



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

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## **Final report: Executive Summary**

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

## Executive Summary

This is the executive summary of the study for the European Commission - *Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union*.<sup>1</sup> The report provides technical support to inform the Commission's Impact Assessment and consideration on initiatives at Union level towards the ratification of the Nagoya Protocol and its implementation by the Union and its Member States. The primary aim of the study is to help identify the most effective way of implementing the Protocol in the EU by analysing the existing legal tools, any requirements for their reform, available implementation options and the likely economic, social and environmental effects of different options.

### The international commitment and associated implementation challenges

In 2010, the year in which the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention of Biological Diversity* (hereafter referred to as the Protocol or NP) was adopted at the CBD COP 10 in Nagoya and 17 years after the CBD entered into force, few effective and efficient measures or regimes on access and benefit-sharing (ABS) were in place. Only a limited number of Parties, mostly provider countries, had adopted comprehensive ABS legislation, mostly focusing on regulating access to genetic resources under their jurisdiction. As a consequence of the lack of clear rules at the international level, the conditions for access in some provider countries had become very restrictive.

Agreement on the ABS Protocol was a *sine qua non* for reaching an overall agreement at Nagoya on the 20 targets under the CBD Strategic Plan 2011-20. The European Union and its Member States had been very active in the negotiation of the Protocol and are regarded as having been instrumental in bringing about consensus among the 193 Parties to the CBD.

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

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

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<sup>1</sup> Service Contract ENV.E.2/2011/ETU/599073.

<sup>2</sup> <http://www.cbd.int/decision/cop/?id=12268>

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

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

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

### Existing state of play and study evidence base

The issue of ABS is important to at least a dozen sectors/activities in the EU. These include academic research institutions, botanic gardens, culture collections, pharmaceutical industry, cosmetics industry, food and beverage industry, seed and green biotechnology industry, animal breeding industry, horticulture, biological control and industrial biotechnology.

A detailed information sheet was produced for each of these sectors/activities on the basis of publicly available data, relevant literature, stakeholders' responses to the EU public consultation on ABS carried out in 2011<sup>3</sup> and targeted interviews with sectors' practitioners and representatives (see Annex 3 of the Report). The information sheets present, *inter alia*, the importance of those sectors in the EU and global market, the relevance of utilisation of genetic resources (GR) and traditional knowledge associated with genetic resources (TKaGR) for these sectors/activities, the type and role of GR/TKaGR used by the sector, the characteristics of GR utilisation chains in the different sectors and their sourcing practices, the existing approaches and good practices for complying with ABS requirements as well as the current problems and key needs of those sectors and activities as regards compliance with ABS rules and procedures. Those sectoral studies formed the basis for the "EU baseline", which provides an overview of the use and exchange of genetic resources falling within the scope of the Nagoya Protocol for both the commercial and non-commercial sectors affected by ABS issues in Europe (see Ch. 10 of the Report and Figures A1 and A2 in the Annex ES1 below).

For the purpose of this study, a distinction has been made between "upstream" and "downstream" activities in the genetic resources user chain. "Upstream" activities include collecting *in situ* genetic resources, importing genetic resources into the EU, storing genetic resources in *ex situ* collections (including identifying and documenting them for this purpose) and handing out genetic resources (see Figure A1 at the end of this document).

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<sup>3</sup> [http://ec.europa.eu/environment/consultations/abs\\_en.htm](http://ec.europa.eu/environment/consultations/abs_en.htm)

“Downstream” activities include research (basic and applied) and development on genetic resources for both commercial and non-commercial purposes – i.e. activities that fall within the Protocol’s definition of “utilization” of genetic resources – and the commercialization of products that are based on the utilisation of genetic resources or associated traditional knowledge (see Figure A2 at the end of this document.)

As regards compliance of users with ABS-related obligations (i.e. access requirements of provider countries, administrative decisions on access, specific use and benefit-sharing conditions set out in contracts) voluntary codes of conduct and standardised procedures have been developed in the last 10 years by a number of sectors. These include, for instance, the International Plant Exchange Network (IPEN) Code of Conduct for Botanic Gardens, the MOSAICC Code of Conduct and the ECCO’s core MTAs for microbial collections and corporate codes of conduct (e.g. guidelines developed by pharmaceutical and biotechnology associations). Nevertheless, knowledge of ABS legislation and the existence of established practices for ensuring compliance are still highly variable within and across EU sectors.

**Member States legal status- user compliance:** In the eight EU Member States studied within the project - Belgium, Bulgaria, France, Germany, the Netherlands, Poland, Spain and the United Kingdom - no specific ABS user compliance measures could be identified as of mid-2011<sup>4</sup>. This implies that no measures were in place in these countries to ensure that genetic resources utilised within their jurisdiction have been accessed in accordance with PIC (prior informed consent) and MAT (mutually agreed terms) legislation of the country of origin of the genetic resource.

**Member States legal status- provider-side access legislation:** In most EU Member States studied no provider-side access legislation exists. Exceptions include France, Spain and Bulgaria where framework legislation has been drafted but not yet put into force. It should be noted that the Netherlands has an explicit free access policy whereby no prior informed consent is required to access its genetic resources. Poland also aims for unrestricted access to genetic resources.

## The Options

Different options on how the EU could implement the Nagoya Protocol have been identified and assessed in the present study, including:

- Provider Measures - options to meet the EU and Member State obligations as a provider of genetic resources (GR) and traditional knowledge associated with genetic resources (TkaGR).
- User Compliance Measures - options to meet the EU and Member State obligations as a user of genetic resources (GR) and traditional knowledge associated with genetic resources (TkaGR) – in particular, measures to ensure compliance of EU operators with access and benefits sharing legislation of provider countries and

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<sup>4</sup> Please note that the country studies have been conducted in the second half of 2011 and have not been updated since then. Therefore the country studies may not take into account recent legislative and policy developments in the countries studied.

hence comply with PIC (prior informed consent) and MAT (mutually agreed terms) requirements.

**Provider Measures** – the three options assessed in the study include (See Box E1 for details):

- Option A: No or Minimal EU Action (diverse approaches by different Member States)
- Option B: EU use of the Open Method of Coordination (OMC) to complement MS actions
- Option C: EU Minimum Legal Standards

#### Box E1. Provider Measures

##### *Option A: No or Minimal EU Action*

In Option A, the EU does nothing or, at most, takes very soft measures such as on awareness-raising or the provision of information, leaving MS the freedom if they want to adopt a PIC requirement or not. Under the NP, parties can generally decide whether or not to require PIC, and most other provider side obligations under the Protocol only become relevant once the decision on PIC has been taken. Under Option A the assumption is that MS deciding to require PIC and MAT for access to their genetic resources will individually comply with the NP core obligations particularly under 6(3), 6(2) and Art 8(a), by taking the implementing measures that are best in line with their national access policy. MS opting for a “free access” policy (no requirements for PIC/MAT), on the other hand, will only take measures under Art 8(a) and Art 6(2) as far as ILCs are involved.

##### *Option B: EU OMC (Open Method of Coordination)*

Under this option, the EU uses (in collaboration with MS) the Open Method of Coordination (OMC) to encourage harmonisation of provider measures among MS. Thus, MS deciding to require PIC and MAT would agree, e.g. on objectives, definitions and procedures and the activities and progress in each MS would be monitored, reported and discussed, benefitting from peer review. This would encourage accelerated “mutual learning”. While it is doubtful whether the EU competence extends to TKaGR, some OMC action could still be pursued as the OMC may also deal with areas outside of EU competence. In line with Art 8(a), the EU will promote best practices and guidelines to encourage MS to facilitate non-commercial research on GR.

##### *Option C: EU Minimum Legal Standards*

**MS Requiring PIC and MAT:** In this option, the EU sets minimum standards for those MS that chose to opt for requiring PIC and MAT for access to their genetic resources in order to achieve a harmonised access system throughout the EU, which complies with the requirements in Art 6(3) NP. Under this option, procedures and certificates of compliance issued by CNAs from the different MS are standardised; the scope of the access legislation would likely also be harmonised across the EU Member States. EU minimum standards would also include provisions aimed at facilitating access to GR for non-commercial research under Art 8(a).

**MS not requiring PIC and MAT:** While respecting the MS choice to provide free access to GR to prospective users without PIC/MAT, the EU in this option imposes an administrative requirement on the MS to issue, upon request from users, a certificate of compliance for genetic resources under their sovereignty that have been accessed by prospective users.

**User compliance** options assessed in the study include (see Box E2 for details):

- Option A: Max member State Action + EU OMC
- Option B: EU Action with Upstream Focus
- Option C: EU Action with Downstream Focus

### **Box E2. User Compliance Measures : Options**

#### *Option A: OMC:*

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

#### *Option B: Upstream focus*

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

#### *Option C: Downstream focus*

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

## **Assessment of measures to implement the Nagoya Protocol**

### ***Synthesis of provider measures:***

- Under provider measures Option A (No or Minimal EU Action), EU inaction would likely entail a fragmentation of access standards throughout the internal market leading to a likely increase of transaction costs for sectors sourcing GR (particularly in situ) across EU MS.
- Option B (EU use of the Open Method of Coordination ) on the other hand seems to better balance, through soft harmonisation under an OMC, the concerns about costs

for the EU and potential costs for users relating to legal uncertainties and fragmentation. The downsides of this option seem to be mostly the uncertainties as to the end result of the OMC process.

- Lastly Option C (EU Minimum Legal Standards) is the one with that offers the most apparent benefits for sectors dealing with GR, in particular biocontrol, *ex situ* collections and small seed breeding companies.
- Option C would also potentially entail international benefits for all EU users of GR as it would put the EU in a leading position in terms of access to GR standard setting. Political opposition from certain MS and the relatively high costs related to enacting and monitoring the compliance with a new piece of legislation could potentially counter-balance the benefits of such a system, at least in the short term.

Options “B” and “C” should not be seen as mutually exclusive – as they can be adopted in sequence.

#### ***Synthesis of user compliance measures:***

- User compliance measures Option A (Max member State Action + EU OMC), which assumes that all Member States implement the NP in national law, only partially addresses the Protocol objectives related to user compliance. It does not provide legal certainty for users regarding their obligations at EU level. The option potentially lacks transparency across EU MS due to likely variation in the approaches taken at this level. As a result Option A would be likely opposed by the sectors involved.
- Option B (EU Action with Upstream Focus) will necessarily increase costs for publicly-funded sectors. The significant benefit of Option B is the ability to secure the good legal status of GR/TKaGR from an early point in the value chain, thus ensuring that materials circulating in the EU can be ‘trusted’ for use by the different sectors involved in high-cost and high-risk downstream activities. A major drawback of this option is the lack of integration of checkpoints in the user chain which may reduce the effectiveness of this approach in monitoring and addressing non-compliance with upstream obligations.
- Option C (EU Action with Downstream Focus) on the contrary will have a light impact on upstream users in the EU, and these users will face few costs. Downstream users relying on GR, conversely, will face significant costs as monitoring and enforcement activities are conducted at a later stage in the user chain after significant time and resource investments. The major benefit of this option is that it reduces or removes the burden of implementation from research activities and places it on commercial activities, thus helping to facilitate R&D at any early stage in the value chain. This option nevertheless presents drawbacks in terms of legal certainty for downstream operators. For this reason several EU commercial operators have expressed significant opposition to this option.
- It is likely that in the short to medium term the upstream focused option would be less onerous and more feasible than the downstream focused options given the existing state of knowledge, documentation of genetic resources and practices. An upstream focus would facilitate and reduce the costs of an eventual future

downstream focused option. In sum, the assessment would support the case for a phasing of options, starting with “B” and then adding monitoring elements (checkpoints) from “C”.

The provider access measures and the user compliance measures have been assessed apart given the different nature of the measures. However, they are not alternatives, but relate to different components of Nagoya Protocol implementation. While all Parties must take measures for implementing the user-compliance pillar of the Protocol, Parties have discretion whether or not to require prior informed consent for access to and benefit-sharing for the utilisation of genetic resources over which they hold sovereign rights. In case a Party decides to require prior informed consent and benefit-sharing it must implement the fairly detailed access provisions of the Protocol.

**Annex ES1**

**Figure A1: EU upstream activities and actors involved**

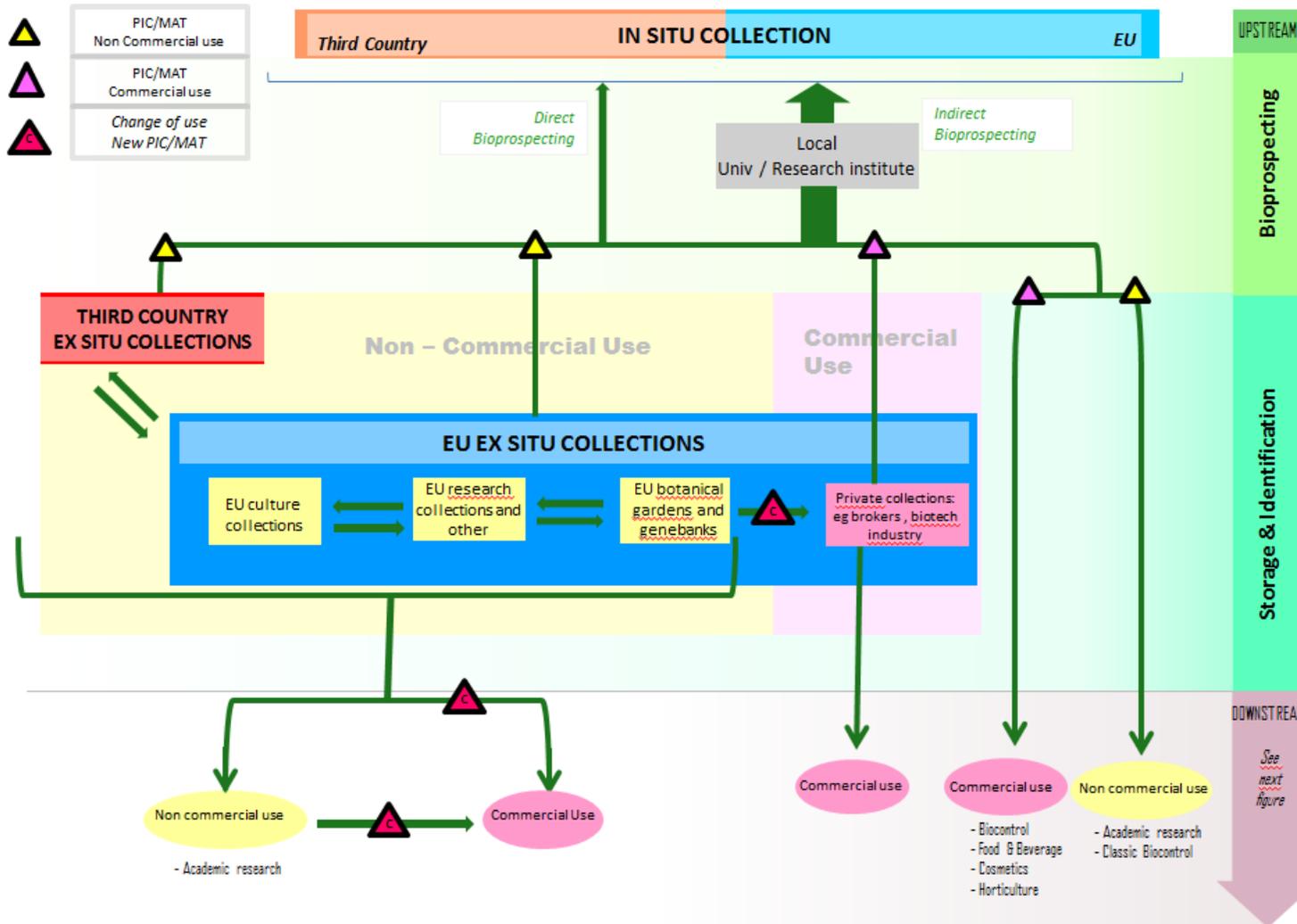


Figure A2: EU downstream activities and actors involved

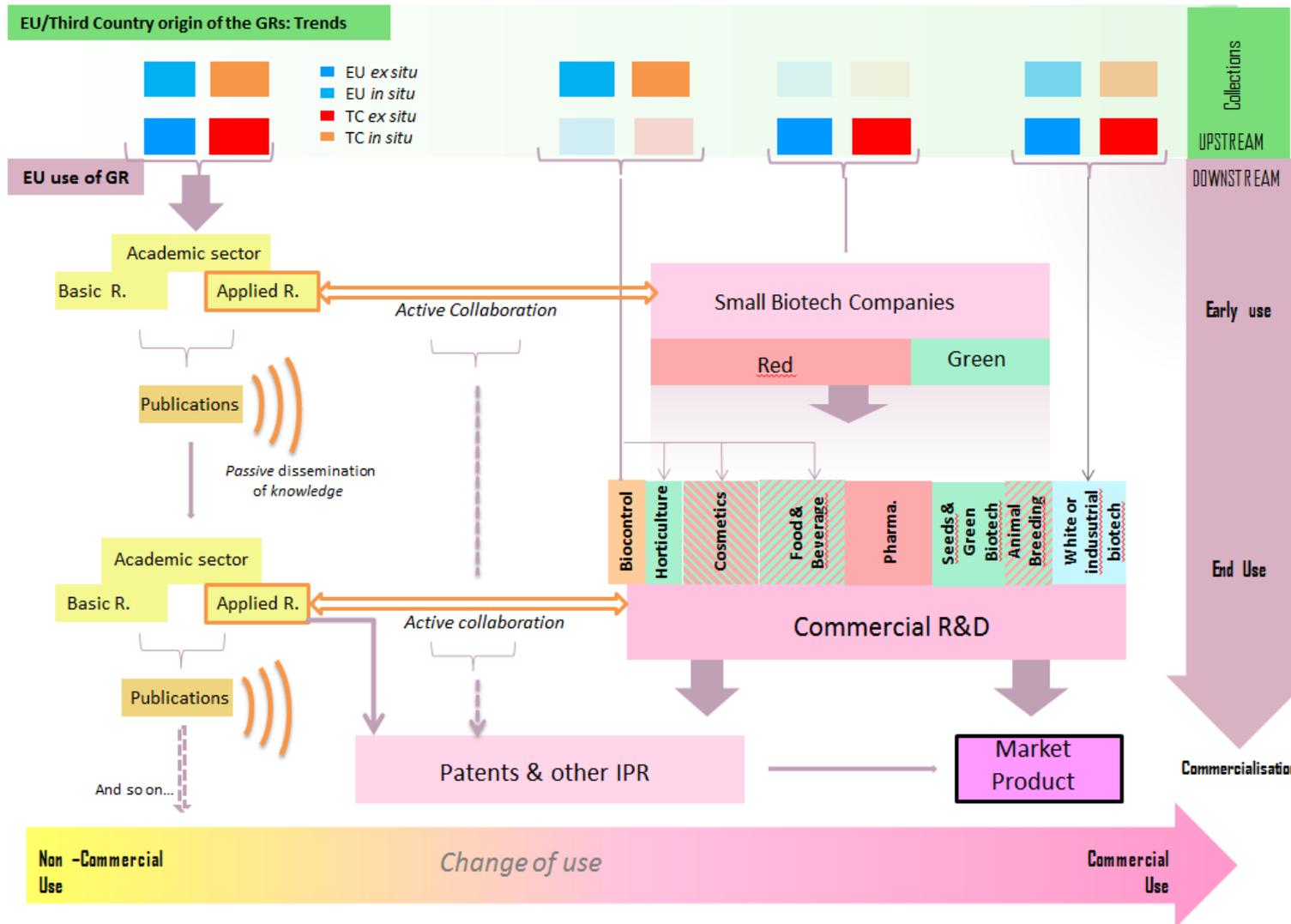


Figure A3: Flowchart of Upstream Measures

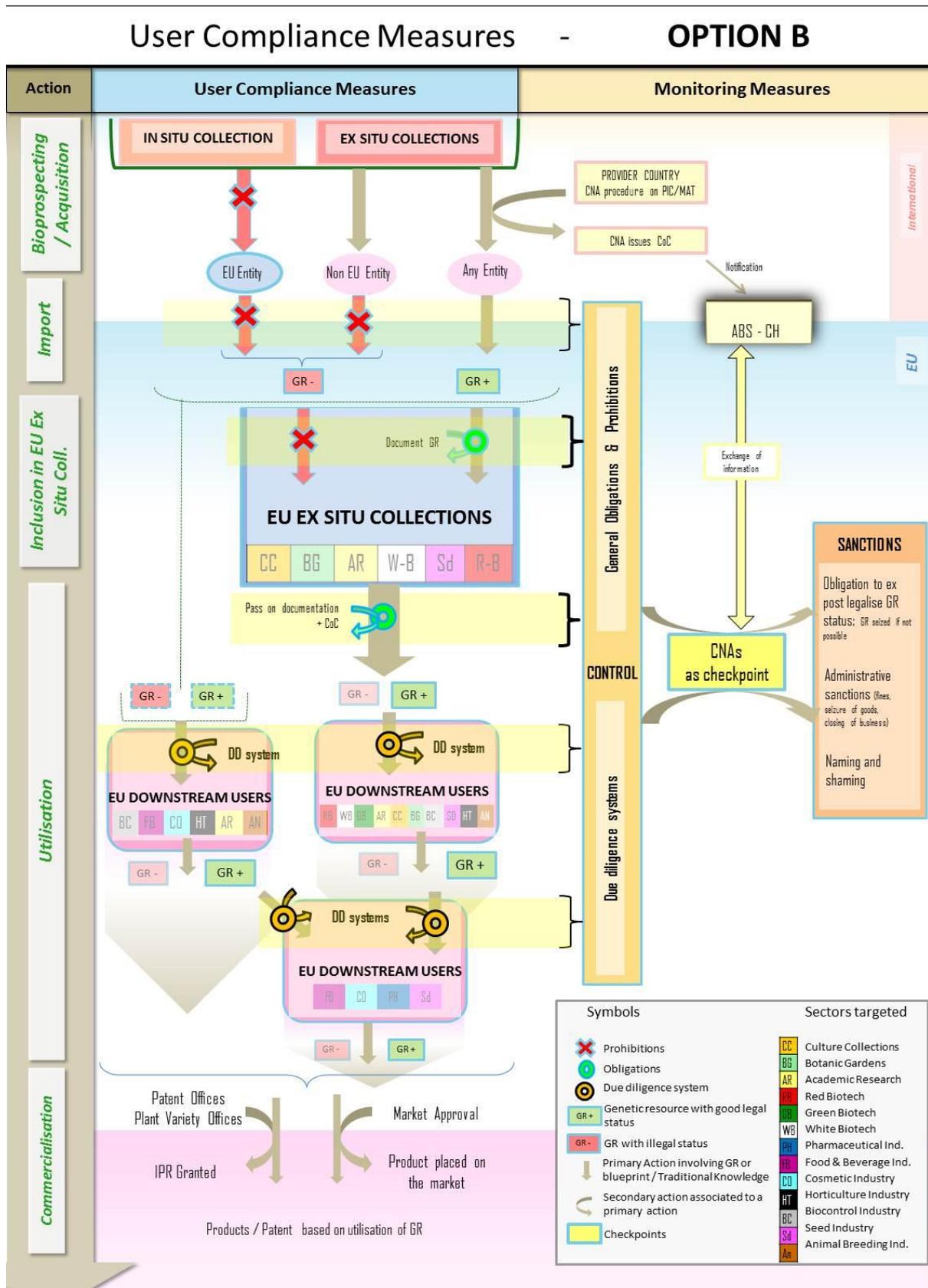


Figure A4: Flowchart of Downstream Measures

