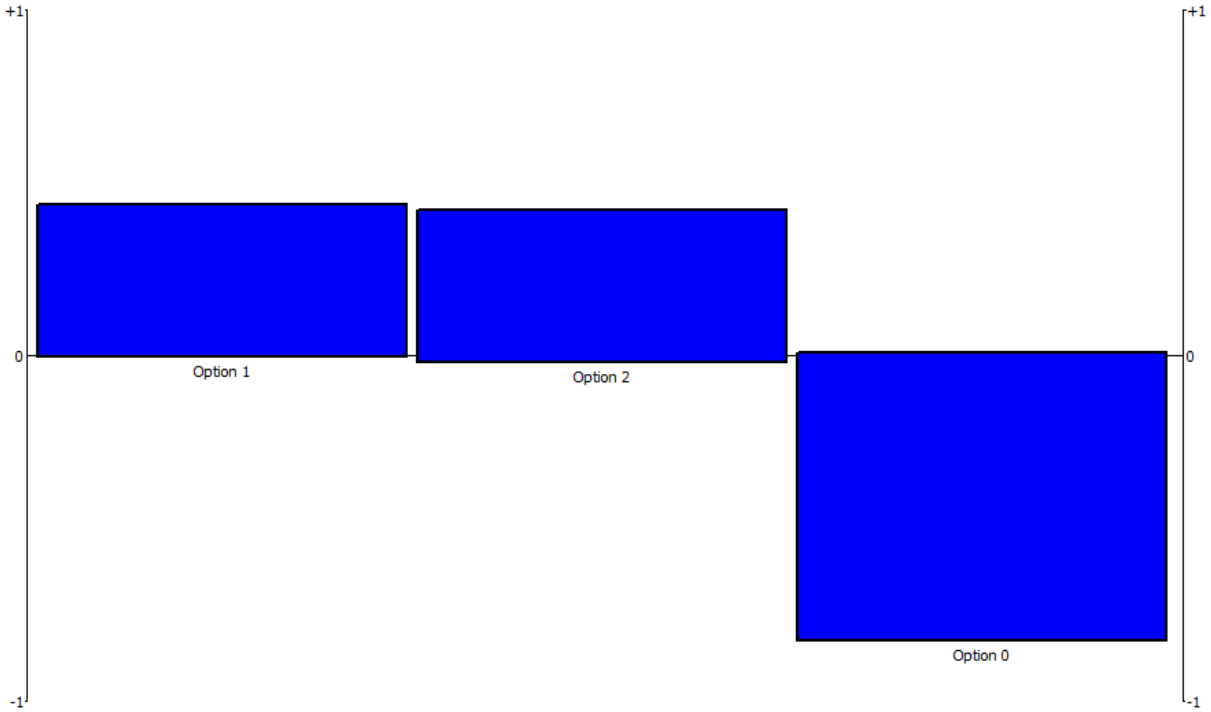
Figure 8 - Performance chart for the options setting up compliance measures



10.5.3 Ranking the alternatives

With our basic allocation key, option 1 stands out as the preferred solution (Figure 9): it performs better or at least as good as other options on all the criteria except on criterion E1. However, the difference with option 2, which comes second, is so small that the ranking is of very little relative value. As can be observed in the performance chart, the only significant difference between option 1 and 2 is that option 1 clearly corresponds better to existing practices. Option 0 is clearly the least preferred option.

Figure 9 - Net flows of the alternatives for setting up compliance measures (basic weighting scenario)



10.6 Designating one or more checkpoints

Summary of the selected options on checkpoints

1. **Specific "0" option**: No checkpoints would be introduced as envisioned under the Nagoya Protocol
2. **Option 1: Monitor PIC in** the ABS Clearing-House
3. **Option 2:** Using the patent office as a checkpoint

For a detailed description of the options please refer to chapter 8.2 and chapter 9.

10.6.1 Performance of the options

Economic impact

E1 – Legal certainty and effectiveness for users and providers of GR, at low cost

Option 0 clearly represents the least favored option as the non-ratification will create high process and legal uncertainty for users. Options 1 and 2 will allow ratifying the Nagoya Protocol and thereby allow users and providers to benefit from the higher legal certainty and transparency created by the Protocol. In addition, the monitoring measures put into place under options 1 and 2 are envisioned as an important contribution to promoting transparency and compliance. In a phased implementation of these measures, it is expected that this additional contribution would only be minor in a first phase (as they would cover a sub-set of GR and/or GR on which information on PIC is already available), but this impact is expected to increase in the later implementation stages. However, creating a common level playing field would provide substantial benefit from the outset.

Under ideal conditions, option 1 would be looking at the available information at the beginning of the development chain, thereby providing users and providers with the possibility to review whether all genetic resources utilized in Belgium have been acquired in compliance with the PIC provisions of the provider country. However, much will depend upon the effectiveness of the ABS Clearing-House(s) (internationally, but also in both the provider country and Belgium, *cf.* chapter 9.5). In case of ineffective transfer of information between the provider country and Belgium, users may face situations of uncertainty. Furthermore, the enforceability of the option is very doubtful, as it will prove hard to systematically control the high quantity of GR being utilized in Belgium from a high variety of sources and by very different users. However, a phased implementation might be a possible answer to these concerns.

Option 2 provides both providers and users with less possibility to monitor the correct use of the GR in Belgium than option 1. The patent stage is an advanced stage in the development process. Collecting proof of compliance at this late stage could generate uncertainty for users using GR that have transited through third-parties. By putting the burden of proof at the end of the development

chain, option 2 does not incentivize early users (if their utilization never makes it to the patent stage) to acquire GR legally, increasing the legal uncertainty of end users[219]. Furthermore, the patent office currently covers only a very small proportion of the transactions concerned by the Nagoya Protocol. In order to be effective to prevent misappropriation of GR, this option will need to be complemented with other checkpoints. But the small amount of transactions covered by option 2 could provide better opportunities for the enforcement procedures for those GR it will possibly cover[220]. By linking the monitoring and the patenting process, it could be easy for the authorities to ensure the monitoring of GR likely to have high(er) commercial value. For users, option 2 also makes it possible to combine patenting and ABS obligations, hence limiting the obligation redundancy.

As indicated in chapter 9.5, option 2 will require amending the existing patent law, whereas option 1 does not require any extra legal drafting beyond what can be foreseen under the obligations regarding PIC and the ABS Clearing-House. Hence, option 2 is likely to generate higher legal costs than option 1.

- **Impact on stakeholders**:
    - Coll.: As users, higher legal and process certainty with option 1 and limiting obligation redundancy under option 2 (for users using patents)
    - Gov. Res.: Higher legal and process certainty with option 1 and limiting obligation redundancy under option 2 (for users using patents)
    - Ag., health and biotech: Higher legal and process certainty with option 1 and limiting obligation redundancy under option 2 (for users using patents)
    - Univ.: Higher legal and process certainty with option 1 and limiting obligation redundancy under option 2 (for users using patents)
    - Land: Option 2 allows more effective enforcement and monitoring of use of genetic resources
    - Other: No impact

E2 – Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs

Option 0 would lead to non-ratification of the Nagoya Protocol, which would likely result in higher distrust with the provider countries and have a negative impact on the acquisition of GR from foreign countries and thereby on the overall capacity of the Belgian GR sector to innovate. Option 1 and 2 on the contrary are expected to increase trust and have a positive overall impact.

Under option 2, users acquiring GR from third-parties will face additional financial and administrative costs and efforts to make sure GR have been legally acquired, in order to avoid complications and unforeseen costs at the moment of patenting. However, the exact cost is unclear as it will strongly vary depending on the type of users, their utilization of GR and the moment in the development

[219] IEEP, Ecologic and GHK (2012), *op.cit.*
[220] Even if the efficiency depends upon additional training of the patent office, or close contribution of a more technically skilled monitoring office

chain at which they acquire GR and the possible combination with a self-monitoring scheme. On the other hand, for users acquiring GR mostly directly from developing provider countries, option 2 could also prove to be positive for the collection of GR. Being "the option favored by developing countries in the negotiations on the Protocol"[221], this measure could foster trust with partner countries and thus facilitate access to GR in these countries. No additional research costs are expected with options 0 and 1.

- **Impact on stakeholders**:
  - Coll.: As users, under option 2, higher costs to make sure GR has been acquired legally (for users using patents)
  - Gov. Res.: Under option 2, higher costs to make sure GR has been acquired legally (for users using patents)
  - Ag., health and biotech: Under option 2, higher costs to make sure GR has been acquired legally (for users using patents)
  - Univ.: Under option 2, higher costs to make sure GR has been acquired legally (for users using patents)
  - Land: No impact
  - Other: No impact

E3 – Minimizing implementation costs

The impact of option 0 under this criterion is unclear, as it will depend on the other measures taken by Belgium to comply with CBD and the ILO 107 Convention.

Options 1 and 2 are roughly equal in terms of costs related to the establishment of new institutions. Both options require an additional monitoring authority to be created. Although this new service will be hosted in the existing patent office with option 2, option 1 will most probably make use of the ABS CH (*cf.* chapter 9.5). Exact costs for the monitoring tasks are difficult to determine, as it will also depend on the interpretation of the term "monitoring", possible requirements at EU level and on how other information exchange measures are implemented such as the ABS Clearing-House. If the task of the checkpoint is understood as being limited to the collection and transfer of information as is currently the case (see chapter 9.5), the cost is roughly limited to the cost of storing and handling the information in a database. This cost is likely to be very small under option 1, as the ABS CH will already be used for the collection of information regarding the implementation of the NP, including on Prior Informed Consent. If, on the other hand, the provided information is to be effectively monitored and verified by the entity collecting the information, cost may be substantially higher. While monitoring costs for the patent office are likely to be reasonable[222], costs related to the monitoring of a very high amount of GR used in the country (full development of option 1) will be much more important. In the absence of specific figures on the utilization of GR in Belgium, it is

[221] IEEP, Ecologic and GHK (2012), *op. cit., p. 139*
[222] Eaton D., Visser B. (2007), *op. cit.*

difficult to assess this financial cost. The latter will also depend on the way the option is implemented in Belgium (*cf.* discussion on the phased approach above).

Implementation costs for users will be differently distributed depending on which option is chosen. Whereas under option 1 the cost of providing the information is incurred by users utilizing GR on Belgian territory, under option 2 this cost is incurred by the users wishing to patent a (semi-)finished product. However, the cost of providing the information will be small for users using legally acquired GR.

- **Impact on stakeholders**:
  - Coll.: As users, impact dependent upon type of utilization and moment of acquiring GR
  - Gov. Res.: impact dependent upon type of utilization and moment of acquiring GR
  - Ag., health and biotech: impact dependent upon type of utilization and moment of acquiring GR
  - Univ.: impact dependent upon type of utilization and moment of acquiring GR
  - Land: no impact.
  - Other: No impact

Table 20 - Economic impacts of the options for designating checkpoint(s)

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
E1	Option 0	Negative	High	Strong	- - -
	Option 1	Positive	Low	Medium	+
	Option 2	Positive	Low	Medium	+
E2	Option 0	Negative	Medium	Medium	-
	Option 1	/	Medium	Weak	0
	Option 2	/	Medium	Weak	0
E3	Option 0	Unclear			
	Option 1	Unclear			
	Option 2	Unclear			

Social impact

S – Achievement of social objectives

Options 1 and 2 have no direct major impact on social circumstances with regard to the access or benefit-sharing of the GR nor on related research and therefore these options are not expected to have a substantial impact on socially relevant objectives. Option 0 could seriously threaten R&D, as access to GR in provider countries will be much more difficult if Belgium's does not ratify the NP.

With regard to the protection of traditional knowledge, in light of the current level of details of the options, both options 1 and 2 offer the same possibilities to protect the TK of local communities in third countries. However, option 1 could offer more opportunities: if all relevant information concerning GR utilized in the country could be monitored (not just collected), this would offer a

higher protection rate against fraudulent use of TK, including in non-commercial settings. But as indicated earlier, this is difficult and costly to enforce, so this impact will depend on the way option 1 will be implemented if it would be selected. Option 0 does not lead to the protection of TK.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: No impact
  - Other: Higher level of protection of TK of communities in third countries under option 1

Table 21 - Social impacts of the options for designating checkpoint(s)

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
S	Option 0	Negative	Medium	Medium	-
	Option 1	Positive	Medium	Medium	+
	Option 2	/	Medium	Weak	0

Environmental impact

M – Promotion of conservation and sustainable use of biodiversity, including biodiversity research

Options 1 and 2 have no direct major impact on conservation or sustainable use of biodiversity.

Better monitoring of the use of GR, and in particular of the PIC and MAT obligations under the Nagoya Protocol, is likely to lead to increased benefit-sharing effectively reaching provider countries, which could in turn benefit activities related to the conservation and sustainable use of biodiversity and raise the awareness on the value of biodiversity for research and innovation. Moreover, both options 2 and 1, being in line with demands of provider countries if properly implemented, could facilitate cooperation activities focusing on conservation and sustainable use of biodiversity, while option 0 could create the opposite effect.

Option 0 could seriously threaten generation of benefits for biodiversity conservation and sustainable use, as access to GR in provider countries will be much more difficult if Belgium does not ratify the NP.

- **Impact on stakeholders**:
  - Coll.: biodiversity research could be hindered under option 0
  - Gov. Res.: biodiversity research could be hindered under option 0
  - Ag., health and biotech: No impact
  - Univ.: biodiversity research could be hindered under option 0

- o Land: Both option 1 and 2 will better contribute to awareness raising, which can contribute to biodiversity conservation activities in general, and in *in situ* environments in particular
- o Other: Generation of benefits for biodiversity conservation and sustainable use in provider countries hindered under option 0

Table 22 - Environmental impacts of the options for designating checkpoint(s)

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
M1	Option 0	Negative	Medium	Medium	-
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+

Procedural impact

G1 – Flexibility to accommodating for sectorial differences

The 0 option would lead to non-implementation of the Nagoya Protocol. The impact of this option on criterion G1 is unclear as it would depend on what alternative measures would be taken to comply with the obligations under the CBD and the Convention ILO 107 and how Belgium would ensure legal consistency between these measures (taken as a non-party) and the measures taken by other countries that would be Party to the Protocol.

Even though option 1 and 2 potentially apply equally to all sectors, adopting option 2 instead of option 1 could impose a relative higher duty on users that are more heavily involved in commercial activities that involve patenting activity. Hence, option 2 is less flexible to accommodate sectorial differences. However, as the upgrading of the patent disclosure procedure is not expected to impose any significant costs other than the amendment to the patent law (*cf.* chapter 9.5), the actual magnitude of this impact can be considered very low.

G2 – Temporal flexibility to allow for future policy and adjustments

The 0 option would lead to non-implementation of the Nagoya Protocol. As discussed under G2 above (section G2 under MAT), this might lead to some additional flexibility in the short term, but would probably lead to higher adaptation costs at a later point in time.

The implementation of the monitoring obligations under option 2 would require an amendment of the federal law transposing the Directive 98/44/EC on the legal protection of biotechnological inventions to include such a new provision, while the option 1 does not require any additional action (*cf.* chapter 9.5). Therefore, option 2 will be less flexible for future adjustments.

G3– Improving knowledge for future policy development and evaluation

The 0 option would lead to non-ratification of the Nagoya Protocol and would not allow benefiting from the measures; in particular the information generated from the PIC procedures that would generate knowledge on the flow and the utilization of GR.

If efficient, the broad-scale collection/reception of information related to PIC under option 1 could strongly contribute to the knowledge on the utilization of GR in Belgium, as most GR accessed after the entry into force of the NP would theoretically be covered. However, this has to be nuanced, as the implementation of this measure would probably be phased and therefore the contribution to the knowledge base will be incomplete in the first implementation phases, especially if the checkpoints tasks are limited to collect the information only, without verification. Knowledge improvement under option 2 will be weak, as it only covers a relatively small sub-set of GR accessed for R&D and would not bring more knowledge on the transaction of GR compared to the existing disclosure of origin requirement in the patent legislation. However, upgrading of the patent disclosure to a checkpoint recognized under the NP could lead to improved knowledge gathering. Indeed, in its current form the disclosure obligation is reported to be ineffective. At the same time, the patent authority is not competent to verify the correctness of the information provided by the user. Moreover, some stakeholders complain about the difficult implementation of the current disclosure obligation.

G4 – Correspondence with existing practices

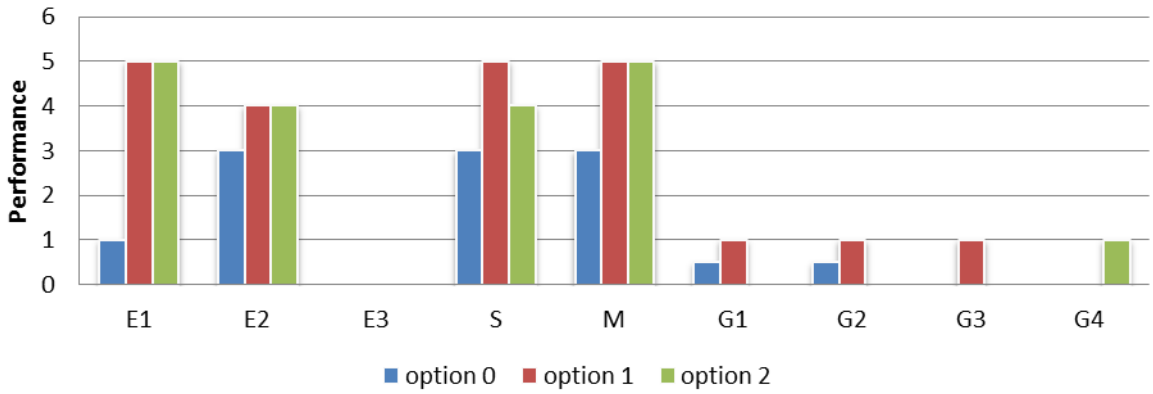
The 0 option would lead to non-ratification of the Nagoya Protocol, which would go against the existing policy and stakeholder efforts to comply with the internationally adopted environmental commitments under the CBD and its Protocol.

There are no existing practices on monitoring the use of GR, hence both option 1 and option 2 represent a change compared to existing practices. However, the requirement for the disclosure of origin is already included in the patent law. While it will still need amending the patent law, option 2 thus corresponds more closely than option 1 to existing practices, due to its link with the patent authority, which is already a necessary step for users willing to patent their products.

10.6.2 Visual dominance analysis

Option 1 is the dominant alternative: compared to options 0 and 2, it scores at least as well on all criteria and is strictly better on the social criterion (note: E3 is undefined). However, this dominance has little relative value. In light of the preceding analysis of the performance and the impact on the stakeholders, what this chart shows is that little difference can be observed between the impact of using the ABS Clearing-House as a checkpoint and using the patent authority as a checkpoint. Furthermore, as mentioned earlier, these two options are not mutually exclusive. In a phased implementation approach, it can be envisioned to implement both options. In this context, the procedural criteria G1, G2 and G3 give an advantage to option 1 compared to option 2 for earlier implementation

Figure 10 - Performance chart for the options designating checkpoints



10.7 Sharing information through the Clearing-House

Summary of the selected options on the ABS clearing-house

12. **Specific "0" option**: not creating a Belgian entry-point to/component of the clearing-house
13. **Option 1**: Royal Belgian Institute of Natural Sciences as ABS Clearing-House (RBINS)
14. **Option 2**: Belgian Federal Science Policy Office (BELSPO) as ABS Clearing-House
15. **Option 3**: Scientific Institute for Public Health (ISP/WIV) as ABS Clearing-House

For a detailed description of the options please refer to chapter 8.2 and chapter 9.

10.7.1 Performance of the options

Economic impact

E1 – Legal certainty and effectiveness for users and providers of GR, at low cost

The 0 option would lead to non-ratification of the Nagoya Protocol and have a major negative impact on legal certainty and effectiveness, as Belgium would not benefit from the transparency and legal clarity advantages of the Protocol.

Options 1, 2 and 3 would equally contribute to the objectives of legal certainty and effectiveness, albeit at a different cost, depending on the final requirements of any ABS CH, as indicated above. Indeed, RBINS is expected to be most cost-effective for more general information tasks (as it is in line with it existent practices and expertise), while BELSPO and WIV-ISP are expected to be most cost-effective for the coordination of more technical information (as it is in line with it existent practices and expertise).

- **Impact on stakeholders**:
  - Coll.: indirect benefit from increased legal certainty and effectiveness
  - Gov. Res.: indirect benefit from increased legal certainty and effectiveness
  - Ag., health and biotech: indirect benefit from increased legal certainty and effectiveness
  - Univ.: indirect benefit from increased legal certainty and effectiveness
  - Land: indirect benefit from increased legal certainty and effectiveness
  - Other: No impact

E2 – Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs

Option 0 would lead to non-ratification of the Nagoya Protocol, which would likely result in higher distrust with the provider countries and have a negative impact on the acquisition of GR from foreign countries and thereby on the overall capacity of users to innovate. Options 1, 2 and 3 on the contrary, as they contribute to the implementation of the Protocol, are expected to increase trust and have a positive overall economic impact.

In general the information tasks of the Belgian input point/component of the ABS CH are expected to generate information on exchanges of GR and on-going innovation activities with GR that are useful for R&D in Belgium. The cost-efficient contribution to research will however be higher if the chosen option also generates more information integration. From that perspective options 1 and 2 are preferable over option 3, as they favor integration of the information handled by the CH with more existing biodiversity initiatives (option 1), or within existing powerful database infrastructures (option 2).

- **Impact on stakeholders**:
    - Coll.: indirect benefit from increased legal certainty and effectiveness
    - Gov. Res.: indirect benefit from increased legal certainty and effectiveness
    - Ag., health and biotech: indirect benefit from increased legal certainty and effectiveness
    - Univ.: indirect benefit from increased legal certainty and effectiveness
    - Land: indirect benefit from increased legal certainty and effectiveness
    - Other: No impact

E3 – Minimizing implementation costs

The impact of option 0 under this criterion is positive, as it would lead to no additional costs. However, this option would lead to non-ratification of the Nagoya Protocol and therefore would still lead to information obligations related to the alternative measures taken by Belgium to comply with CBD and the ILO 107 Convention in the absence of the ratification of the Nagoya Protocol.

All three options would potentially offer cost-effective solutions to the CH as they all host some expertise that could be relevant for the CH's task. The main criterion for comparing the cost-effective implementation amongst the options is the possible synergies with the existing infrastructures and/or existing tasks under the CBD. For the general information tasks, this is likely to give an advantage of options 1 and 3 over option 2. Indeed, in terms of software, both RBINS and ISP/WIV already have an online portal for their respective tasks with the Clearing-House. Hence, creating an additional ABS CH portal might not be such a big additional cost. The system at RBINS has the advantage to be designed for easy replication as it is used to set up national Clearing-House nodes in partner countries, leading to an additional advantage. For the coordination of the technical information, both BELSPO and ISP/WIV have existing infrastructure for the management of technical data that could support the information on the working of the PIC/checkpoints/ABS CH. Given this analysis, and pending the final outcome of the international negotiations on the ABS CH, it would seem logical to propose a collaboration of all three, as this would create the highest level of synergy with existing infrastructures.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: No impact
  - Other: No impact

Table 23 - Economic impacts of the options for the ABS CH

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
E1	Option 0	Negative	High	Strong	- - -
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+
	Option 3	/	Medium	Weak	0
E2	Option 0	Negative	High	Strong	- - -
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+
	Option 3	/	Medium	Weak	0
E3	Option 0	Positive	High	Medium	++
	Option 1	Positive	Medium	Medium	+
	Option 2	Positive	Medium	Medium	+
	Option 3	Positive	Medium	Medium	+

Social impact

S – Achievement of social objectives

The impact of option 0 is likely to be negative on socially relevant objectives. On the contrary, the impact of options 1, 2 is positive while option 3 is neutral.

A particular social impact deserves to be highlighted. RBINS is running development projects on establishing CBD CHMs in partner countries. Entrusting RBINS with additional information tasks pertaining to NP issues could promote interesting synergies and additional capacity building in developing countries that are Party to the Protocol for handling NP and CBD requirements in a coherent and efficient way.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: No impact
  - Other: No impact

Table 24 - Social impacts of the options for the ABS CH

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
S	Option 0	Negative	High	Strong	- - -
	Option 1	Positive	High	Medium	++
	Option 2	Positive	Medium	Medium	+
	Option 3	/	Medium	Weak	0

Environmental impact

M – Promotion of conservation and sustainable use of biodiversity, including biodiversity research

The impact of the 0 option is likely to have a negative impact on conservation and sustainable use of biodiversity. On the contrary, the impact of options 1, 2 and 3 is respectively positive and neutral.

RBINS is running development projects on conservation and sustainable use of biodiversity, including capacity building, biodiversity research and technology transfers, in partner countries. RBINS also organizes educative and communication actions towards stakeholders and broader awareness-raising campaigns on conservation and sustainable use of biodiversity. Reinforcing the role of RBINS in ABS will create synergies between ABS and the conservation/sustainable use initiatives, both nationally and internationally. Option 2 would be ideal for biodiversity research that contributes to sustainable development as BELSPO already hosts the Biodiversity Platform, which has as main task to foster such research. BESLPO also hosts several other consultative bodies linking scientific and policy analysis and is involved at international level with digitalization of collection databases. ISP-WIV has little connection with conservation or sustainable use of biodiversity and would therefore be the least preferable option for this criterion.

- **Impact on stakeholders**:
  - Coll.: No impact
  - Gov. Res.: No impact
  - Ag., health and biotech: No impact
  - Univ.: No impact
  - Land: No impact
  - Other: No impact

Table 25 - Environmental impacts of the options for the ABS CH

Selection criteria	Option	Pos/Neg	Likelihood of occurrence	Effect magnitude	Score
M	Option 0	Negative	High	Strong	- - -
	Option 1	Positive	High	Medium	++
	Option 2	Positive	High	Medium	++
	Option 3	/	Medium	Weak	0

Procedural impact

G1 – Flexibility to accommodating sectorial differences

The general information exchange tasks and the organization of the technical information do not make any differences amongst the sectors. Therefore, the options can be considered neutral in regards to this criterion.

G2 – Temporal flexibility to allow for future policy and adjustments

The 0 option would lead to non-implementation of the Nagoya Protocol. As discussed under G2 above (section G2 under MAT), this might lead to some additional flexibility in the short term, but would probably lead to higher adaptation costs at a later point in time.

The temporal flexibility of the other 3 options will highly depend on the initial set-up costs of the various obligations. If these are high, then it might lead to less flexibility to change the options later on. In addition, if high level of technical expertise was required this might lead to less temporal flexibility in the change of the options, as it would necessitate to acquire again the same expertise by other actors. Both these arguments lead to favor options that build upon existing practices and expertise, over options that less do so. This applies equally to all three options.

G3 – Improving knowledge for future policy developments and evaluation

The option 0 would lead to non-implementation of the Nagoya Protocol and would not allow the necessary generation of PIC/checkpoints etc. that is useful for informing future policy developments. In contrast, the other options would allow improving and systematizing this knowledge base. As in the case of criterion G2, solutions that build upon existing practices and expertise would probably give a better guarantee of knowledge quality and integration, compared to solutions that less do so.

G4 – Correspondence with existing practices

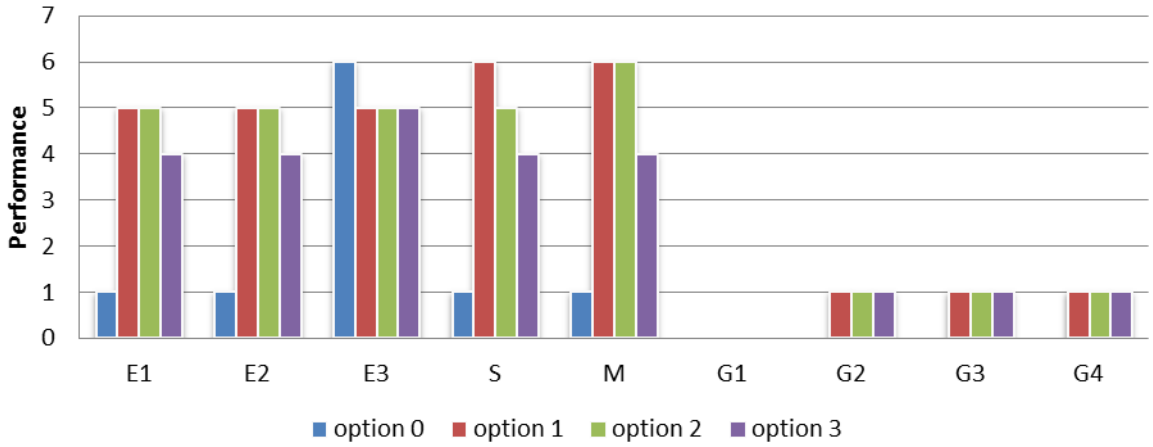
The impact of option 0 over this criterion is unclear. Indeed, it would depend on the other measures taken by Belgium to comply with CBD and Convention ILO 107.

For options 1, 2 and 3, all three options build upon existing practices for information coordination on ABS issues in Belgium and/or biodiversity policy matters. The RBINS already hosts the Belgian component of the CBD Clearing-House Mechanism (CHM) and the NFP to the CBD. RBINS is, together with BELSPO, part of the Belgian Biodiversity Platform (BBP), while the ISP/WIV hosts the Belgian Biosafety Clearing-House (BCH).

10.7.2 Visual dominance analysis

No ideal point can be identified in the performance chart.

Figure 11 – Performance chart of the alternatives for the ABS CH

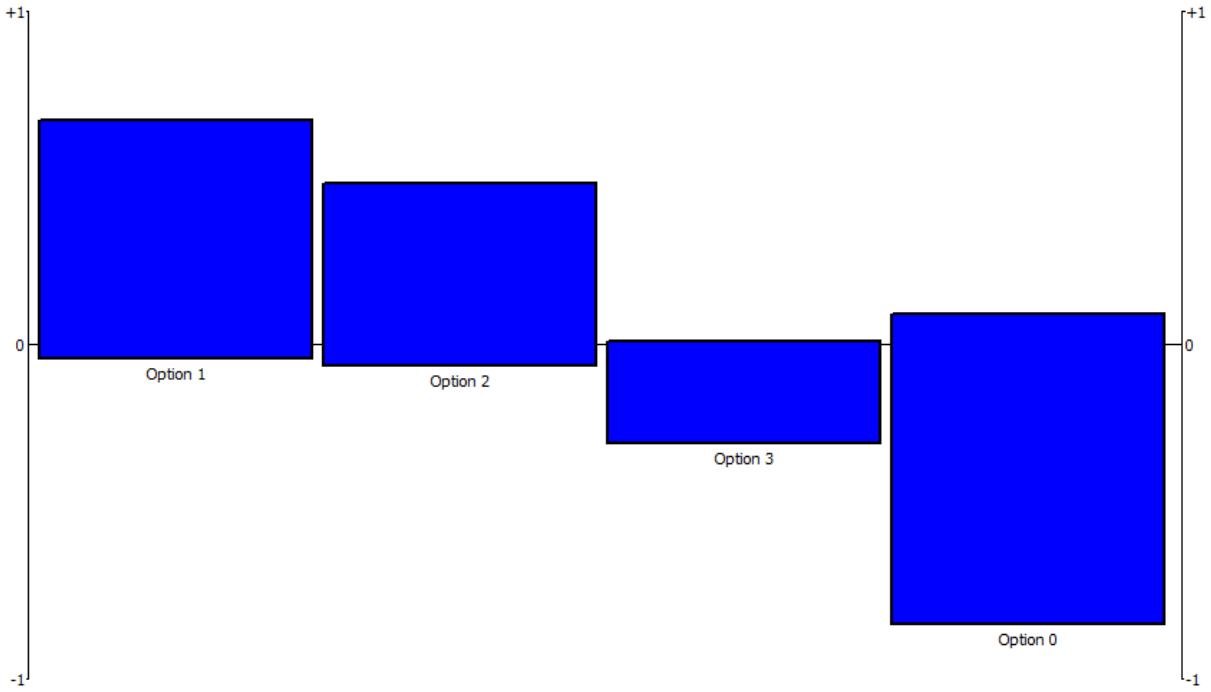


10.7.3 Ranking the alternative

From an environmental perspective, options 1 and 2 are the preferred alternatives (**Figure 12**). They both have similar performances on most of the criteria, but option 1 has a better social impact. This outcome is confirmed in the equalized weighting scenario. But, in line with what can be observed from the visual dominance analysis, the difference between the two options is to be nuanced, with the preference for the two options being almost equal. As RBINS and BELSPO are related institutions, a combination of these two alternatives could produce an ideal outcome. Again, as for the checkpoints, it is important to note that both options 1 and 2 rank substantially better than the "0" option and option 3.

An important note of caution is in order here. Although this rank might usefully inform decision making on the choice between the options in Belgium, the final evaluation of the most appropriate mechanism will mainly depend on the decisions still to be taken globally on the ABS CH.

Figure 12 - Net flows of the alternatives for the ABS CH (basic weighting scenario)



11 RECOMMENDATIONS ON INSTRUMENTS AND MEASURES RESULTING FROM THE IMPACT ASSESSMENT

As explained in chapter 5 and 8, the impact assessment in this study considers policy options for implementing 6 core measures that are minimally needed to implement the Nagoya Protocol in Belgium:

- Operationalizing Prior Informed Consent;
- Specification of the Mutually Agreed Terms;
- Establishment of the Competent National Authorities;
- Setting up compliance measures;
- Designation of one or more checkpoints;
- Sharing of information through the Clearing-House.

The impacts of the selected options for each of these measures were assessed in chapter 10 on a double comparative basis. First, the impacts of the options were compared to the impacts of the "no policy change" base line (0 options). Second, for each measure, the impacts of the options were compared amongst each other.

Two general recommendations result from the analysis in chapter 10, along with a set of more specific recommendations for each of the measures.

First, the analysis shows that the" no policy change baseline" (the “0” option) for each measure clearly has the worst performance. Amongst other reasons, this is due to the lack of legal clarity that the “no policy change” would entail for users in Belgium and the absence of the environmental benefits that would follow from not implementing the Protocol. This result leads to a **first general recommendation**, which is to implement both PIC and benefit-sharing as a general legal principle in Belgium.

Second, the analysis confirmed the validity of a phased approach to the implementation of the Protocol, which is the **second general recommendation**. As seen throughout the impact assessment, a phased approach will allow to benefit from the implementation of the basic principles in a timely manner and to deal with more fine-grained choices in a later stage. These more fine-grained choices can then be based on the experience the administrations and/or users will gather on the utilization of Belgian and foreign genetic resources, through the operation of the Competent National Authorities, the checkpoints and the Clearing-House amongst others. Moreover, the phased approach will be necessary in order to be able to ratify the Nagoya Protocol before June 2014 in order to participate as Party to the next COP/MOP in October 2014.

The phased approach could be organized through a 3 step process. Such a process could consist of,

5. In the first step, a political agreement in the form of a declaration of intent from the competent governments on the general legal principles, along with some specification of the actions to be undertaken by the federal and the federated entities to establish these principles and put them into practice.

6. In a second step, the specified actions would be subsequently implemented, for example through a cooperation agreement and/or by adding provisions in the relevant legislations such as the environmental codes of the federated entities and the Federal Government, along with other possible requirements.
7. In a third step, additional actions can be undertaken once there is more clarity from the negotiations on the EU and the international level.

The impact assessment has led to a **set of specific recommendations on each of the 6 measures** that have been analyzed. Not all the options have a clear preferred ranking in the basic weighting scenario, in part because of the ongoing discussions under the Nagoya Protocol, in particular regarding the modalities for the ABS Clearing-House. This result did not change by adjusting the weighting scenario through the sensitivity analysis. For these measures the study recommends to combine features of the best options that came out of the assessment.

For 3 of the 6 measures a clear first best ranking came out of the impact assessment:

- For the **establishment of the Competent National Authorities**, a centralized input system clearly came out as the **recommended option**. This option scores best on all the criteria and is strictly better on legal certainty and effectiveness for users and providers of GR, at low cost.
- For the setting up of compliance measures, the option to **refer back to provider country legislation regarding PIC and MAT, with Belgian law as fallback** is the **recommended option** that comes out of this analysis. This can be explained by the closer conformity of this option with existing practices (under the Belgian code of private international law).
- For the **designation of one or more checkpoints**, the option of using the PIC available in the Access and Benefit-sharing Clearing-House,as a checkpoint stands as the **recommended option**. It allows timely ratification, while additional checkpoint systems could evolve from there, in particular by adding other checkpoints to further collect or receive, as appropriate, relevant information related to PIC, to the source of the genetic resource, to the establishment of MAT, and/or to the utilization of genetic resources, (such as through an upgraded patent disclosure or monitoring of PIC upon public grants for research).

For the other 3 measures, more than one remaining best option came out of the assessment or the remaining best options were very close:

- For the **operationalization of PIC**, the bottleneck option and the refined fishing net option came out very close. These options require establishing as a general legal principle that access to Belgian GR requires PIC. This could be included in a political agreement from the competent governments, expressing the intent to establish such principle while specifying that this would be implemented afterwards for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the basic environmental codes. The two options also have a common component, namely the refinement of the PA/PS relevant legislation. This refinement considers that the access to specimens under PA/PS relevant legislation,[223], would also be considered as PIC in the context of the Nagoya Protocol

[223] *cf.* The detailed analysis in section 3.1 on "Access and use of genetic resources under national jurisdiction in Belgium".

by the Belgian federated entities. This general principle would be included in the analogous provisions of the relevant legislation of the three Regions and at the federal level. The actual refinement could then be implemented in the third step (additional actions for further implementation) for example through executing acts, specifying which access provisions exactly are considered as PIC[224]. Therefore, the **recommendation** that comes out of the analysis of the operationalization of PIC is to proceed with such a refinement of the PA/PS relevant legislation in the third step.

As the two first best options rank very close (and in a contrasted way on different criteria), the best way forward when considering GR beyond PA/PS, might be to combine these options in a phased manner. Therefore, the **recommendation** resulting from the analysis is to implement first the 'fishing net' approach with a general registration/notification requirement to the Competent National Authorities for GR outside PA/PS. In a later stage, the 'bottle neck' approach, through which access requests are processed through qualified Belgian *ex-situ* collections in conformity with the Nagoya Protocol, could be organized through a set of administrative arrangements between the Competent National Authorities and the collections. In addition, in this later stage the adjustment of other GR relevant legislation can be implemented as envisioned under the refined fishing net model[225].

- For the specification of the **Mutually Agreed Terms**, the two options that impose specific BS requirements by the Belgian State both ranked better than the option where no specific BS requirements are imposed. Nevertheless, as the specification of Mutually Agreed Terms is not a prerequisite for ratification, this can be done in the third step of the implementation. The choice between these two options can therefore be part of a later phase. The **recommendation** is therefore not to take action on this point before ratification (and therefore by default implement the "no specific benefit-sharing requirements" option) and to consider, in a later stage, a combination of the options that consider introducing specific benefit-sharing requirements to further implement the Protocol. As indicated in chapter 9.2, this further specification would entail specifying rules for the specific BS requirements in relevant legislation for example in the provisions of the environmental code of the three Regions and at the federal level, including rules for the use of standard agreements for some types of uses if needed. It is considered under this option that the implementation of these rules will be done through executive orders of the federated entities.

- Finally, for the **sharing of information through the ABS Clearing-House**, the assessment makes a distinction between the basic information sharing tasks on Access and Benefit-sharing by the Clearing-House and the more technical tasks related to the organization of the

[224] Non-exhaustive list of examples of legislation covering PA/PS which do not expressly cover access of GM or GR for utilization as defined under the NP: Ordonnance du 1 mars 2012 relative à la conservation de la nature; Besluit van de Vlaamse Regering van 15 mei 2009 met betrekking tot soortenbescherming en soortenbeheer; Besluit van de Vlaamse Regering van 5 december 2008 betreffende de toegankelijkheid van de bossen en de natuurreservaten; Décret du 15 juillet 2008 relatif au Code forestier; Decreet van 21 oktober 1997 betreffende het natuurbehoud en het natuurlijk milieu; Arrêté du Gouvernement wallon du 26 janvier 1995 organisant la protection des cavités souterraines d'intérêt scientifique; Decreet van 13 juni 1990 Bosdecreet; Arrêté de l'Exécutif régional wallon du 8 juin 1989 relatif à la protection des zones humides d'intérêt biologique, modifié par l'arrêté du 10 juillet 1997; Loi du 12 juillet 1973 sur la conservation de la nature

[225] For examples of other relevant legislation please refer to footnote 187

technical information to be provided to the central ABS Clearing-House, amongst others. The first task is already ongoing at the Royal Belgian Institute of Natural Sciences (RBINS) within the framework of the CBD CHM. The **recommendation** from the analysis is therefore to further strengthen the RBINS to fulfill the information sharing tasks on Access and Benefit-sharing under the Nagoya Protocol. In a second stage, based on the modalities to be determined at COP/MOP1, administrative arrangements between this Clearing-House and other relevant institutions might be necessary to extend the tasks.

Before summarizing the final outlook of the phased approach based on these recommendations, it is worthwhile to clarify that the three step approach to the implementation presented here is based on a concern for maximum legal clarity for all parties concerned and compliance as a Party with the core obligations of the NP, while at the same time allowing a timely ratification. The proposed approach is therefore to start with a political agreement which would include, in general terms, the principles on which the federated entities and the Federal State will take subsequent actions.

The reason for recommending such a political agreement with a specification of the actions that will have to be taken to implement the Protocol in Belgium is double. On the one hand, such an agreement provides for a clear political commitment to the core obligations of the NP as it specifies the intentions of the competent authorities, within the limits of the decisions already taken at the international and European level at the time of the agreement. On the other hand, it does not prejudge the political decisions to be taken by the different authorities and thus allows for sufficient flexibility to further adjust the implementation process in a later stage. The latter is especially important given the many questions that are still undecided at the present stage, both at the EU and international level, as mentioned and taken into account in the assessment report.

Based on the above considerations, the recommended phased approach for implementation of the Protocol that results from this study can be summarized as follows.

1. A political agreement by the competent authorities with a clear statement on the general legal principles for a minimal implementation of the Nagoya Protocol in Belgium that came out of the study :
    a. Establishment of benefit-sharing as a general legal principle in Belgium, which will be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the environmental codes of the three Regions and at the federal level[226] (IMP 1.1.1 (1))
    b. Establishing as a general legal principle that access to Belgian GR requires PIC, which will be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the environmental codes of the three Regions and at the federal level (IMP 1.1.2 (1))

[226] The provisions under (1) a, b and c would require a Federal Law and Decrees of the Federated Entities, to amend the basic environmental codes of the Regions and the Federal State : Natuurdecreet, 21st October 1997 (Vlaams Gewest) ; Loi sur la Conservation de la Nature, 12th July 1973 (Région Wallonne) ; Ordonnance sur la conservation de la nature, 1st of March 2012 (Région Bruxelloise) ; Law on the protection of the Marine Environment, 20th January 1999. For a detailed description of these laws, cf. above section 3.1 of the study on the "Access and use of genetic resources under national jurisdiction in Belgium".

c. Establishment of the general principle concerning the designation of four Competent National Authorities, which will be implemented for example through a cooperation agreement and/or relevant legislations. This would be implemented by the respective authorities dealing with legislations and measures related to protected areas and protected species at the Regional level and in the respective authority dealing with environmental issues at the federal level[227] (IMP 3.1.1. (1)).
d. Commitment that legislative measures will be taken to provide that GR utilized within Belgian jurisdiction have been accessed by PIC and MAT as required by provider country legislation and to address situations of non-compliance (IMP 4.1 (1); IMP 5.1).
e. The CBD CHM, managed by the RBINS, will be considered as the Belgian contribution to the ABS CH, for dealing with the information exchange on ABS under the Nagoya Protocol and if required, further steps will be taken after the first COP/MOP to develop the correct modalities for the ABS CH. (IMP 6.1 (1))

2. Subsequent implementation of the principles stated in the political agreement, for example through a cooperation agreement and/or the introduction of analogous provisions relevant legislations such as the environmental codes of the three Regions and at the federal level (*cf.* footnote 226). (IMP 1.1.1 (2); IMP 1.1.2 (2); IMP 3.1.1. (2))

3. Subsequent legal and policy measures as soon as more clarity is provided on EU level and on the global level and more practical experience is gained with the implementation of the NP. This will especially apply to the measures on compliance (after conclusion of discussions on compliance at EU level and at COP/MOP1), the subsequent measures on PIC and MAT, and the administrative agreements to further implement the ABS Clearing-House provisions of the Protocol. These subsequent measures might imply, at a later stage, the need for a second cooperation agreement (IMP 1.1.3, possibly with IMP 1.3.1 in addition; IMP 1.1.4/ IMP 1.2.4 combined; IMP 2.2/IMP 2.3 combined; IMP 3.2.2; IMP 4.1 (2); IMP 6.1 (2))

[227] That is, as stipulated above, the "Agentschap voor Natuur en Bos" in the Flemish Region, the "Division de la nature et des forêts" in the Walloon Region, the "Institut Bruxellois pour la gestion de l'environnement" in the Brussels Region and one authority to be established at the Federal level, probably at the Directorate-General Environment of the Federal Public Service "Health, Food Chain Safety and Environment" (for GR that are not under competences of the federated entities, such as Marine GR and ex-situ GR held at federal institutions).

12 CONCLUSIONS

This study addresses the implementation in Belgium of the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity. For an appropriate understanding of the recommendations presented in this study, it is important to recall the various steps and the intermediary conclusions that have led to these recommendations.

The report proceeds through **four core phases**. Chapters 2 to 5 analyze the current state of the art of ABS law and policy in Belgium (phase 1). Chapters 6 to 9 analyze, present and describe the different options for the minimal implementation of core measures stemming from the NP (phase 2). The argument in these chapters served as a basis for the choice of a set of options selected by the Steering Committee and discussed with relevant stakeholders, for further study. Chapters 10 and 11 conducted a multi-criteria impact assessment of the selected options (phase 3) and concluded with a set of recommendations for the implementation of the Nagoya Protocol in Belgium (phase 4).

Conclusion of the first phase of the study

The main conclusion of the first step is that the existing legislation that addresses physical access to genetic material and the instruments regulating benefit-sharing between users and providers of genetic resources need to evolve and be complemented by additional instruments in order to implement the obligations of the Protocol.

In particular, under the current legislation in Belgium, access to GR is not subject to Prior Informed Consent (PIC) by the Belgian State as a Party to the NP (that is based on a written decision by a Competent National Authority (CNA) on access and benefit-sharing). Even if it is not compulsory for compliance with the Nagoya Protocol, the Belgian State can nonetheless decide to subject access to its GR to a PIC-requirement and take the necessary legislative, administrative or policy measures, as appropriate, to provide for access permits by one or more Competent National Authorities. Alongside the requirement for PIC, Belgium needs to require its users to share benefits arising from the utilization of GR and TKaGR, based on mutually agreed terms.

Further, for the implementation of the core obligations on compliance, monitoring through checkpoints and the ABS Clearing-House, additional legal measures need to be put into place for the implementation of the Protocol. While the Belgian code of private international law already contains a set of principles that can be directly used for the implementation of the compliance provisions, these principles are insufficient to comply with the Nagoya Protocol. In particular, the “utilization of GR under the Nagoya Protocol” is not explicitly mentioned within the current scope of the Belgian code of private international law. For the monitoring obligations, the Belgian patent law already requires the disclosure of information on the country origin of biological material in patent applications. However, this measure still needs to be completed by other measures in order to comply with Article 17.1 of the NP, as it is not organized nor designated as a formal checkpoint. Finally, a dedicated ABS Clearing-House for information sharing under the Nagoya Protocol will need to be put into place, whether simply as a node of the international ABS Clearing-House or as a separate Belgian ABS Clearing-House.

It is important to highlight the provisional nature of these findings, as the on-going discussions on the implementation of the Nagoya Protocol in international and European *fora* will further influence the results of this analysis. This is particularly relevant for the issue of compliance, some aspects of which will be addressed in the EU regulation on the Implementation of the Nagoya Protocol, and the issue of information sharing through the ABS Clearing-House, as the international mechanism still needs to be clarified.

Conclusion of the second phase of the study

The main conclusion of the second step is the importance of a phased approach to the implementation, which would first address a set of options for minimal implementation. As such, the analysis lead to distinguish two categories of actions to be undertaken for the implementation:

1. A first set of actions, which form the basis of compliance with the NP and address the core obligations for the implementation of the NP in Belgium, including :
    - The establishment of National Competent Authorities and the National Focal Points (Article 13)
    - Conformity with the national legislation of the provider country and the contractual rules (Articles 15,16,17 and 18)
    - Access to genetic resources and traditional knowledge (Articles 6, 7 and 8).
    - Benefit-sharing (Articles 5 and 9)
    - Monitoring of the use of genetic resources and the designation of one or several checkpoints (Article 17)
    - Compliance with the legislations or the requirements of the provider country (Articles 15 and 16)
    - The compliance with the Mutually Agreed Terms (MAT) (Article 18)

2. A second set of additional measures which are important elements during implementation of the obligations, but that are less urgent (going beyond the core obligations).

The detailed analysis of the first set of actions, has led to the formulation of a set of options for 6 implementation measures that were the basis of the multi-criteria impact assessment in the third step:

1. Operationalizing Prior Informed Consent
2. Specification of the Mutually Agreed Terms
3. Establishment of the Competent National Authorities
4. Setting up compliance measures
5. Designation of one or more checkpoints
6. Sharing of information through the Clearing-House

Conclusion of the third and fourth phase of the study

The main conclusions of the third step have been presented in detail in the chapters 10 and 11 of the report and resulted in two general recommendations, along with a set of more specific recommendations for each of the 6 implementation measures.

First, the analysis shows that the "no policy change" baseline for each measure clearly has the worst performance. This result has led to a **first general recommendation**, which is to implement both Prior Informed Consent (PIC) and benefit-sharing as general legal principles in Belgium.

Second, the analysis confirmed the validity of a phased approach to the implementation of the Protocol, which is the **second general recommendation** and could be organized through a 3 step implementation process:

1. In the first implementation step, through a political agreement by the competent authorities which would include a clear statement on the general legal principles, along with the specification of the actions to be undertaken by the federal and the federated entities to put these principles into practice.
2. In a second implementation step, the specified actions would be subsequently implemented for example through a cooperation agreement and/or analogous provisions in the relevant legislations such as the environmental codes of the federated entities and the Federal Government, along with other possible requirements.
3. In a third implementation step, additional actions can be undertaken once there is more clarity on the EU and the international level.

Finally, a **set of specific recommendations on each of the 6 measures** arise from third step of this study:

1. For the establishment of the Competent National Authorities, a centralized input system clearly came out as the recommended option.
2. For the setting up of compliance measures, the option to refer back to provider country legislation, with Belgian law as fallback option, is the recommended option that comes out of this analysis.
3. For the designation of one or more checkpoints, the option of using the PIC of users available in the international ABS Clearing-House (and therefore also through the Belgian node/or the Belgian ABS CH), in the first step of the implementation, stands as the recommended option.
4. For the operationalization of PIC, the bottleneck option and the refined fishing net option came out very close.
    a. First, both these options require establishing as a general legal principle that access to Belgian GR requires PIC. This could be implemented for example through a cooperation agreement and/or analogous provisions in relevant legislations such as the environmental code of the three Regions and at the federal level
    b. Second, additional measures should be envisioned afterwards, the most important of which are the refinement to existing PA/PS relevant legislation and the general registration/notification requirements to the Competent National Authorities for GR outside PA/PS.

5. For the specification of the Mutually Agreed Terms, the two options that impose specific BS requirements by the Belgian State both ranked better than the option where no specific BS requirements are imposed. Nevertheless, as the specification of Mutually Agreed Terms can be done in the third step of the implementation, the choice between these two options can be part of a later phase.
6. Finally, for the sharing of information through the ABS Clearing-House, the assessment makes a distinction between the basic information sharing tasks on Access and Benefit-sharing by the Clearing-House and the more technical tasks related to the organization of the technical information to be provided to the ABS Clearing-House mechanism, amongst others. The first task is already ongoing at the Royal Belgian Institute of Natural Sciences (RBINS). The recommendation from the analysis is therefore to further mandate the RBINS to fulfill the information sharing tasks on Access and Benefit-sharing under the Nagoya Protocol. In a second stage, administrative arrangements between this Clearing-House and other relevant institutions could be put into place to extend the tasks, as soon as more clarity is provided by the international negotiations.

ANNEX 1 – OVERVIEW OF ARTICLES OF THE NAGOYA PROTOCOL THAT CONTAIN LEGAL OBLIGATIONS FOR A PARTY/PARTIES

This list contains an analysis of the legal obligations emanating from the NP that has been provided with the terms of reference of this study, by the four Belgian environmental administrations that commissioned this study. This list serves as the background for this study.

(GR = Genetic Resources; TK = Traditional Knowledge)

Article 4.2

a. Subject	The Parties
b. obligation	do not develop or implement other relevant international agreements which are not supportive of or do run counter to the objectives of the Convention and this Protocol.
Applies to	GR+TK

Article 4.3

a. Subject	**??** (everyone with an implementing obligation)
b. obligation	implement Protocol in a mutually supportive manner with other international instruments under this Protocol
Applies to	GR+TK

Article 5.1 + 5.3

a. Subject	Each Party
b. obligation	take legislative, administrative or policy measures, as appropriate, for benefit-sharing with providing party, upon MAT
Applies to	GR

Article 5.2

a. Subject	Each Party
b. obligation	Take legislative, administrative or policy measures, as appropriate, with the aim of ensuring benefit-sharing with ILCs holding GR's, based on MAT
Applies to	GR

Article 5.5

a. subject	Each Party
b. obligation	take legislative, administrative or policy measures, as appropriate, for benefit-sharing with ILC's holding TK, upon MAT
Applies to	TK

Article 6.1 + 6.3

a. subject	Each Party
b. obligation	- if requiring PIC for access: take legislative, administrative or policy measures, as

	appropriate, containing minimum requirements for access rules and procedures - OR determine that access is not subject to PIC
Applies to	GR

Article 6.2

a. subject	Each Party
b. obligation	take measures to ensure that PIC of ILCs is obtained for access to these GR
Applies to	GR

Article 7

a. subject	Each Party
b. obligation	take measures, as appropriate, with the aim of ensuring that TK is accessed with PIC and MAT of the ILC holding TK
Applies to	TK

Article 8

a. subject	Each Party
b. obligation	In developing and implementing ABS legislation: - Create conditions to promote and encourage biodiversity research, including simplified measures on access for non-commercial research - Pay due regard to cases of present and imminent emergencies that threaten or damage human, animal or plant health - Consider the importance of GRFA
Applies to	GR+TK

Article 9

a. subject	The Parties
b. obligation	Encourage users and providers to direct benefits towards conservation of biological diversity and sustainable use of its components
Applies to	GR

Article 10

a. subject	Parties (MOP)
b. obligation	Consider the need for and modalities of a global multilateral benefit-sharing mechanism for 1) GR and TK that occur in transboundary situations or 2) for which it is not possible to grant or obtain PIC
Applies to	GR+TK

Article 11

a. subject	Each Party
b. obligation	Endeavour to cooperate in instances: - where the same GR are found in situ within the territory of more than one Party

	- where the same TK is shared by one or more ILCs in several Parties
Applies to	GR+TK (Article 11.1 = GR, Article 11.2 = TK)

Article 12

a. subject	Parties
b. obligation	- In implementing protocol, take into consideration indigenous and local communities customary laws, community protocols and procedures, with respect to TK - Establish mechanisms to inform potential users of TK about their obligations - Endeavour to support the development by ILCs, in relation to TK, of community protocols in relation to ABS, minimum requirements for MAT, model contractual clauses for BS - As far as possible, not restrict the customary use and exchange of GR and TK within and amongst ILCs
Applies to	TK, except Article 12.4= TK+GR

Article 13.1,2 and 4

a. subject	Each Party
b. obligation	- Designate a national focal point (NFP), which shall make certain information available - Designate one or more Competent National Authorities (CAN) - Notify the Secretariat of contact details of NFP and CANs
Applies to	- Article 13.1 = GR +TK - Article 13.2=GR+TK

Article 14.2

a. subject	Each Party
b. obligation	Making certain information available on the ABS Clearing-House
Applies to	GR+TK

Article 15.1

a. subject	Each Party
b. obligation	Adoption of legislative, administrative or policy measures to provide that GR utilized within jurisdiction have been accessed by PIC and MAT as required by provider country legislation
Applies to	GR

Article 15.2

a. subject	Parties (!), (compare with Article 16.2)
b. obligation	Adoption of measures to address situations of non-compliance with Article 15.1
Applies to	GR

Article 15.3

a. subject	Parties
b. obligation	As far as possible cooperate in cases of alleged violation of provider country legislation
Applies to	GR

Article 16.1

a. subject	Each Party
b. obligation	Legislative, administrative or policy measures to provide that TK utilized within jurisdiction has been accessed in accordance with PIC and MAT with legislation of country where ILCs are located
Applies to	TK

Article 16.2

a. subject	Each Party (!)
b. obligation	Adoption of measures to address situations of non-compliance with Article 16.1
Applies to	TK

Article 16.3

a. subject	Parties
b. obligation	As far as possible cooperate in cases of alleged violation of legislation of country where ILCs are located
Applies to	TK

Article 17.1

a. subject	Each Party
b. obligation	Adoption of measures to monitor and enhance transparency about the utilization of GRs, which shall include a) the adoption of one or more checkpoints, b) encouraging the inclusion of provision on the sharing of information on the implementation in MAT, c) encourage the use of cost-effective communication tools and systems
Applies to	GR

Article 17.2-4 (indirect obligation)

a. subject	Each Party
b. obligation	Minimum-information to be made available to the CHM when notifying permits (read in conjuncture with Article 14.2.c) Permits or equivalents issued in accordance with Article 6.3.e) and made available to CH have to be accepted as internationally recognized certificates of compliance and have to be accepted as evidence that GR have been accessed with PIC and that MAT have been established, as required by provider country.
Applies to	GR

Article 18.1

a. subject	Each Party
b. obligation	Encourage providers and users of GR and TK to include provisions in MAT to cover dispute resolution
Applies to	GR+TK

Article 18.2

a. subject	Each Party
b. obligation	Ensure that an opportunity to seek recourse is available for disputes arising from MAT
Applies to	GR+TK

Article 18.3

a. subject	Each Party
b. obligation	Take effective measures regarding: - Access to justice - Utilization of mechanisms regarding mutual recognition and enforcement of foreign judgements
Applies to	GR+TK

Article 19.1

a. subject	Each Party
b. obligation	Encourage the development, update and use of model contractual clauses for MAT
Applies to	GR+TK

Article 20.1

a. subject	Each Party
b. obligation	Encourage the development, update and use of ABS voluntary codes of conduct, guidelines and best practices and/or standards
Applies to	GR+TK

Article 21

a. subject	Each Party
b. obligation	Take measures to raise awareness of the importance of GR and TK, and related access and benefit-sharing issues
Applies to	GR+TK

Article 22.1 + 2

a. subject	The Parties
b. obligation	- Cooperate in the capacity-building, capacity development and strengthening of

	human resources and institutional capacities to effectively implement the Protocol in developing country parties - Facilitate the involvement of ILCs and relevant stakeholders - Take into account their needs
Applies to	GR+TK

Article 23

a. subject	The Parties
b. obligation	- Collaborate and cooperate in technical and scientific research and development programmes - Promote and encourage access to technology and transfer of technology, Where possible in and with provider countries
Applies to	GR+TK

Article 24

a. subject	The Parties
b. obligation	Encourage non-parties to adhere to the Protocol and to contribute information to the CHM
Applies to	GR+TK

Article 25.1+4

a. subject	Parties (25.4 The Parties)
b. obligation	- In considering financial resources for the implementation of the Protocol, take into account Article 20 CBD - Take into account the needs of developing country Parties in their efforts to identify and implement their capacity building and development requirements
Applies to	GR+TK

Article 29

a. subject	Each Party
b. obligation	- Monitor the implementation of its obligations - Report to MOP on measures taken to implement the Protocol
Applies to	GR+TK

ANNEX 2 – LIST OF GENERAL ABS INDICATORS (BOTH FOR QUALITATIVE AND QUANTITATIVE DATA) AND QUESTIONNAIRE RELATED TO QUANTITATIVE DATA

Code	Indicator	Description	Examples of questions for interview	Types of stakeholder
Access provision				
IND 1.1	**Amount of requests received**	Overall amount of GR provided for R&D by an organisation per year on average/for exemplary years	How many access requests for GR do you honor on average per year?	Provider
IND 1.2	**Destributio n of Belgian GR**	Amount of Belgian GR provided for R&D by an organisation per year on average/for exemplary years (*cf.* target group list)	How many of these access requests are related to Belgian genetic resources (as compared to foreign resources)?	Provider
IND 1.3	**Commercial requests received**	Overall amount of GR provided for commercial R&D by an organisation per year on average/for exemplary years	How many commercial access requests for GR do you honor on average per year?	Provider
IND 1.4	**Transaction registration**	When providing Belgian GR, is the transaction registered in a database ? If so for what % of the provided GR ? Is information on users or type of use encoded in the database ?	When providing Belgian GR, is the transaction registered in a database ? If so, what information is registered?	Provider
Access requests				
IND 2.1	**Amount of requests made**	Overall amount of GR acquired/accessed by an organisation per year on average/for exemplary years (*cf.* target group list)	How many access requests to genetic resources do you make on average per year?	User
IND 2.2	**Popularity of Belgian GR**	Amount of Belgian GR acquired/accessed an organisation per year on average/for exemplary years (*cf.* target group list)	How many of these requests are related specifically to Belgian genetic resources?	User
IND 2.3	***Ex-situ* vs *In-situ***	*Ex-situ*/*in-situ* ratio in the accessed GR	How many of the accessed GR are coming from *in-situ* environments/How many from *ex-situ* environments?	User
Access related costs				
IND 3.1	**Cost for requesting access**	Average cost per transaction for acquiring/accessing a GR by an organisation	How much is the average cost you endure when requesting access to GR?	User
IND 3.2	**Cost for providing access**	Average cost per transaction for providing a GR by an organisation	How much is the average cost you endure when providing access to GR?	Provider
Patenting and commercialisation rates				
IND 6.1	**Patenting rate**	percentage of accessed genetic resources that make it to the patent stage	What's the percentage of accessed genetic resources that make it to the patent stage?	User
IND 6.2	**Commercial isation rate**	percentage of accessed genetic resources that make it to the commercialisation phase	What's the percentage of accessed genetic resources that make it to the	User

			commercialisation phase?	
Discovery & collection rate of BE GR				
IND 7.1	**Microbes discovery rate**	Amount of Belgian GR that are micro-organisms still unknown for biodiversity taxonomy	How much of the Belgian genetic resources is known and/or already in the collections (for microbial/plant/animal)? Do you store information on Belgian GR in digital databases? If so, which information is actually available?	Provider
IND 7.2	**Plants discovery rate**	Amount of Belgian GR that are plants still unknown for biodiversity taxonomy		
IND 7.3	**Animals discovery rate**	Amount of Belgian GR that are animals still unknown for biodiversity taxonomy		
IND 7.4	**GR Databases**	Gaps/available information on Belgian GR in the available databases in Belgium (for microbial/plant/animal)		Provider
IND 7.5	**Strains Databases**	What are the gaps/the available amount of specimen/strains of Belgian GR in Belgium collections (for microbial/plant/animal)		
Collection & storage cost				
IND 8.1	**Microbes collections cost**	Costs of taxonomic research in microbiology (average costs for adding taxonomic entity)	What is the cost of adding a toxonomic entity in the collection (for microbial/plant/animal)?	Provider
IND 8.2	**Plants collections cost**	Costs of taxonomic research in plants (average costs for adding taxonomic entity)		
IND 8.3	**Animals collections cost**	Costs of taxonomic research in animals (average costs for adding taxonomic entity)		
IND 8.4	**Strain storage cost**	Cost (administrative and financial) of keeping a physical copy of a specimen/strain of GR in your collection (for microbial/plant/animal)	How much does it cost to keep a physical copy of specimen/strain?	Provider
IND 8.5	**Data storage cost**	What is the cost (administrative and financial) of keeping an information record of a specimen/strain of GR in the database of your organisation (for microbial/plant/animal)	How much does it cost to keep an information record of a specimen/strain?	Provider User
Benefit-sharing				
IND 9.1	**Cost of BS procedure**	Administrative, financial cost of the BS procedure	What is the administrative, financial cost of the BS procedure ?	Provider
IND 9.2	**Cost of BS obligations**	Part of overal profit going to benefit-sharing obligations	What percentage of the overal profit goes to BS obligations, monteray and non-montary?	Users
Permit Delivery				
IND 10.1	**Cost of permit delivery**	Financial (cost of delivery, minus fee if charged), legislative (to create the permit system, to deal with litigation and dispute resolution) and administrative cost (estimated man-hour per demand) of delivering a permit.	What is the average cost of delivering an access permit?	GOV/EXC
IND 10.2	**Length of permit delivery procedure**	Average waiting time for delivering a permit	How long does it take to deliver a permit?	GOV/EXC

Notification requirement				
IND 11	**Notification procedure**	Administrative, financial and legislative cost of existing notification/registration requirement in an existing organisation (in another field, but that can reasonably be taken as a benchmark for the study). What is the fix costs of setting up the operations of such an organisation (website, database, others) and the variable costs (average costs per transaction).	/	EXC/UNI/PFP/GOV/CSO
Protection rate of PA/PS				
IND 12.1	**Protection rate of PA/PS**	Proportion of Belgian GR that would be specifically in PA/PS or specifically outside of PA/PS. Probability of accessing GR for utilization in R&D compared to accessing it from outside PA/PS	How much GR can only be found inside PA?	EXC/UNI
IND 12.2	**Legal protection rate for GR outside of PA/PS**	Amount of GR covered by existing access legislations to genetic material, but not by Protected Areas/Protected Species legislation (such as legislation on landraces or other). For these GR probability of accessing it for utilization in R&D (high/medium/low).	Is there any GR subjected by access legislation by not protected under PA/PS?	EXC/UNI
Other				
IND 13.1	**Cost of CHM**	Administrative, financial and legislative cost of the CBD Clearing-house mechanism hosted by RBINS	How much does it cost to host the CBD CHM?	RBINS
IND 13.2	**Cost of BCH**	Administrative, financial and legislative cost of the Biosafety Clearing-House hosted by ISP	How much does it cost to host the BCH?	ISP

ANNEX 3 – CORRESPONDENCE TABLE BETWEEN THE CRITERIA AND THE QUANTITATIVE INDICATORS

Criteria	Selected indicators (relevance of **indicator for identifying progress or gaps in the main criteria**; some indicators also have relevance for other criteria in addition to the main (for clarity not indicated in this table))
E1 Legal certainty and effectiveness for users and providers of GR, at low cost	IND10.1; IND10.2
E2 Maximizing economic innovation and product development (in particular through its contribution to R&D) at reasonable financial and administrative costs	IND 1.1; IND 1.3 ; IND 2.1; IND 6.1; IND 6.2
E3 Minimizing implementation costs	IND 9.1; IND11; IND 13.1; IND13.2
S Achievement of social objectives	
M Promotion of conservation and sustainable use of biodiversity, including biodiversity research	IND 1.2; IND 2.2.; IND 2.3; IND 7.1; IND 7.2; IND 7.3 ; IND 7.5; IND 9.2; IND12.1
G1 Flexibility to accommodating sectorial differences	
G2 Temporal flexibility to allow for future policy and adjustments	
G3 Improving knowledge on the exchange of GR and existing ABS agreements for future policy development and evaluation	IND1.4; IND 7.4;
G4 Correspondence with existing practices	IND 3.1; IND 3.2; IND 8.1; IND 8.2; IND 8.3; IND 8.4; IND 8.5; IND 12.2

ANNEX 4 – QUESTIONNAIRE RELATED TO QUALITATIVE DATA

	Question	Type of stakeholder
Access		
Existing access requirements	What are the current obligations for users to access genetic resources in your collection / area ?	Provider
Evaluation of options	What would be the advantages or disadvantages of a bottleneck-type of access system, compared to a notification-based access system?	User + Provider
Cost projection of options	What would be the projected type and magnitude of cost of requesting access in the case of : • A centralized access provisions through the *ex-situ* collections • A notification obligation	User
Benefit-sharing		
Evaluation of options	Is the standardization of MAT perceived as negative or positive by the stakeholder? Why?	User + Provider
Characteristic of BS procedure	What kind of benefit-sharing schemes are used by the stakeholder, if any? For which types of benefits? What is the level of standardization of these procedures?	User + Provider
Competent National Authority		
Structure	How can/should the future CNA be organized and structured? • Composition • Legal/Administrative/Institutional status	User + Provider
Compliance		
Evaluation of options	What are the risks and opportunities of a self-standing obligation vs relying on provider-country legislation?	User
Checkpoints		
Evaluation of options	What do you think of the idea to use the PIC/patent authority as a checkpoint?	User + Provider
Additional checkpoints	At a later stage of the implementation, which additional checkpoints do you think are relevant/effective?	User + Provider
NFP/Clearing-House		
Relation with NFP & CH	How is the current relation with the NFP and the Clearing-House, if any, and how do you imagine this to evolve?	User + Provider

ANNEX 5 – LIST OF INTERVIEWEES

Ann Strobbe, Bayer Cropscience, 27/07/2012, Gent

Catherine Hallet, Département de la Nature et des Forêts, DGARNE, 20/08/2012, Namur

Didier Breyer, Scientific Institute of Public Health, 08/08/2012, Brussels

Dominic Muyldermans, CropLife International, 08/08/2012, Brussels

Esmeralda Prat, Bayer Cropscience, 27/07/2012, Gent

Frank Michiels, Bayer Cropscience, 27/07/2012, Gent

Han De Koeijer, Royal Belgian Institute of Natural Sciences, 02/08/2012, Brussels

Isabelle Donnay, Institut des sciences de la vie, Université catholique de Louvain, 14/08/2012, Louvain-la-Neuve

Jan Rammeloo, National Botanic Garden of Belgium, 30/07/2012, Meise

Jan Van Rompaey, Bayer BioScience, 08/08/2012, Brussels

Jean-Louis Rolot, Agricultural Research Centre of Gembloux, 17/08/2012, Libramont

Philippe Barret, Earth and Life Institute, Université catholique de Louvain, 30/07/2012, Louvain-la-Neuve

Philippe Desmeth, Belgian Co-ordinated Collections of Micro-organisms, 25/07/2012, Brussels

Piet Stoffelen, National Botanic Garden of Belgium, 30/07/2012, Meise

Stephane Declerck, Mycothèque, Université catholique de Louvain, 27/07/2012, Louvain-la-Neuve

Steven Dessein, National Botanic Garden of Belgium, 30/07/2012, Meise

Thierri Walot, Earth and Life Institute, Université catholique de Louvain, 23/07/2012, Louvain-la-Neuve

BIBLIOGRAPHY

Anonymous (2012) *Submission by the EU and its Member States in reply to notification 2012-106 on the progress towards ratification and implementation of the Nagoya Protocol additional issues that may need to be addressed in preparation for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol*. 7th of September 2012

Belton V., Stewart T.J. (2002), *Multiple criteria decision analysis: an integrated approach*. Kluwer Academic Publishers

Biber-Klemm S., Martinez S.I., Jacob A. (2010), Access to Genetic Resources and Sharing of Benefits – ABS Program 2003–2010 of the Swiss Academy of Sciences, Swiss Academy of Sciences, Bern, Switzerland : http://abs.scnat.ch/downloads/documents/ABS_Report2003-2010_SCNAT_web.pdf

Bioversity International (1996), *Access to Plant Genetic Resources and the Equitable Sharing of Benefits: A Contribution to the Debate on Systems for the Exchange of Germplasm: a Feasibility Study*.

Born C.H. (2004), *Guide Juridique des Zones Protégées en Wallonie*. Ministère Région Wallonne, 2004

Brans J.P., Marechal B. (2002), *Prométhée-Gaia. Une méthodologie d'aide à la décision en présence de critères multiples*. Editions de l'Universite Libre de Bruxelles.

Burton G. (2009), Access and Benefit-sharing: ABS Law and Administration in Australia. *Revista Internacional de Direito e Cidadania*, n. 5, p. 93-101, October 2009

Byerlee D. and Dubin J. (2010), Crop improvement in the CGIAR as a global success story of open access and international collaboration. *International Journal of the Commons* (4) 1.

Carrizosa S., Brush B.S., Wright B.D., McGuire P.E. (2004), Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity. *IUCN Environmental Policy and Law* Paper No. 54

Castiaux J. (2011), Extradition en Belgique. In Chome P., Klees O., Lorent A. (red.), *Droit pénal et procédure pénale*, Mechelen: Kluwer

CBD (2012) *Progress Report on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization and Related Developments*. Conference of the Parties to the Convention on Biological Diversity, Eleventh meeting, Note by the Executive Secretary, UNEP/CBD/COP/11/11

CBD (2007), *Report on the Legal Status of Genetic Resources in National Law. Including Property Law, where applicable, in a Selection of Countries*. Fifth meeting of the Open-Ended Ad Hoc Open-Ended Working Group on Access and Benefit-sharing. UNEP/CBD/WG-ABS/5/1.

CBD (2002) *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*. Secretariat of the Convention on Biological Diversity

CCIEP (2006), *Belgium's National Biodiversity Strategy 2006-2016*. Belgian Coordination Committee for International Environment Policy, Directorate-General for the Environment.

Chiarolla C. (2010), Making Sense of the Draft Protocol on Access and Benefit-sharing for COP 10. *Idées pour le débat*, Institut du Développement Durable et des Relations Internationales (IDDRI)

Chiarolla C. (2012), Biopiracy and the Role of Private International Law under the Nagoya Protocol. *IDDRI Working Paper,* February 2012

CIDD/ICDO (2008) *Federaal plan inzake duurzame ontwikkeling 2004-2008/Plan Fédéral de DéveloppementDurable 2004-2008*. Interdepartmental Commission for Sustainable Development

Correa C. (2000*),* Implications of national access legislation for germplasm flows, *In Strengthening partnerships in agricultural research for development in the context of globalization, proceedings of the GFAR Conference, 21-23 May 2000*, Dresden, Germany. FAO/Global forum on agricultural research

Costello C., Ward M. (2007), Research, bioprospecting and biodiversity conservation, *Journal of environmental economics and management*, 53: 158-179

Crawford V.P. (1990), Relationship-Specific Investment. *The Quarterly Journal of Economics*, 105(2), pp. 561-574

Dedeurwaerdere T., Iglesias M., Weiland S., Halewood M. (2009), The use and exchange of microbial genetic resources for food and agriculture. *Background Study Paper of the Commission on Genetic Resources for Food and Agriculture* No.46, 67pp.

Duran M., Criekemans D. (2008), *Een vergelijkend onderzoek naar en bestedingsanalyze van het buitenlands beleid en de diplomatieke representatie van regio's met wetgevende bevoegdheid en kleine staten*. Rapport, Antwerpen: Steunpunt BuitenlandsBeleid, 418 p.

Eaton D., Visser B. (2007) Transaction Costs of Tracking and Monitoring the Flows of Genetic Resources. In Muller and Lapeña (eds.) *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows*, IUCN Environmental Policy and Law Paper No. 67/3

EC (2012), *Impact Assessment accompanying the document "Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, European Commission Staff Working Document, COM(2012) 576 final

EC (2012b), *Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*. COM(2012) 576 final

FAO (2009), The use and exchange of animal genetic resources for food and agriculture. *Background Study Paper of the Commission on Genetic Resources for Food and Agriculture* 43: 55.

Frison C., Dedeurwaerdere T. (2006), *Infrastructures publiques et régulations sur l'Accès aux ressources génétiques et le Partage des Avantages qui découlent de leur utilisation pour l'innovation dans la recherche des sciences de la vie : Accès, conservation et utilisation de la diversité biologique dans l'intérêt général,* Centre de Philosophie du Droit (CPDR) for the Belgian Federal Public Service – Environment.

Geeraerts K., Bursens P., Leroy P. (2004), *Vlaams milieubeleid steekt de grenzen over. De Vlaamse betrokkenheid bij de totstandkoming van Europees en multilateraal milieubeleid*. Steunpunt Milieubeleidswetenschappen

Glowka L., Burhenne-Guilmin F., Synge H., in collaboration with McNeely J.A. and Gündling L. (1994), A guide to the convention on biological diversity. *Environmental Policy and Law Paper* No. 30, IUCN Environmental Law Center

Goux C. (1996), *La recherche scientifique dans la Belgique fédérale: examen de la répartition des compétences*, Série Faculté de droit de Namur Centre de droit régional, La Charte, Bruges.

Greiber T., Peña Moreno S., Åhrén M., Carrasco J.N., Kamau E.C., Cabrera Medaglia J., Julia Oliva M., Perron-Welch F. in cooperation with Ali N. and Williams C. (2012), *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing*. IUCN, Gland, Switzerland. xviii + 372 pp.

Hansenne J. (2011), L'accession immobilière, in X., *Guide de droit immobilier*, 2011, liv. 64, Kluwer, Waterloo

IEEP, Ecologic and GHK (2012), *Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union*, Final report for the European Commission, DG Environment. Institute for European Environmental Policy, Brussels and London, April 2012

Jadot B., Vagman A. (2011), Avis de la section de législation du Conseil d'État [urbanisme et environnement]. *Amén.* 2011, liv. 2, pp. 147-153.

Kamau E.C., Fedder B. and Winter G. (2010), The Nagoya Protocol on Access to Genetic Resources and Benefit-sharing: What is New and What Are the Implications for Provider and User Countries and the Scientific Community? *Law, Environment and Development Journal*, 6(3): p.246

Kamau E.C. and Winter G. (2009), *Genetic Resources, Traditional Knowledge & the Law. Solutions for Access & Benefit-sharing*. London: Earthscan

Koo B., Pardey P.G., Wright B.D. and others (2004), *Saving Seeds; The economics of conserving crop genetic resources ex-situ in the future harvest centre of CGIAR*, CABI Publishing

Laird S., Wynberg R. (2012), *Bioscience at a crossroads: Implementing the Nagoya Protocol on Access and Benefit-sharing in a Time of Scientific, Technological and Industry Change,* CBD

Mansfield E. (1991), Academic research and industrial innovation. *Research Policy* 20:1-12.

Mansfield E. (1995), Academic research underlying industrial innovations: sources, characteristics and financing. *Review of Economics and Statistics* 77: 55-62.

Mansfield E. (1998), Academic research and industrial innovation: an update of empirical findings. *Research Policy* 26: 773-776.

Marchal P. (2008), Le droit comparé dans la Jurisprudence de la Cour de Cassation. *Revue de Droit International et de Droit Comparé*, liv.2-3, 2008.

Martin B.R. and Tang P. (2007), The benefits from publicly funded research. *SPRU Working Paper*: 161.

OECD (2002), *Handbook of Biodiversity Valuation: A Guide for Policy Makers*. Organisation for Economic Co-operation and Development, 2002

Paquin S. (2003), Paradiplomatie identitaire et diplomatie en Belgique fédérale : le cas de la Flandre. *Canadian Journal of Political Science/Revue canadienne de science politique*, 36 : pp 621-642

Peeters H., Franklin A., Van Goethem J-L. eds (2003), *Biodiversity in Belgium.* RBINS, Belgium

Plan T. (1999), *The economic valuation of biological diversity*. Tropical Ecology Support Program (ToB).

Prathapan K. D., Priyadarsanan Dharma Rajan, Narendran T. C., Viraktamath C. A., Aravind N. A. and Poorani J. (2008), Death sentence on taxonomy in India. *Current Science*, 94 (2). pp. 170-171.

Podvezko V., Podviezko A. (2010), *Use and choice of preference functions for evaluation of characteristics of socio-economical processes*. 6th International Scientific Conference, May 13–14, 2010, Vilnius, Lithuania;

Rausser G.C., Small A. (2000), Valuing Research Leads: Bioprospecting and the Conservation of Genetic Resources. *Journal of Political Economy*. 108(1), pp. 173-206

Ruiz M., Lapeña I., Clark S.E. (2004), The Protection of Traditional Knowledge in Peru: A Comparative Perspective. *Washington University Global Studies Law Review*, 3(3): 755–97

Schloen M., Louafi S., Dedeurwaerdere T. (2011), *Access and benefit-sharing for genetic resources for food and agriculture – Current use and Exchange practices, commonalities, differences and user community needs report from a multistakeholder expert dialogue*, UN Commission on Genetic Resources for Food and Agriculture, Background Study Paper, No.59.

Stromberg P., Dedeurwaerdere T., Pascual U. (2007), *An empirical analysis of ex-situ conservation of microbial diversity*. Presentation at the 9th International BIOECON Conference, Kings College Cambridge, 19-21 September 2007

Suneetha M.S., Pisupati B. (2009), *Benefit-sharing in ABS: Options and Elaborations*. UNU-IAS Report

Täuber S., Holm-Müller K., Jacob T., Feit U. (2011), *An Economic Analysis of new Instruments for Access and Benefit-sharing under the CBD – Standardisation options for ABS Transactions*. Research project of the Federal Agency for Nature Conservation, Germany

Toole, A. (1999), *The impact of federally funded basic research on industrial innovation: evidence from the pharmaceutical industry*. Stanford Institute for Economic Policy Research. Stanford CA. Discussion Paper 98(8).

Tvedt M.W. and Fauchald O.K. (2011), Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit-sharing in Norway. *The Journal of World Intellectual Property*, 14: 383–402

UNEP, Natural Justice and IUCN (2011) *Report of the International Experts Meeting on Access & Benefit-sharing and Protected Areas*, Gland, Switzerland, 6 – 8 July 2011

Van Den Haselkamp-Hansenne V. (2011), L'étendue de la propriété immobilière. In X., *Guide de droit immobilier*, 2011, liv. 64, Kluwer, Waterloo

Van Overwalle G. (2006), Implementation of the Biotechnology Directive in Belgium and its After-Effects. *International Review of IP and Competition Law*, 37:8

Van Overwalle G. (2004), Van groene muizen met rode oortjes: de EU-Biotechnologierichtlijn en het Belgisch wetsontwerp van 21 september 2004. *Intellectuele Rechten – Droits Intellectuels (IRDI)*, pp. 357-386

Visser B., Eaton D., Louwaars N., Engels J. (2000), *Transaction costs of germplasm exchange under bilateral agreements. Strengthening Partnership in Agricultural Research for Development in the Context of Globalization*, Conference 21-23 May, Dresden, Germany

Vatn A. (2005), *Institutions and the Environment*. Edward Elgar Pub

Watanabe M.M., Suzuki K., Seki T. (2004), *Innovative Roles of Biological Resource Centers. Proceedings of the Tenth International Congress for Culture Collections*, Japan Society for Culture Collections, World Federation for the Culture Collections

Wautrequin J. (2011), *Nouveaux Transferts de Compétences en Matière de Politique Scientifique? Critères D'appréciation*. Intervention au colloque 'Paroles de chercheurs. Etats des lieux et solutions', 4 mars 2011

Willieme C., Boland M., Simon V. (2010), Valorization des biens situés dans le domaine public : Quel encadrement juridique? *Rec. gén. enr. not.*, 2010, pp. 253-271 (at p. 256).

Williamson O.E. (1985), *The Economic Institutions of Capitalism*, New York: Free Press

Young T. (2006) Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime. *IUCN Environmental Policy and Law P*aper No. 67/5

Yun M. (2005), *Economic Valuation of Biodiversity*, Final Report for the MOSAICS Project. Korea Institute for International Economic Policy.