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# Consultancy on the Notion of 'Utilisation' in the Nagoya Protocol and the EU ABS Regulation for the Upstream Actors

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**Summary:** This consultancy identifies the particular challenges that upstream actors face with regard to the EU-level implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit-sharing (ABS). Notably, the consultancy investigates the questions of upstream actors regarding the precise subject-matter scope of the Nagoya Protocol and the EU ABS Regulation and applicable obligations to the particular activities that are conducted in the upstream part of the value chain. These questions are identified on the basis of a desk-based review of academic literature and a series of semi-structured interviews with upstream stakeholders.

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## 1 Introduction

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits from their Utilization (ABS), to the Convention on Biological Diversity, entered into force on 12 October 2014. With a view to implementing it at EU level, on 9 June 2014, Regulation 511/2014 on compliance measures for users from the Nagoya Protocol in the Union (EU ABS Regulation) entered into force.<sup>1</sup> Article 4 on due diligence and article 7 on the monitoring of user compliance through reporting requirements have only become applicable as of 12 October 2015 (one year after the date of entry into force of the Nagoya Protocol for the Union). An Implementing Regulation with regard to, among others, clarification on the due diligence declaration was adopted on the same day and entered into force in November 2015. Guidance documents will be developed to clarify the notion of due diligence: the obligation to seek, keep and transfer internationally recognised certificates of compliance or equivalent information (article 4(3), EU ABS Regulation). The due diligence obligation and the corresponding reporting requirements fall upon *users* of genetic resources and traditional knowledge associated with genetic resources (hereafter, ‘traditional knowledge’).

### 1.1 Terms of reference and objectives of the consultancy

This report is based upon the premises that different actors have different approaches to genetic resources that are relevant in regulating ABS. Actors involved in *upstream* activities include collections (e.g. botanic gardens, culture collections and seed archives) and academic research institutions. These actors would be involved in activities like the import, storage, exchange, description and testing of genetic resources, as well as basic and non-commercial research on them. Upstream actors differ from the *downstream* actors, such as the biotechnology and pharmaceutical industry, who are engaged in activities characterised by the objective to develop and commercialise products. Against this background, this consultancy aims to identify the particular challenges that upstream actors face with regard to EU-level implementation of the Nagoya Protocol on the basis of the EU ABS Regulation. Notably, the consultancy seeks to investigate the questions of upstream actors regarding the precise subject-matter scope of the Nagoya Protocol and the EU ABS Regulation and applicable obligations to the particular activities that are conducted in the upstream part of the value chain.

### 1.2 Methodology and structure

The consultancy was carried out through a desk-based review of the academic literature on the subject-matter scope of the Nagoya Protocol, specifically the concept of *utilisation* (research and development) and on the relationship between articles 2 and 8(a) of the Nagoya Protocol. This has informed a series of semi-structured interviews with upstream stakeholders. The selection of interviewees was partly based upon a list of upstream stakeholders that were identified by the Commission, partly through our own research as to the range of stakeholders that work with genetic resources, our own contacts within this field, and lastly by contacts that

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<sup>1</sup> Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance [2014] OJ L 150/59.

were made at the first training workshop on ABS for the upstream sector held in Brussels on 13 October 2015. The selection aimed to include a diverse range of interviewees from 8 different Member States, based upon the genetic resources that they use (collections) and the type of research that they conduct (research institutions). The guide for the semi-structured interviews was discussed with the Commission (see Annex A). Only two interviewees were completely uninformed about the access and benefit-sharing obligations under the Nagoya Protocol. However, although most interviewees had a basic understanding of ABS obligations, only nine interviewees identified *due diligence* as a self-standing obligation<sup>2</sup> and few had a clear understanding of the distinction between access legislations in the provider countries and legislation focused on compliance, such as the EU ABS Regulation, in user countries. The interviewees that were unaware of the obligations under the Nagoya Protocol and the EU ABS Regulation – notably articles 4 and 7 – were informed about them by the interviewer with a view to prompting them to express opinions on the obligations.

The findings of the literature review are presented in section 2 and include a legal analysis of the definition of *utilisation* and initial thoughts arising from the literature on the practical implications of a narrow or extensive understanding of the subject-matter scope with regard to the activities of upstream actors. The following sections draw on the results of the semi-structured interviews. Section 3 gives a factual overview of the upstream sector, including the sources for genetic resources and for the funding of upstream activities. Section 4 describes the range of activities on genetic resources and traditional knowledge in the upstream sector, interviewees' categorisation of activities as research or research and development (R&D), and existing due diligence practices. Lastly, section 5 outlines the interviewees' doubts and concerns regarding the definition of utilisation, the implementation of due diligence and reporting requirements, and other issues that are perceived as challenges to compliance. Section 6 offers conclusions that bring together the findings of the legal analysis and the analysis of the data arising from the semi-structured interviews.

## **2 Defining Utilisation: a Legal Analysis**

### **2.1 Background: defining utilisation based on the *intent***

The objective of the Nagoya Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources.<sup>3</sup> The Protocol defines the “utilisation of genetic resources,” to clarify the Protocol’s subject-matter scope, with reference to a broad definition

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<sup>2</sup> Five collections and four research institutions.

<sup>3</sup> 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 (adopted on the 29 October 2010, entered into force 12 October 2014), Article 1.

of the *type of material* used,<sup>4</sup> and to the conduct of “research and development,” which seems to point to the *intent* of the actors involved in order to determine their ABS responsibilities.<sup>5</sup>

This definition was copied into the EU ABS Regulation (article 3(5), EU ABS Regulation)<sup>6</sup> and thus likewise delineates its scope of application, including for the due diligence obligations (article 4) and associated reporting requirements (article 7), which the EU ABS Regulation imposes on *users*.<sup>7</sup> Although the definition was meant to be comprehensive and enhance legal certainty, it raises several interpretative questions. Among these, the Nagoya Protocol does not provide a definition of utilisation of traditional knowledge, which also falls under its benefit-sharing objective. It has been argued that utilisation of traditional knowledge could be interpreted along similar lines to the definition of “utilization of genetic resources.” In other words, as traditional knowledge under the Protocol would serve as lead information for the utilisation of genetic resources, it can be understood as hinging on the same intent (research and development) as in the case of genetic resources.<sup>8</sup>

For the purpose of this consultancy focused on the activities of the upstream actors, notably *ex situ* collections and research institutions, a very pertinent question is whether *research and development* (R&D) are cumulative or alternative requirements (section 2.2) for the occurrence of *utilisation*. We find that a systematic interpretation of the Protocol’s provisions and an analysis of preparatory and explanatory documents favour an alternative interpretation. The meaning of *research* in the context of the Protocol is thus explained (section 2.3). Lastly, this study reflects on the practical issues related to the different (restrictive or extensive) legal interpretations of R&D (section 2.4).

## 2.2 Research and/or development as alternative requirements

A significant point of debate from the viewpoint of the upstream sector is the cumulative or alternative nature of the R&D requirements for the occurrence of *utilisation*, since these actors mostly conduct non-commercial research activities without a *development* (commercialisation) objective. At first sight, the conjunction “and” in “research *and* development” seems to support a cumulative interpretation, which has previously been advocated by the scientific community.<sup>9</sup> However, this restrictive interpretation may not be in

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<sup>4</sup> Article 2(c) and (e) Nagoya Protocol. See discussion in E Morgera, E Tsioumani and M Buck, *Unravelling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity* (Brill 2014) <http://www.brill.com/products/book/unraveling-nagoya-protocol-open-access> version accessed July 2015, 64-73.

<sup>5</sup> Morgera, Tsioumani and Buck (n 4) 63; T Greiber, 'An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing' (IUCN Environmental Policy and Law Paper No. 83, 2012) 63; and K Bavikatte and B Tobin, 'Cutting the Gordian Knot: Resolving conflicts over the term “utilisation’ (Biores ICTSD, 14 October 2010) <http://www.ictsd.org/bridges-news/biores/news/cutting-the-gordian-knot-resolving-conflicts-over-the-term-%E2%80%99Cutilisation%E2%80%99D> accessed July 2015; Buck, M and Hamilton, C 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity' (2011) 20 RECIEL 47, 56.

<sup>6</sup> Regulation 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union [2014] OJ L 150/59.

<sup>7</sup> A ‘user’ is, according to article 3(4) of the Regulation “a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources”.

<sup>8</sup> Morgera, Tsioumani and Buck (n 4) 74.

<sup>9</sup> See e.g. Verkley, G ‘How will the Nagoya Protocol Affect our Daily Work?’ (2015) 6(1) IMA Fungus 3, 4.

accordance with the ordinary meaning of this generally accepted combination of terms to describe “two intimately related processes by which new products and new forms of old products are brought into being through technological innovation,”<sup>10</sup> considering the context of articles 2(c) of the Protocol and 3(5) of the EU ABS Regulation, as well as their object and purpose.<sup>11</sup>

Notably, article 8(a) of the Nagoya Protocol provides that Parties shall “promote and encourage research [...] including through simplified measures on access for *non-commercial research* purposes,” thus assuming that these activities in principle fall within the Protocol’s subject-matter scope.<sup>12</sup> Article 5(4) and the Annex to the Nagoya Protocol moreover identify various non-monetary benefits, which need to be shared and which will likely be generated through non-commercial research only.<sup>13</sup> Article 17 of the Nagoya Protocol further obliges Parties to designate checkpoints for the monitoring of the *utilisation* of genetic resources, “at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization,” implying that all these separate stages are covered by the term *utilisation* and thus by R&D.<sup>14</sup> The EU ABS Regulation establishes as a checkpoint the recipients of research funding involving the utilisation of genetic resources (article 7). The Implementing Regulation laying down detailed rules for, *inter alia*, the monitoring of user compliance, has further specified that all grants from commercial or non-commercial sources are considered as “funding” for the purpose of this checkpoint.<sup>15</sup> If funding is allocated to non-commercial research projects, these will fall under the purview of the checkpoint according to the EU ABS Regulation. Arguably, only checkpoints that also look into non-commercial research are likely to be appropriate to fulfil the objective of the Protocol.<sup>16</sup>

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<sup>10</sup> Encyclopaedia Britannica Online, <http://www.britannica.com/topic/research-and-development> which in its commentary explicitly holds that: “Research can be either basic or applied”. Supportive on this interpretation based on the ordinary meaning of R&D: Morgera, Tsioumani and Buck (n 4) 63-64; E C Kamau, 'R&D under the CBD and Nagoya Protocol' in E C Kamau, G Winter and P Stoll (eds), *Research and Development on Genetic Resources. Public Domain Approaches in Implementing the Nagoya Protocol* (Routledge 2015) 30; Explanatory Guide to the Nagoya Protocol (n 5) 65.

<sup>11</sup> Article 31(1) Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331.

<sup>12</sup> The distinction between non-commercial or commercial research is therefore only relevant to determine the specific rights and obligations of actors under the Protocol, e.g. to distinguish between different access conditions and the sharing of either monetary or non-monetary benefits, and does not concern the Protocol’s scope of applicability, see in this regard C Von Kries, G Winter, 'Defining commercial and non-commercial research and development under the Nagoya Protocol and in other contexts' in E C Kamau, G Winter and P Stoll (eds), *Research and Development on Genetic Resources. Public Domain Approaches in Implementing the Nagoya Protocol* (Routledge 2015) 65 and Morgera, Tsioumani and Buck (n 4) 63-64.

<sup>13</sup> E.g. collaboration in scientific research and admittance to collections and databases, see hereafter also §2.3.

<sup>14</sup> G S Nijar, 'The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries' (*South Centre*, March 2011) [http://www.southcentre.int/wp-content/uploads/2013/05/RP36\\_The-Nogoya-Protocol\\_EN.pdf](http://www.southcentre.int/wp-content/uploads/2013/05/RP36_The-Nogoya-Protocol_EN.pdf) accessed July 2015, p. 15.

<sup>15</sup> Article 5(5) Commission Implementing Regulation (EU) laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices, available at <http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.documentdetail&tKx5uU4uzHBhCOdSR OCSNG3UQIcWvTUG+fw5z7KIOPn5kpF44eMOD+/2LACOB4f3> accessed October 2015.

<sup>16</sup> Morgera, Tsioumani and Buck (n 4) 274-278.

An alternative interpretation, which supports a broad scope of application, is moreover reinforced by the Protocol's *travaux préparatoires*.<sup>17</sup> The negotiators drafted a very broad list of activities, which constitute *utilisation*, including non-commercial research activities.<sup>18</sup> Yet, the definition of utilisation in article 2(c) of the Nagoya Protocol was considered to be “comprehensive enough to cover all possible uses of genetic resources, allowing for rapidly evolving techniques and the changing uses of genetic resources occurring with advances in knowledge and technology,”<sup>19</sup> thus being more inclusive, rather than more restrictive, than the original list of uses. Moreover, the *Frascati Manual*, the standard of conduct for R&D surveys in the OECD and the EU that was recognised in the context of the Commission's Framework for state aid for research and development to be an authoritative document for the classification of activities,<sup>20</sup> identifies both basic research (research “without a particular application or use in view”) and applied research as activities falling within the term R&D.<sup>21</sup>

### 2.3 Distinguishing between activities with and without a research component

Having concluded that both research activities with and without a commercialisation objective fall within the subject-matter scope of the Protocol and the EU ABS Regulation, a subsequent question is which particular activities by upstream actors qualify as *research*. According to its ordinary meaning, research is the “systematic investigation or inquiry aimed at contributing to knowledge of a theory, topic, etc., by careful consideration, observation, or study of a subject.”<sup>22</sup> This definition resembles the definition of R&D in the *Frascati Manual*, comprising “creative work undertaken on a systematic basis in order to increase the stock of knowledge [...], and the use of this stock of knowledge to devise new applications.”<sup>23</sup> In the context of the Protocol, it has been interpreted to mean “all types of systematic work on the genetic or biochemical composition of genetic resources aimed to discover potentially interesting properties.”<sup>24</sup> Whereas this study includes a factual examination of the activities by the upstream stakeholders based on semi-structured interviews (sections 3-5 below), it must be noted from the outset that the negotiating history of the Nagoya Protocol and the academic literature are inconclusive on the qualification of activities in the early stages of the upstream value chain, between access and (fundamental) research. These activities include the

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<sup>17</sup> Article 32 Vienna Convention on the Law of Treaties.

<sup>18</sup> Ad-hoc Open-ended Working Group on ABS, 'Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectorial Approaches' (Paris, 12 December 2008) UNEP/CBD/WG-ABS/7/2, Annex, p. 12.

<sup>19</sup> Explanatory Guide to the Nagoya Protocol (n 5) 64; Bavikatte and Tobin (n 5).

<sup>20</sup> Commission, 'Framework for state aid for research and development and innovation' C(2014)3282 par 12, 75.

<sup>21</sup> OECD, 'OECD, 'Frascati Manual. Proposed Standard Practice for Surveys on Research and Experimental Development' (OECD, 2002) [http://www.oecd-ilibrary.org/science-and-technology/frascati-manual-2002\\_9789264199040-en;jsessionid=2j32nwi9l3na8.x-oecd-live-02](http://www.oecd-ilibrary.org/science-and-technology/frascati-manual-2002_9789264199040-en;jsessionid=2j32nwi9l3na8.x-oecd-live-02), accessed July 2015, p. 30.

<sup>22</sup> Oxford English Dictionary Online, <http://www.oed.com/view/Entry/163432?rskey=ydZKC2&result=1&isAdvanced=false#eid> accessed July 2015,

<sup>23</sup> *Frascati Manual* (n 21) 30.

<sup>24</sup> E C Kamau and G Winter, 'Unbound R&D and bound benefit sharing. Introduction, synthesis and conclusions' in E C Kamau, G Winter and P Stoll (eds), *Research and Development on Genetic Resources. Public Domain Approaches in Implementing the Nagoya Protocol* (Routledge 2015) 2.

collection, conservation, storage and classification of resources, and are conducted by commercial and (mostly) non-commercial intermediaries like collections.<sup>25</sup>

A systematic interpretation of the Nagoya Protocol and the EU ABS Regulation, once again, supports a broad subject-matter scope, although the particular obligations of the actors which conduct pure research activities would still be determined by article 8(a) of the Nagoya Protocol on simplified measures.<sup>26</sup> Firstly, the non-monetary benefits in article 5(4) and the Annex of the Protocol explicitly include the “admittance to *ex situ* facilities of genetic resources and to databases” and “access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies,”<sup>27</sup> suggesting that these activities themselves fall within the Protocol’s scope. Preambular recital 28 to the EU ABS Regulation furthermore recognises the important role of collections as suppliers, “in helping *other* users in the chain of custody to comply with their obligations”, providing an indication that these collections themselves also qualify as users. The aforementioned list of possible uses, which were identified in the preparatory phase of the Nagoya Protocol, moreover also explicitly mentions the collection, conservation and the characterisation of genetic resources.<sup>28</sup> The document bases the categorisation of uses on the presumption that the “actual or potential use of genetic material indicates an attribution of value.” Whereas with regard to taxonomy the realisation or attribution of value lies in the creation of knowledge and a better understanding of the living world,<sup>29</sup> Scheid and Tvedt have argued that preserving potential value through conservation likewise falls within the definition and also creates benefits for researchers.<sup>30</sup>

This definition and categorisation of utilisation based on the realisation or attribution of value resembles the definition of R&D above based on a (potential) increase in knowledge. Yet, the *Frascati Manual* seems to exclude the specialised activities of “collecting, coding, recording, classifying, analysing and evaluating” from R&D.<sup>31</sup> Only if these *related* activities support R&D, because they are characterised by an appreciable element of novelty and the resolution of scientific uncertainty, will they themselves become R&D.<sup>32</sup> This categorisation, however,

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<sup>25</sup> See e.g. on the activities of public *ex situ* collections in the context of the Protocol, S Biber-Klemm *et al*, 'Governance options for ex-situ collections in academic research' in Oberthür, S and Rosendahl, G K, *Global Governance of Genetic Resources. Access and Benefit Sharing after the Nagoya Protocol* (Routledge 2014) 213 and also preamble 27 and 28 of the EU ABS Regulation.

<sup>26</sup> See above (n 12).

<sup>27</sup> Paragraph 2(e) and (k) of the Annex to the Nagoya Protocol.

<sup>28</sup> Annex to GLTE Report (n 18) p. 8 (categories 5 and 6) and p. 12-13 on different uses by the non-commercial research sector and *ex situ* conservation, including collection, identification, preservation, distribution, conservation, characterisation and evaluation, production of naturally occurring compounds and DNA synthesis as part of a research process as forms of utilisation. This interpretation seems initially to be supported by the non-commercial research sector: Schindel, D E, et al, 'Preserving International Access to Genetic Resources for Non-commercial Biodiversity Research' (*Consortium for the Barcode of Life*) circulated as UNEP/CBD/WG-ABS/8/INF/6 (Montreal, 9 November 2009).

<sup>29</sup> Group of Technical and Legal Experts, 'Concepts, Terms, Working Definitions and Sectoral Approaches Relating to the International Regime on Access and Benefit-Sharing' (Windhoek, 2-5 December 2008) UNEP/CBD/ABS/GTLE/1/INF/2, p. 4.

<sup>30</sup> P J Schei and M W Tvedt, 'Genetic Resources' in the CBD: the Wording, the Past, the Present and the Future' (*Fridtjof Nansen Institute*) circulated as UNEP/CBD/WG-ABS/9/INF/1 (Cali, 22-28 March 2010).

<sup>31</sup> *Frascati Manual* (n 21) 31.

<sup>32</sup> *Frascati Manual* (n 21) 35.

supposes that it will be obvious in advance to the upstream actor if the resource collected or classified will be used for further research. Since these other research activities may or not be conducted by the collector itself, categorisation of activities may thus be contingent on the intentions of subsequent actors, making it very difficult for the upstream actor to know its precise obligations and thus undermining legal certainty. Furthermore, it is not clear why, based on the observations above, classification has no self-standing value. The Institute for European Environmental Policy (IEEP) study on the legal and economic aspects of the Protocol prepared to support the development of the EU ABS Regulation recognises taxonomy, which includes characterisation, classification, and nomenclature,<sup>33</sup> to fall within the definition of utilisation.<sup>34</sup> The European Economic and Social Committee (outside the context of ABS) explicitly included “encyclopaedic research (e.g. to complete our knowledge about substance properties, new substances, active substances, etc.)”<sup>35</sup> within the scope of R&D. Based on the considerations above, *research* in the context of the Protocol and EU ABS Regulation could include taxonomy research, and possibly by extension, conservation by collections, only leaving upstream activities without *any* research component outside the scope, such as arguably the collection and transfer of material.<sup>36</sup>

## 2.4 Practical issues regarding the role and activities of upstream actors

The above analysis regarding the legal definition of *R&D* and consequently of *utilisation* in the context of the Protocol and the EU ABS Regulation is evidently not of a theoretical nature only. While directly linked to the scope of their operational provisions through the terms ‘use, user, utilised or utilisation’ etc,<sup>37</sup> both stakeholders and scholars have raised various practical issues based on whether one opts for a restrictive or extensive interpretation of utilisation.

Firstly, any attempt to differentiate between non-commercial and commercial research, e.g. if a cumulative understanding of research and development is privileged, is grounded on the assumption that a distinction between both types of activities can easily be made. Traditionally, the divide has been based on the anticipated standard sequence of activities in

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<sup>33</sup> See e.g. E R B Moore et al, 'Microbial systematics and taxonomy: relevance for a microbial commons' (2010) 161 (6) *Research in Microbiology* 430, 431.

<sup>34</sup> K Geeraerts et al, 'Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union' (*Institute for European Environmental Policy*, 10 August 2012)

[http://www.ieep.eu/assets/1227/ABS\\_FINAL\\_REPORT.PDF](http://www.ieep.eu/assets/1227/ABS_FINAL_REPORT.PDF) accessed July 2015 (hereinafter, IEEP Study), p. 186. See also K Davis et al, 'Ex situ collections and the Nagoya Protocol: A briefing on the exchange of specimens between European and Brazilian ex situ collections, and the state of the art of relevant ABS practices' (Conference Paper for the International Workshop on ‘The role to be played by biological collections under the Nagoya Protocol’, Brasilia 18-20 June 2013) [http://sectordialogues.org/sites/default/files/acoeps/documentos/background\\_paper.pdf](http://sectordialogues.org/sites/default/files/acoeps/documentos/background_paper.pdf).

<sup>35</sup> EESC, 'Opinion of the Economic and Social Committee on the 'Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - Towards a European research area' 2000/C 204/16, par 7.1.

<sup>36</sup> See on the ambiguous relationship between access (collection/taking) and utilisation Explanatory Guide to the Nagoya Protocol (n 5) 97 and Kamau (n 10) 41 and for a restrictive interpretation IEEP Report (n 34) 90. See however E C Kamau, 'Model agreements on ABS for non-commercial research and development' in E C Kamau, G Winter, P and Stoll, *Research and Development on Genetic Resources. Public Domain Approaches in Implementing the Nagoya Protocol* (Routledge 2015) who argues that basic research includes collection, identification, evaluation, characterisation etc., the added value of these activities being the revelation of “the *existence*, the *use*, and the *nature*” of our natural wealth, thus thereby expanding knowledge.

<sup>37</sup> Buck and Hamilton (n 5) 56.

the R&D chain, from basic/fundamental ('upstream') to applied ('downstream') research. However, nowadays the distinction appears blurred by developments concerning the patenting of natural phenomena and advances in genomic studies that allow for the identification of the functions of genomes at the basic research stages,<sup>38</sup> and the fact that actors which have normally been categorised as *upstream* may now also engage in commercial projects.<sup>39</sup> It has been argued that a functional distinction between non-commercial and commercial research may be better suited to deal with this changed scientific landscape: it would deduce the actor's intention to realise economic value from the fact that commercially relevant research results are privatised and conversely the actor's non-commercial intent would be deduced from the fact that research results are made public.<sup>40</sup> Besides the generalisation made in this argument, another issue arises from the possible change of intent along the value chain, when genetic resources flow from the non-commercial sector into commercial hands. The risk of a physical transfer of the actual specimen may be dealt with through material transfer agreements (MTAs),<sup>41</sup> yet physical access may not be necessary if commercially valuable information deriving from genetic material can be directly derived from the publicly available products of non-commercial research like databases and scientific publications.<sup>42</sup> If non-commercial activities were to be exempted completely from the subject-matter scope of the Protocol and the EU ABS Regulation, it would be very difficult for the provider to keep track of the use of the resource after access. Moreover, any supporting and possibly simplified treatment of non-commercial research may create a possible loophole in the ABS system.<sup>43</sup>

Secondly, when categorising activities with or without a research component, special attention should be paid to the role and activities of intermediaries in the value chain. The EU ABS Regulation explicitly recognises the role of non-commercial intermediaries for the collection and supply of genetic resources.<sup>44</sup> The activities in the initial stages of the upstream value chain appear significant to preserve the chain of information when the genetic resource or information generated by the intermediaries passes down the value chain towards an actor which can be qualified as a downstream user. This is often a non-linear process since intermediaries like *ex situ* collections frequently exchange samples with other collections.<sup>45</sup> It

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<sup>38</sup> Von Kries and Winter (n 12) 66.

<sup>39</sup> See e.g. M Tvedt, 'Beyond Nagoya. Towards a legally functional system of access and benefit sharing' in S Oberthür and G K Rosendahl, *Global Governance of Genetic Resources. Access and Benefit Sharing after the Nagoya Protocol* (Routledge 2014) 158, 167.

<sup>40</sup> Von Kries and Winter (n 12) 66. Compare Annex to GLTE Report (n 18) 17 on the characteristics of the non-commercial sector.

<sup>41</sup> See on the (limited) risk of physical transfers notably S Biber-Klemm et al, 'Access to Genetic Resources & Sharing of Benefits. ABS Program 2003 to 2010' (Swiss Academy of Sciences, 2010) [http://abs.scnat.ch/downloads/documents/ABS\\_Report2003-2010\\_SCNAT\\_web.pdf](http://abs.scnat.ch/downloads/documents/ABS_Report2003-2010_SCNAT_web.pdf), 17.

<sup>42</sup> See notably the Matrix in Biber-Klemm et al (n 41) 18-19; Tvedt (n 39) 167 and for a particular example of the use of publicly available research results and data by the commercial seed sector, R Jefferson, 'Science as Social Enterprise: The CAMBIA BiOS Initiative' (2006) 1 innovations 13.

<sup>43</sup> Article 8(a) Nagoya Protocol; Von Kries and Winter (n 12) 65; Buck and Hamilton (n 5) 59; T Dedeurwaerdere, A Broggiato and D Manou, 'Global scientific research commons under the Nagoya Protocol: governing pools of microbial genetic resources' in E C Kamau and G Winter (eds), *Common Pools of Genetic Resources. Equity and Innovation in International Biodiversity Law* (Routledge 2014) 236.

<sup>44</sup> Preamble 27 and 28 and article 5, EU ABS Regulation.

<sup>45</sup> S Biber-Klemm et al, 'Ex situ collections of plants and how they adjust to ABS conditions' in E C Kamau, G Winter and P Stoll (eds), *Research and Development on Genetic Resources. Public Domain Approaches in Implementing the Nagoya Protocol* (Routledge 2015) 209.

has been argued that the risk of information getting lost between accessors and users, requires the extension to intermediaries of the due diligence obligation to “seek, keep and transfer to subsequent users” relevant information, through extensive interpretation of the definition of utilisation or by accepting a derived duty for intermediaries.<sup>46</sup> A due diligence obligation that would stretch out to possible non-users has been read into article 5 of the EU ABS Regulation on registered collections, the selection criteria of which require, *inter alia*, standardised procedures on the exchange of samples and information with other collections, the supply of resources to third parties only with documentation and the keeping of records on all samples and information supplied to third parties.<sup>47</sup>

Lastly, it should be noted that in any discussion on the breadth of the obligations of upstream actors, there is a tension between the legal and the practical issues discussed above and the desire not to put excessive burdens on these non-commercial actors, particularly when they operate in the public interest. Various mechanisms have already been developed and implemented by the actors themselves to secure implementation of ABS obligations and to create transparency through the documentation and exchange of information on the movements of genetic resources along the value chain.<sup>48</sup> Some of these mechanisms have been analysed and described,<sup>49</sup> although the literature seems to indicate that further stakeholder input is necessary to determine to what extent ABS obligations would place additional burdens on upstream actors, compared to those that they have accepted at their own discretion.

### 3 Upstream Actors: a Brief (Factual) Overview of the Sector

Actors which are held to be typically involved in upstream activities include botanic gardens, culture collections, seed banks and other *ex situ* collections (hereafter ‘collections’).<sup>50</sup> Additionally, research institutions are believed to play an important role in the value chain. The following sections will provide a factual overview of the selected interviewees for this consultancy, as well as present findings from the interviews with regard to upstream actors’ wide range of sources to supply their collections and/or to conduct their research activities, as

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<sup>46</sup> C Godt, ‘Networks of *ex situ* collections of genetic resources’ in E C Kamau and G Winter (eds), *Common Pools of Genetic Resources. Equity and Innovation in International Biodiversity Law* (Routledge 2014) 260-261 and within the context of the EU ABS Regulation, C Godt, ‘The Multi-Level Implementation of the Nagoya Protocol in the European Union’, B Coolsaet *et al* (eds), *Implementing the Nagoya Protocol. Comparing Access and Benefit-sharing Regimes in Europe* (Martinus Nijhoff 2015) 312.

<sup>47</sup> Biber-Klemm *et al* (n 45) 222.

<sup>48</sup> E.g. the European Culture Collections’ Organisation (ECCO) CORE MAT 2003; the Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC); the Principles on Access to Genetic Resources and Benefit Sharing (‘the Principles’ for botanic gardens and herbaria); the model documents by the Consortium of European Taxonomic Facilities (CETAF); the International Plant Exchange Network (IPEN) code of conduct; OECD Best practice guidelines for Biological Resource Centres.

<sup>49</sup> E.g. Godt (n 46); Biber-Klemm *et al* (n 45); D Fritze and André Oumard, ‘*Ex situ* collections of microbes and how they adjust to ABS conditions’ in E C Kamau, G Winter and P Stoll (eds), *Research and Development on Genetic Resources. Public Domain Approaches in Implementing the Nagoya Protocol* (Routledge 2015) 226; T Dedeurwaerdere *et al*, ‘Governing Global Scientific Research Commons under the Nagoya Protocol’ in Buck, M, Morgera, E and Tsioumani, E (eds), *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective. Implications for International Law and Implementation Challenges* (Martinus Nijhoff 2013), 389.

<sup>50</sup> IEEP Report (n 34) 176.

well as wide variety of (public/private and national/ international) funding sources that are used to finance the collection and research activities.

### 3.1 Collections

Eight interviewees were selected and interviewed in their principal capacity as collection. Two of those collections are botanic gardens operating under ‘the Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions’.<sup>51</sup> One collection is a botanic garden that operates within the network under the IPEN Code of Conduct.<sup>52</sup> Two community-based, private seed archives for rare vegetables and fruits (horticultural crops) were selected and interviewed. Furthermore, a natural history museum which hosts a department of biology with, among others, a large collection of invertebrates, a culture collection and an association of zoos and aquaria were included in this consultancy.

Moreover, although the selection of interviewees was focused on a distinction between collections and research institutions, five out of ten research bodies which were part of this study, hold their own collections and therefore also directly operate – either through a separate entity or through the research institution itself – as provider of resources. These include a campus-based collections that acts as a worldwide provider for particular crops, e.g. potato, tomato, pepper and onion, a gene bank for domestic animal breeds, a germplasm collection, a university-based herbarium and a depository for local marine organisms that operates *via* the European Marine Biological Resource Centre (EMBRC).

### 3.2 Research Institutions

Nine out of ten research institutions that were interviewed for the purpose of this consultancy were part of the organisational structure of an academic institution (university). The only independent, non-profit research organisation, moreover, indicated that it often operates in collaboration with universities or other research institutions. The selected research institutions cover a very wide range of focuses within the research areas of biological, agricultural and medical sciences. These include plant sciences of an (ethno)botanical nature. Additionally, research in plant sciences may be of a more advanced biotechnological nature. Included also are zoology and animal sciences and cross-cutting research in the field of marine sciences. Lastly, two medical institutions were interviewed, which are involved in infection- and immunobiology, pharmaceutical sciences and molecular biosciences.

Furthermore, the staff of six out of eight of the aforementioned collections (section 3.1 above) is involved in activities of a taxonomic and/or phylogenetic nature.<sup>53</sup>

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<sup>51</sup> BGCI, ‘Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions’ available at [http://www.bgci.org/files/ABS/Principles\\_English.pdf](http://www.bgci.org/files/ABS/Principles_English.pdf) accessed November 2015.

<sup>52</sup> IPEN, ‘Code of Conduct for botanic gardens governing the acquisition, maintenance and supply of living plant material’ available *via* <https://www.cbd.int/abs/instruments/> accessed November 2015.

<sup>53</sup> One of the collections that states that is not involved in activities of taxonomic and/or phylogenetic nature has outsourced these research activities to a separate unit which is not included in the study. The other collection held that it did not have the capacity for taxonomic research.

***- Findings from the analysis of the data:***

- The distinction between collections and research institutions can be artificial as it was found that collections are often – although not always – hosted or closely linked to research institutions.
- Additionally, collections are often involved in basic research activities that can be similar to the research activities conducted by (biological) research departments.

### **3.3 Sources of Genetic Resources and Exchange Networks**

The interviewees were asked from where and whom their institutions obtained genetic resources. Seven out of eight collections that were interviewed in their capacity as collections and four out of four collections that are part of a research institution indicated that they collect genetic resources directly from the wild through field expeditions and requests to collectors in the country of origin. Only the culture collection held that it does not directly source resources, while it is nearly completely stocked by deposits from national and international researchers. Although incidentally research institutions may also rely on direct collections, six institutions indicated that (national and global) gene banks and other public/private *ex situ* collections are their primary source for genetic resources. Only the three research institutions that are primarily involved in ecological and botanical studies indicated they mainly use locally sourced genetic resources. Yet, only one research institution indicated that its researchers often import resources to conduct their (basic) research activities. The other two research institutions said their researchers leave the genetic resources in the place of origin or in local collections after they conclude their activities locally, due to obstacles to exports in the legislation of the country of origin or due to a lack of capacity to maintain collections in the organisation respectively.

Seventeen out of eighteen interviewees, furthermore, stated that exchanges with other actors are an important source of genetic resources. In some cases, notably with regard to networks set up by or amongst collections that support continuous and numerous exchanges (an estimated 2 million exchanges between European botanic gardens annually)<sup>54</sup> the relationships have been formalised through membership-based networks. These include: the aforementioned IPEN, a network of 500 botanic gardens and 200 individuals; the EMBRC, a research infrastructure of coastal marine biological stations and laboratories in Europe and various members-only, seed-savers' networks including amateur gardeners, organic farmers and researchers. Inter-researchers exchanges are held to be conducted on a more case-by-case basis, within a more informal exchange structure.

***- Findings from the analysis of the data:***

- Access to genetic resources abroad is more important as a source of genetic resources for collections than for research institutions. The primary source for research institutions are *ex situ* collections, including gene banks, and exchanges between researchers.

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<sup>54</sup> As indicated by one of the interviewed collections.

- The frequent exchange practices of both collections and research institutions, *within* the upstream part of the value chain, emphasise the intermediary character of almost all upstream actors and their possible role as users *and* providers.

### **3.4 Sources of Funding**

When asked about the kind (public/private) of funding institutions seek to carry out their work, seventeen interviewees indicated that they rely on a combination of public and private funding, whereas only one collection indicated that it is 100% publicly funded (although it still also relies on private fees to cover the costs of quality checks and shipping). Additionally, some interviewees, indicated that they are funded through the organisation's internal structure, notably funding streams flowing from the overarching university (which itself relied on various public and private funding sources). Public funding includes funding from regional or national governmental bodies (e.g. agricultural and economic ministries and research councils) or from the European Union (e.g. Horizon 2020). Private funding includes membership fees, entry fees to visit collections, donations, private grants and partnerships.

#### **- Findings from the analysis of the data:**

- Private funding seems to become an increasingly important source for all stakeholders, including public (non-departmental) bodies.
- Only sometimes is the main source of (private/public) funding directly linked to the private or public (legal) character of the organisation.<sup>55</sup>

## **4 The Activities of Upstream Actors**

Based on the input by the interviewees, this section describes the wide-range of genetic resources used and the activities carried out on genetic resources and traditional knowledge in the upstream sector. Additionally, this section describes the interviewees' categorisation of their activities in relation to the scope of the EU ABS Regulation and their existing due diligence practices.

### **4.1 Factual description**

When asked to what extent genetic resources are significant for the work and daily activities of the interviewees' institution and what their particular activities are in detail, the interviewees identified a broad range of resources and activities. Moreover, the majority of interviewees indicated that they work with traditional knowledge on a case-by-case basis.

#### **4.1.1 Genetic Resources**

Interviewees indicated that they conduct their daily maintenance and research activities on genetic resources from animal, plant and/or microbial origins. In addition to whole plants and trees, the most widely handled plant genetic resource is plant germplasm, being living tissue from which new plants can be grown. Interviewees referred mainly to seeds (ranging from vegetables, fruits, flowers, aquatic and ornamental plant seeds), but also to other plant parts like leaves, tree tissues, and root and bulb vegetables like potatoes and onions. Herbarium

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<sup>55</sup> E.g. one private collection stated that it relies for 70% on private funding. One of the public-sector research institutions, however, stated that it relies for 2/3 of its funding on public-private and private funding.

specimens – dead plant materials that are preserved through pressing – were, moreover, an important part of plant collections. Lastly, with regard to plant materials, one research institution referred to the use of plant fluids/extracts like apple juice and olive oil as a subject of research. The animal (vertebrates) genetic resources used include whole animals, reproductive specimens, animal tissue and DNA samples. Lastly, microorganisms (e.g. fungi, bacteria and yeasts) and invertebrate species make up an important category of resources.

#### **4.1.2 Activities Carried out on Genetic Resources**

When asked which activities their institution carry out on genetic resources, the interviewees indicated that they are involved in a wide range of activities. These include the import of resources,<sup>56</sup> quality checks and verification of identity, conservation, breeding, descriptive and comparative research, and more functional research and modification.

##### **4.1.2.1 Maintenance of Collections, Quality Checks and Breeding**

All the collections describe as their main function and activity the maintenance of their collection for conservation purposes, including storage of resources and proper preservation and the replenishment of collections through collection, exchange (often involving the import and export of genetic resources) and possibly through propagation and breeding programmes. The botanic gardens, seed archives and zoos may also rely on the aesthetic value of the specimens for public display, e.g. through horticulture activities, and may be involved in educational and public awareness activities. Lastly, two collections indicated that they conduct quality (purity) and phytopathology checks and verify the identity of materials upon acceptance, as part of their depository/conservation activities.

##### ***- Findings from the analysis of the data:***

- Preservation with the objective of long-term conservation is mainly done by well-established collections, whereas storage and preservation of genetic resources within the research departments is mainly done for the duration of the research project only.
- Activities related to conservation within collections are therefore more evolved within collections than within research departments and may include quality checks (and the verification of identity), as well as long-term conservation strategies (including propagation, breeding and the use of advanced conservation techniques).

##### **4.1.2.2 Descriptive and Comparative Research (Taxonomy and Phylogeny)**

In addition to their conservation activities, ten out of twelve collections (interviewed in their capacity of collection or as part of a research institution)<sup>57</sup> indicated that they are involved in characterisation activities. Similarly, all twelve research institutions held that characterisation (identification and description of resources) are at the basis of their research activities.

The typical characterisation activities conducted by collections include taxonomy – the identification, naming and systematic arrangement of species – and phylogeny – the study of the evolutionary development and relations of species. As explained in detail by one of the interviewed collections these basic research activities can be conducted through phenotyping

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<sup>56</sup> See on the import of resources notably section 3.3 on direct collection of resources abroad.

<sup>57</sup> See also above section 3.2.

or genotyping, or a combination of both. Whereas phenotype-based research studies the observable (physical and biochemical) characteristics of an organism, including morphology (forms and structures), descriptive genomics is the study of the organism's genetic/hereditary makeup. These pure/typical characterisation techniques are similarly used by the ecological (zoology, botany) departments of universities to identify species and map evolutionary relationships. One collection and one research institution explicitly indicate that they are still involved in purely phenotype-based research. However, both interviewees emphasise that research of such a purely morphological (non-molecular) nature is becoming more and more infrequent, due to technological advancements and the fact that molecular research may increase the chances of publication in international peer-reviewed journals.

Genomic (DNA) and transcriptomic (RNA) characterisation is also at the basis of the research activities done by the interviewed research institutions. All institutions refer in this regard to the techniques of genotyping (the analysis of particular gene patterns in DNA) and DNA sequencing (analysis of entire genomes/sequences). This genomic and phenomic data may be used for more advanced ecological research into physiological responses and for functional genomics research within the molecular biosciences disciplines (section 4.1.2.3 below).

#### **4.1.2.3 Physiology, Functional Genomics and Modification**

Four research institutions explicitly indicated that they study the physiological, biochemical and metabolic processes within organisms. The research institutions referred to their evaluations of the performance of the genetic resource in different environments (ecophysiology), its reaction to various abiotic and biotic stresses (e.g. temperatures, droughts and seasons in the case of plants) and its development of tolerances and resistances (e.g. against disease or antibiotics) as the subjects of study.

Additionally, all research institutions with the exception of one indicate that they are (on a small or large scale) involved in targeted characterisation activities. The objective of these activities is to identify genes that relate to particular traits, thereby moving beyond descriptive genomics towards functional genomics. One research institution explained that research in this regard includes forward and reverse genetics. Forwards genetics is an approach to determine an unknown gene that is responsible for a known phenotype (trait), e.g. particular milk quality or disease resistance, through the isolation of mutations within genes of interest. Reverse genetics, conversely, studies the unknown function/trait/ phenotype of a particular known gene (identified through DNA sequencing), by manipulation of the gene outside the organism (in a test tube). When the gene with the mutation is put back into the organism, researchers study how the mutation affects the organism's biological processes.

Lastly, two research institutions refer to modification techniques that are used for the cloning of genes and for further development of materials ('half materials')<sup>58</sup> that incorporate the identified (beneficial) traits. Techniques used go beyond hybridisation, forming near-introgression and recombinant inbred lines. One interviewee explained: "The materials that we develop have in their elite background part of the wild species' background to make it easier to track and trace the traits that are located on the fragments of specific wild species or

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<sup>58</sup> Wording of one of the interviewed research institutions.

to have introgressed resistance in lines. That material is then given or sold to companies in order for them to breed varieties. So we do not do actual breeding, but we do ‘pre-breeding’: researching the actual traits and developing ‘half-material’ which breeding companies can use to develop into crop varieties.”

**- Findings from the analysis of the data:**

- The descriptive and comparative characterisation activities undertaken by collections (taxonomy and phylogeny) are similar or even identical to research activities conducted within ecology, botany and zoology-focused research departments.
- Whereas particular identification techniques and notably DNA-sequencing may lie at the basis of both pure (taxonomic) characterisation and more targeted characterisation, in the latter instance the data generated is used (by, notably, researchers in the field of molecular biosciences and biotechnology) for functional genomics and pre-breeding.

#### **4.1.3 Traditional Knowledge Associated with Genetic Resources**

When asked whether traditional knowledge associated with genetic resources is of significance to the work of their institutions, the majority of interviewees indicated that they are using traditional knowledge on an occasional, non-systematic basis. Six interviewees indicated that traditional knowledge is not of relevance for their activities on genetic resources. Various reasons were put forward in this regard: e.g. while genetic resources are used as isolated samples only, traditional knowledge is considered to be biased and lacking proof or considered to be part of general public knowledge. Lastly, one collection presumed farmers’ knowledge to fall outside the scope of the Protocol and EU ABS Regulation, whereas, conversely, such knowledge was found to be an important source of traditional knowledge by four interviewees.<sup>59</sup> Three interviewees, one collection and two research institutions, indicated that the collection and stocktaking of local and indigenous knowledge about (the specific qualities of) genetic resources is a significant part of their daily work as collections and ethnobotanists. Those interviewees that (occasionally or systematically) use traditional knowledge indicated that it is mainly used to identify interesting resources and the beneficial traits within resources: e.g. metabolic, antimicrobial or pesticide properties, resistances, tastes and health benefits.

**- Findings from the analysis of the data:**

- Few actors are very actively involved in the use of traditional knowledge associated with genetic resources, although the majority of interviewees do use traditional knowledge on an occasional, non-systematic basis.
- In the absence of a clear definition in the Nagoya Protocol and the EU ABS Regulation of traditional knowledge associated with genetic resources, the interviewees differ in their understanding of what traditional knowledge relevant for the purposes of complying with the Nagoya Protocol entails.

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<sup>59</sup> One collection and three research institutions.

## **4.2 Categorisation of upstream activities under the EU ABS Regulation: research and R&D**

In addition to providing a factual description of their activities on genetic resources, the interviewees were asked which of their activities they considered having a research or R&D dimension. Eight interviewees, all collections, explicitly or implicitly identified activities that they believed not to qualify as research within the meaning of the EU ABS Regulation. However, categorisation by interviewees mainly focussed on the distinction between research and R&D, and the direct or indirect applied potential of academic research.

### **4.2.1 Activities without a research or R&D dimension**

Three collections explicitly referred to their horticulture activities and the public display of animals, as well as the educational activities within the collections, as activities at the very beginning of the upstream value chain may not be regarded as research on genetic resources. Additionally, all activities involved in the maintenance of collections and conservation of genetic resources were explicitly mentioned by one of the collections as potentially ‘non-research’. Similarly, it follows from the answers of one of the botanic gardens, that the garden chooses to limit transfers of resources to researchers to avoid involvement in ABS issues, that it does not believe its conservation activities as such qualify as ‘research’. Moreover, closely related to conservation and the maintenance of collections are the quality checks, including the verification of a genetic resource’s supposed identity. Although the techniques used include DNA-sequencing, they are separated from taxonomic research.

Closely related to preservation of genetic resources are, furthermore, the zoological breeding programs by zoos with the aim of *ex situ* conservation. These breeding activities differ from the creation of domestic hybrids (breeding), e.g. domestic animal and plant breeds and hybrid yeasts, although this process to improve populations step by step over time was also put forward as possibly lacking a research or R&D dimension.<sup>60</sup>

#### **- Findings from the analysis of the data:**

- Educational and horticultural activities are regarded mainly as activities that indirectly concern the biological specimen rather than a research activity on the genetic resource. Analogies may be drawn with the teaching activities of academic institutions; an activity that was put forward as potentially non-research during the Workshop.
- Everyday conservation activities (preservation, quality checks and the maintenance of collections) were, moreover, considered to possibly be lacking a research dimension.

### **4.2.2 Fundamental/basic and applied research**

Ten out of twelve collections interviewed in their capacity as collection or as part of a research institution (section 4.1.2.2) and seven research institutions explicitly indicated that they are involved in basic or fundamental research activities, although research institutions had more difficulty in drawing a distinction between their fundamental and applied research activities. Conversely, only one collection indicates that it incidentally conducts research that

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<sup>60</sup> As put forward by one of the interviewed research institutions and also follows from the input from the ABS Workshop in Brussels on 13-10-2015.

directly aims to answer an applied question (agronomic assessments), whereas nine out of ten research institutions stated that they are involved in applied research.

Activities that are put forward as being of a fundamental nature are the pure characterisation activities: descriptive (taxonomy) and comparative (phylogeny) research that could be based on both genomic and phenomic data. Additionally, one of the research institutions refers to cloning. However, several interviewees noted that it may become increasingly difficult to distinguish fundamental research activities from applied research, due to developments in research technologies that may directly attribute commercial value to fundamental results. On the one hand, as noted by one of the collections, “taxonomy is not merely a scientist looking at a plant under a microscope anymore.” On the other hand, as explained by one of the research institutions, the research departments of commercial companies (e.g. the seed industry) are evolving to allow for the direct use of basic knowledge for the making of markers that can be used in commercial breeding programs. Two collections, moreover, indicated that changing funding streams also demand fundamentally non-commercial actors like botanic gardens to explore the applied value of their basic research activities. The decreasing availability of public funding and the changing focus of grants, e.g. allocation on the basis of potential for poverty alleviation and food security, require a more applied focus and closer collaboration with private actors.

Activities that are categorised as potentially being of an applied or commercial nature include the breeding of new varieties, the development of half-materials to facilitate commercial breeding, targeted characterisation activities, e.g. based on functional genomics techniques to identify particular traits that are valuable notably for pharmaceutical and agricultural purposes and biotechnological activities. Three research institutions indicated that they exploit the applied value of their research outputs themselves through the commercial arms of their universities or through start-up companies. In other instances, research activities were commissioned by private actors or were embedded in consortia or other public-private partnership arrangements.

Moreover, even when research is not initially driven by private interests, it may still have applied/commercial value and a change of intent may occur if interesting discoveries are made during the research project. Nine research institutions indicated that they (sometimes or often) seek intellectual property rights (IPR) to allow for commercialisation through licensing agreements by third parties. However, the mere existence or absence of IPRs may not be a sufficient criterion to distinguish between basic/applied and non-commercial/commercial research, due to the legislative and practical considerations that may determine whether IPRs are sought. For instance, one research institution indicated that IPRs are always sought, while “it is part of our remit as a public sector body in the UK to safeguard intellectual property.” However, realisation of applied value will in any case be dependent on third parties and may happen only in a fraction of cases. Also, the one research institution emphasised that IPRs may be sought by academic institutions to ensure (rather than limit) widespread use, by preventing others from patenting findings. Conversely, the results of applied research with commercial value may not be patented due to the high costs of seeking IPRs or due to legislative constraints.

***- Findings from the analysis of the data:***

- Most collections are only involved in basic (descriptive and comparative) research activities. Such activities (e.g. DNA-sequencing) may also be conducted by academic institutions, but often only as a basis for more (applied) genomic research.
- Interviewees, notably research institutions, which conduct both fundamental and applied research activities, have more difficulty drawing a clear distinction between the two. In all events, the distinction may in the future become as difficult with regard to the activities of collections, which operate with an increasingly applied focus.
- The distinction that is drawn between basic and applied research seems to be based mostly on the interviewees' awareness of, and active involvement in, the application and exploitation of their research results for commercial purposes.
- IPRs are used to safeguard commercial value. However, due to practical and legal considerations that may be equally important to determine the reasons why IPRs are sought, the existence of IPRs may not be a sufficient basis for determining whether research is basic or applied.

**4.2.3 Publication of research results and (genetic) data**

In addition to the direct links between upstream and downstream actors established through various collaboration forms, some interviewees explicitly recognise that the downstream sector may indirectly benefit from the (basic and applied) research done by collections and research institutions through the publication of results. Interviewees hold that the most important platforms for publication of specific results are scientific (online) journals. Basic taxonomic data is, furthermore, often made available by collections through internal or external (e.g. the Global Biodiversity Information Facility – GBIF) databases. However, some collections and most research institutions are still working on improving document management.<sup>61</sup> Only one research institution states that publication of results may not always be their primary ambition, as the commercial benefits may outweigh the public benefits involved. All other interviewees state that publication into the public domain is their principle objective. When results are generated in collaboration with private partners, they may, however, be kept secret during an embargo period (e.g. of six months) during which IPRs may be sought.<sup>62</sup>

As emphasised by one research institution, the precise commercial value of publications and publicly available data is often unknown to the upstream actor as further uses are beyond their control. Two collections suggest that the commercial value of taxonomic and phylogenetic data is more obscure, although one of them believes genomic data to be more relevant than morphological data (DNA sequences over the description of a flower colour).<sup>63</sup>

***- Findings from the analysis of the data:***

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<sup>61</sup> One research institution, which holds its own collection, notes that document management is often well-developed by collections, but more dispersed and still paper-based in the case of research groups.

<sup>62</sup> As noted by two of the interviewed research institutions.

<sup>63</sup> See similarly IEEP Report (n 34) 192.

- The published results of functional (genomic) research in the field of e.g. agricultural sciences and pharmaceutical sciences are more likely to have applied value than taxonomic data, although this may change in light of evolving technologies.
- It is unclear to what extent the interviewees take into consideration the potential commercial value of their research publications when distinguishing between research with and without an applied value (as they may be unaware of the realisation of commercial value further down the value chain).
- The increased use by interviewees of intangible materials (bioinformatics) generated by colleagues rather than physical material appears to generate doubts as to whether sequence data falls within the subject-matter scope of the EU ABS Regulation. This question is particularly significant for the research field of synthetic biology, which relies heavily on generated data.

### **4.3 Existing upstream practices related to due diligence and benefit-sharing**

When asked which information interviewees kept together with the genetic resources and shared with others, all but one of the interviewees indicated that they are already involved in some form of data management and sharing. Interviewees, however, differed significantly in the type and amount of information that they share with recipients of genetic resources. Information on the origin of the resource (e.g. place and date of collection) was mentioned most frequently. Additionally, data on the make-up of the genetic resource itself, e.g. phenotype- and genotype-data and information on modifications is often shared directly with the recipient or shared through publicly available databases. However, only five interviewees indicated that they directly share (restricted or comprehensive) ABS-related information on permits and terms of use, PIC and MAT, and only two interviewees explicitly stated that they share such information upon request. Some collections referenced the best-practice rules for the acquisition, use and supply of genetic resources within their formalised exchange networks, which often demand more comprehensive sharing of information in this regard. An example is the use of numbers within the ‘IPEN,’ which correspond to restrictions on use. Other collections indicated that they are currently actively working on the integration of terms of use into their document management systems. One collection, however, underlined that information-sharing on ABS terms is complicated by the fact that hundreds of specimens may be obtained under a single agreement, which requires substantial rethinking of data management processes. Moreover, one research institution emphasised that research institutions are often lacking document management system and are unaware of ABS obligations. The type and amount of information shared upon exchange of genetic resources is mirrored by the type and amount of information shared upon publication of data (which then often requires for the genetic resource to be made available to allow for repetition and verification of research). This information is mostly of a factual nature only. Even where a proper documentation system is in place, e.g. through the documenting of *publicly available* specimen labels, one interviewee stated that he is concerned about completing the documentation because he is unsure about how to do it in a way that complies with ABS rules

in that regard.<sup>64</sup> The keeping and transferring of ABS information on acquired traditional knowledge is more limited and on a more *ad hoc* basis.

In addition to the interviewees' existing practices to comply with national ABS laws upon access and to keep and transfer records as proof of compliance, most interviewees indicated that they are already involved in benefit-sharing. One collection illustrated that such benefit-sharing in the case of collections may involve capacity building, providing formal and informal training (e.g. on how to do collections), as well as providing access to databases and research results. It also indicated that arrangements are of an informal, good-practice nature, under the framework of long-lasting collaborations with partner institutions. Likewise, several research institutions indicated that they share benefits through joint publications and PhD programs. Moreover, one research institution held its activities often to be directly targeted to provide benefits in the country of origin, to allow for the identification and domestication of interesting varieties.

**- Findings from the analysis of the data:**

- The current due diligence practices seem to be directly related to the awareness of interviewees about ABS rules. Awareness is generally higher in collections, so these actors may thus often be involved in more institutionalised (best) practices.
- Information on the origin of the genetic resource and its (genetic) make-up is often shared, whereas information-sharing is far more limited with regard to PIC and MAT.
- In the case of collections, the absence of sharing of particular types of information, e.g. on the permit, may be related to the practical (administrative) issues in light of the large number of exchanges between collections. In the case of research institutions, the limitations in amount and type of information shared is more likely to be connected to the general lack of awareness about ABS obligations among researchers.
- Most interviewees indicate that they are already involved in benefit-sharing practices. Such practices are based upon long-lasting collaborations with partners in the country of origin, which follow a win-win logic: the exchange of resources upon the exchange of (mostly non-monetary) benefits.<sup>65</sup>

## **5 Issues for Clarification with Regard to the Activities of Upstream Actors**

When asked whether they considered their activities to be subject to the Nagoya Protocol as implemented by the EU, ten interviewees had great difficulty distinguishing between the obligations under the EU ABS Regulation and the obligations under the Nagoya Protocol as implemented in the provider countries. The obligation to follow national laws upon access through the establishment of PIC and MAT and to share (monetary and non-monetary) benefits, were among the most important obligations identified. Only nine out of eighteen

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<sup>64</sup> As put forward by one of the interviewed collections and also follows from the input from the Workshop, Brussels, 13-10-2015.

<sup>65</sup> Note, however, that some actors during the Brussels Workshop expressed concerns that formalisation of benefit-sharing obligations could prevent good-faith based cooperation with partners and could let benefits flow to the (wrong) authorities.

interviewees identified the formal due diligence obligation to keep and transfer information as a separate obligation.<sup>66</sup>

This section identifies the different activities that the interviewees consider potentially falling outside the scope of the EU ABS Regulation, their understanding of due diligence obligations under the EU ABS Regulation and the (practical) difficulties they encounter in seeking compliance with the obligations, as well as other general issues in the implementation of ABS laws. It must be noted that the interviewees differed in their beliefs as to who should clarify their doubts and address their problems, with answers ranging from the EU (Commission) to national authorities or their own superiors (e.g. university board).

## **5.1 Issues in relation to compliance with the Nagoya Protocol and the EU ABS Regulation**

### **5.1.1 The Scope**

Various interviewees seem to have doubts about the subject-matter scope of the EU ABS Regulation, in particular with regard to what the notion of utilisation applies to: e.g. whether bioinformatics generated for biosynthetic research would fall within the scope, whether the Protocol applied to bred varieties which may only have a small fraction of wild material in them, and which crops are covered by the EU ABS Regulation and which by the ITPGRFA.

Interviewees also seem to have doubts as to whether the particular activities that upstream actors perform on these materials fall within the scope of the EU ABS Regulation. Three collections and one research institution expressly indicated that they believe that all of their activities were not intended to be officially covered by the definition of utilisation (research and development) under ABS legislations.<sup>67</sup> Other interviewees questioned whether some specific activities at the beginning of the chain fall within the scope of the EU ABS Regulation. These activities firstly include those activities discussed above under section 4.2.1 that possibly lack a research or R&D dimension, namely collection, conservation and related quality checks, and propagation and hybridisation (breeding), notably for conservation purposes. Secondly, basic (descriptive and comparative) research activities, taxonomy and phylogeny, were put forward as being of such a fundamental nature that they may not qualify as utilisation or R&D.

#### **5.1.1.1 Collection, conservation and related quality checks**

Four collections, interviewed in their capacity as collection or as part of a research institution, explicitly questioned whether (or presumed that)<sup>68</sup> conservation and the proper maintenance of collections to ensure *ex situ* conservation fell outside the scope of the EU ABS Regulation. Conversely, two collections in principle believed all of their activities as collections (including conservation) to be falling within the scope. In particular, one collection found that: “Everything, even conservation and maintenance, could be regarded as use of genetic

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<sup>66</sup> See above section 1.2 on the approach taken with regard to those that could not identify the due diligence obligation and reporting requirements (Articles 4 and 7 EU ABS Regulation).

<sup>67</sup> One research institution held: “We do not consider ourselves users of genetic material. Of course we are using the material, but not – I think – within the meaning of the ABS legislation.”

<sup>68</sup> See above section 4.2.1.

resources.” The interviewee did, however, emphasise the practical value of exempting conservation activities from the scope, as this would allow collections to accept for conservation only genetic resources from an unknown or uncertain source. The risk of loss of genetic resources, running counter to the conservation objectives of the international ABS regime, was noted by several interviewees as an important concern. However, one collection disputed the usefulness of such an exemption, due to the implied restriction on the freedom to operate in absence of paperwork:

*“If conservation would be out of the scope, we would be able to keep specimens that are donated to us, but of which the origin is unknown. However, we could not ‘use’ them and we would not be able to transfer them for further use. The question then is: why keep them? We are not a cabinet of curiosia. The collections that we have are a tool for further research. We are not keeping materials for keeping’s sake, like in a museum only.”*

Additionally, one collection stated that it at first believed all its depository activities, including extensive quality checks (and the verification of identity) to fall outside the scope of the EU ABS Regulation. While such checks do involve the “cutting and opening up” of materials – although with the objective of verifying identity – it considered that guidance is needed in order to know whether such activities can be considered utilisation.

***- Findings from the analysis of the data:***

- The fact that not all interviewees (notably collections) had doubts as to whether conservation and collection maintenance fall within the scope, may be explained by interviewees' understanding that such activities are not (active) *use* or lack a research dimension.
- Practical considerations, such as a collection’s ability to conserve resources from unknown sources, seem to underpin the argument that conservation activities should be considered outside the scope.
- Practical arguments may, however, be more important for collections that have separated conservation activities from research completely – as the argument was put forward by the collections that do not carry out basic research activities – while it may be less relevant to collections with a conservation *and research* focus.

**5.1.1.2 Propagation and hybridisation (breeding)**

The propagation or multiplication of specific genetic resources, with the purpose of increasing their number, was assumed by one collection to be falling outside the scope (‘non-use’), whereas, conversely, these activities were expected to fall within the EU ABS Regulation’s scope by another collection. Likewise, interviewees' opinions diverged as to whether the multiplication of resources through the creation of hybrids (breeding) fell within the scope of the EU ABS Regulation. (Commercial) breeding was put forward by one collection and one research institution as a clear instance of use or R&D, drawing analogies with the downstream sector. However, another research institution questioned whether breeding as the “step-by-step improvement of populations” could indeed be qualified as R&D.

Breeding activities for the development of domestic plant and animal varieties were set aside from breeding programs in zoos. One interviewee held that, whereas in the first instance the selection of genetic materials was aimed at the development (over time) of varieties with beneficial traits, in the instance of zoos the selection of animals for breeding only aims to prevent inbreeding, thus contributing to the conservation of genetic diversity. He thus argued that breeding in zoos is (even) more likely not to be categorised as R&D.

**- Findings from the analysis of the data:**

- The interviewees differed significantly in their understanding of whether propagation and hybridisation could or not be regarded as R&D.
- The breeding of plants and animals for domestication should be distinguished from breeding for conservation only, notably in zoos. Both the breeding and the underlying genetic identification and selection serves different purposes in these instances.

**5.1.1.3 Fundamental Research: Taxonomy and Phylogeny**

The collections that are involved in fundamental research activities and one of the research institutions have doubts as to whether taxonomy and phylogeny fall within the scope of the EU ABS Regulation. The identification and description of genetic resources (taxonomy) and the comparing of resources to find relationships and evolutionary trees (phylogeny) were believed to be of a purely fundamental nature. Such research would not have a development objective and may not be qualified as *use*, while the fundamental research activities only study and do not modify the genetic resources. Conversely, two research institutions and one collection saw both taxonomy and phylogeny as a clear form of *research* covered under the EU ABS Regulation. Another collection believed that taxonomy possibly falls out of the scope, but phylogeny is clearly within it. This collection also suggested distinguishing in this regard between descriptions and comparisons that are based on genomic data (DNA sequencing and barcoding) and basic research that is of a morphological nature only (based on phenotypic expressions). Since morphological research (although decreasing in relevance) does not study the genetic make-up of resources, it would be more likely not to be qualified as research on genetic resources.

**- Findings from the analysis of the data:**

- Interviewees greatly differed in their understanding of whether taxonomy and phylogeny fall within or outside the scope. Some drew distinctions between morphological (out the scope) and genomic-based (possibly within the scope) fundamental research.
- Some interviewees believed basic research activities to be so fundamental that they cannot be considered as R&D, as researchers would only describe the resource but not modify or *use* it.
- More important than the conceptual discussion, however, seems to be the practical concerns of collections regarding the inclusion of taxonomy and phylogeny within the scope of the EU ABS Regulation. Due to fast evolving technologies, taxonomic research and DNA sequencing take place on a large scale with large amounts of

genetic resources being exchanged for this purpose. This volume of activities explains concerns of unmanageable bureaucracy arising from ABS regulation.

#### **5.1.1.4 Being part of the due diligence chain and preserving the freedom to operate**

The doubts about which activities fall within the scope of the EU ABS Regulation that are listed above were voiced by collections and by one research institution, who held that its institution's fundamental research activities were 100% comparable to the work of natural collections. Doubts with regard to whether particular activities fell within the scope of the EU ABS Regulation were not raised as primary concerns by the research institutions, except for the example of domestic breeding by one research institution. Many researchers emphasised the difficult distinctions between commercial/non-commercial research within most contemporary research departments and their increasingly close links to the downstream sector. They thus held that they are affected by the Protocol and EU ABS Regulation, since they could not work with or provide materials to commercial actors, if they did not exercise due diligence for their materials and activities. This is confirmed by one additional interviewee from a commercial company who was interviewed for the consultancy.

*“If a non-commercial institute wants to collaborate with a commercial institution, they must exercise due diligence or otherwise we would not use their materials and knowledge. What purpose would the research of non-commercial institutes serve if knowledge is trapped in non-commercial institutions and cannot be used for societal purposes?”*

This interviewee, furthermore indicated that it is actively involved in increasing awareness among the research community to allow for future cooperation. However, awareness is still limited and he believes that a top-down approach, in terms of commitment at management level, may be needed to ensure compliance in the upstream sector. Exercising due diligence, therefore, as one research institution put it, “allows researchers freedom to operate.” The “freedom to operate” does not only apply now, but also extends to the future. Two of the interviewed collections, which are currently cooperating directly with the downstream to a lesser extent, further indicated that the sector cannot predict future uses.

*“You may not always ‘use’ the resource upon accession, but it may be used in the future. I can imagine that bacteria in the guts of flies that we have in our collection may be studied when technologies evolve to find information on how to control pests, which is applied research. This may happen tomorrow or within five, ten or twenty years, but the potential will always remain. I can thus see the EU ABS Regulation and all the due diligence obligations working across the entire field, unless we can anticipate the kind of use.”*

In fact, one research institution argued that there would be a significant danger in exempting part of the value chain from formal due diligence requirements, while the actors (especially those researchers that are less aware of the obligations) could in this way unknowingly greatly restrict their freedom to operate (alone or in cooperation) in the future. However, two collections held that the actors' inability to predict future uses may not be a good enough reason to control the entire chain in light of the associated bureaucratic burdens, which may thus require substantial rethinking of the process.

***- Findings from the analysis of the data:***

- Whether or not they would be subject to formal due diligence obligations under the EU ABS Regulation is not the most pressing concern for interviewees that are already actively cooperating with, and providing resources to, commercial actors, as commercial actors demand from non-commercial actors to exercise (voluntarily) due diligence with regard to their materials.
- Collections and researchers that are not yet actively cooperating with, and providing resources to, commercial actors cannot, moreover, predict future uses. They feel they should thus equally exercise (voluntarily) due diligence to ensure freedom to operate.
- A risk lies in the partial exemption of less aware stakeholders from the scope of the EU ABS Regulation, as they may not be inclined to exercise voluntarily due diligence and may thus be restricted in the future in their use of materials for activities that would require retrieving the relevant due diligence paper trail.
- Awareness is currently still lacking in the research community and a top-down approach (through commitment at management level, or possibly through legislation) may be needed to ensure compliance along the chain, to ensure freedom to operate.

## **5.2 Due diligence requirements**

This section describes the interviewees' general understanding of due diligence obligations, their voluntary due diligence practices, and the challenges that they experience or foresee when seeking to comply with the due diligence obligation and the reporting requirements, as well as any other issues that interviewees experience in ensuring compliance with (national) ABS legislations.

### **5.2.1 Understanding of the due diligence obligations**

When asked which obligations arising from the EU ABS Regulation they considered applicable to their institution, only nine interviewees identified due diligence as a self-standing, binding obligation under the EU ABS Regulation.<sup>69</sup> However, some interviewees that lacked an understanding of these legal obligations did recognise the importance of keeping, sharing and tracking information to allow for cooperation with those parties that they know to be subject to ABS obligations or to preserve freedom to operate in the future (see section 5.1.1.4 above). Only one research institution recognised that formalisation of the due diligence obligation would likely affect the length of time for which records have to be stored, although it is less likely to affect the amount of data that is documented. Moreover, only three interviewees, all collections, identified the due diligence declaration as an obligation that could potentially apply to them.

***- Findings from the analysis of the data:***

- Awareness is lacking on the due diligence obligations under the EU ABS Regulation, although many interviewees were already aware or were becoming increasingly aware about the importance of keeping and transferring documents, under pressure from the research community and their (commercial) partners.

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<sup>69</sup> Four collections and five research institutions.

- The interviewees were generally unaware of the requirement of a due diligence declaration. Clear guidance seems to be needed as to whether and how the reporting requirements will apply to the non-commercial sector.

### **5.2.2 Challenges in exercising due diligence and reporting**

When asked whether the obligations stemming from the EU ABS Regulation change their institution's standard ABS procedures and whether they experience any uncertainties with regard to the obligations under the EU ABS Regulation, several interviewees emphasised difficulties in accessing appropriate information on national ABS legislation. Seven interviewees highlighted the mal-functioning of the international ABS Clearing House and of national focal points. Several others pointed to problems in approaching the right authorities upon access to receive proper paperwork.

Similarly, when asked whether the obligations stemming from the EU ABS Regulation change their institution's standard procedures with regards to access to genetic resources, both those interviewees that were aware of the reporting requirements under the EU ABS Regulation, as well as those interviewees that were informed by the interviewer about the declaration, held it to be an additional and potentially significant administrative burden. Several interviewees noted that to the extent they would be subject to the reporting requirements, they would need help in managing and easing the administrative burden, which would require substantial financial resources and would put great pressure on their small and increasingly limited economic capacities.

#### **5.2.2.1 Demonstrating compliance: The standard of proof**

A pressing area of uncertainty that was identified by the interviewees concerns the standard of proof for due diligence. As illustrated by one collection:

*“We are planning a new research project, which involves collecting material in Tanzania, Kenya, France, Italy and South Africa. I checked the websites of the [international] ABS Clearing House: the Tanzanian email address does not exist, the Kenyan email address is not listed and the Italian and South African contact persons did not answer. What do we do? Do we abandon research in Tanzania, because the person in charge does not have a proper email address? Or, is it sufficient for us to work with our local partners to make an agreement with them as evidence, in addition to keeping track of the steps we have taken to try to obtain PIC? In other words, when have I done enough to show due diligence?”*

#### **5.2.2.2 Facilitating compliance: capacity building and best practices**

Additionally, to prevent additional administrative burdens, the interviewees that are currently involved in ABS documentation are interested in exploring whether existing practices, such as the CEFTA Code of Conduct and Best Practice for Access and Benefit-Sharing<sup>70</sup> that was sent to us by two interviewees, could be recognised as best practices. In addition, they mentioned that the reporting requirements would need to take account of the large number of exchanges in certain sectors, notably between botanic gardens and other natural collections.

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<sup>70</sup> E.g. the CEFTA Code of Conduct and Best Practice for Access and Benefit-Sharing, available at <<https://www.cbd.int/abs/submissions/icnp-3/EU-Taxonomic-practices.pdf>> accessed October 2015.

Lastly, where due diligence practices are currently lacking, interviewees are looking for capacity-building opportunities, e.g. through the creation of a platform that allows for the exchange of experiences between actors.

**- Findings from the analysis of the data:**

- The main challenges in compliance with the obligations under the EU ABS Regulation are of a practical nature. They concern the standard of proof of due diligence in absence of clear, step-by-step guidance on how to follow national ABS laws and the implementation of obligations concerning document management systems.
- In order to overcome practical challenges with regard to compliance with the EU ABS Regulation, interviewees emphasise the need to work towards a better functioning international ABS Clearing House, to recognise existing best practices and to explore possibilities for (publicly funded) capacity building and the sharing of experiences.

### **5.3 Other issues identified through the consultancy**

When asked whether the interviewees experience any uncertainties with regard to their obligations under the EU ABS Regulation or whether they foresee any other issues in the implementation of their obligations, many interviewees reported on increased difficulties in access to genetic resources for research purposes in the countries of origin. These difficulties, that one research institution indicated that it had already been experiencing since the entry into force of the CBD, were felt to potentially stop *ex situ* conservation and research in certain fields, thereby undermining the realisation of the objectives of the CBD. Although these issues go beyond the mandate of this consultancy it must, once again, be noted that many interviewees did not fully grasp the distinction between provider and user country legislations on ABS. Doubts regarding the subject-matter scope have therefore often been raised in light of the obligations under access laws (often inhibiting access), rather than the due diligence and reporting obligations under the EU ABS Regulation.

**- Findings from the analysis of the data:**

- Guidance from the EU on the subject-matter scope must be developed keeping in mind that users are interested in better access to genetic resources in countries of origin for non-commercial research purposes.

## **6 Conclusion**

### **6.1 The Definition of Utilisation**

This consultancy primarily sought to investigate the questions of upstream actors regarding the subject-matter scope of the Nagoya Protocol and the EU ABS Regulation: the definition

of *utilisation* in relation to the particular activities that are conducted in the upstream part of the value chain. Accordingly, eighteen interviewees working in the upstream part of the value chain were asked about their particular activities (section 4.1.2), which activities they believed to have a research and/or R&D dimension (section 4.2) and whether they considered their activities to be subject to the obligations of the EU ABS Regulation or whether they had questions in this regard (section 5.1.1). Besides educational and horticultural activities that are regarded mainly as activities that indirectly concern the biological specimen rather than a research activity on the genetic resource (section 4.2.1), the interviews confirmed that questions regarding the subject-matter scope of the EU ABS Regulation (the definition of *utilisation*) mainly concern activities in the early stages of the upstream section of the value chain. Put forward by interviewees to potentially be falling outside the scope of the EU ABS Regulation as they are lacking a research and/or R&D dimension, are everyday **conservation activities** like preservation, quality checks and maintenance of collections (sections 4.2.1 and 5.1.1.1). However, in most cases these activities are closely linked to research and it has been indicated by some interviewees that it is impossible to predict if and when genetic resources that are now only conserved, will be *used* (for research and/or for R&D purposes) in the near or distant future (section 5.1.1.4). Furthermore, some interviewees argued that **breeding** activities might lack a research and/or R&D dimension and would therefore possibly fall outside the subject-matter scope of the EU ABS Regulation (sections 4.2.1 and 5.1.1.2). However, the interviewees differed significantly in their understanding of whether propagation and hybridisation for the breeding of plants and animals for domestication could or not be regarded as R&D. These activities (and the related work on genetics) were, moreover, distinguished from breeding for conservation purposes only, notably in zoos, which is held to be less likely to be categorised as research and/or R&D.

In addition to conservation-related activities, fundamental research activities were also identified by some interviewees as potentially falling outside the subject-matter scope of the EU ABS Regulation (sections 4.2.2 and 5.1.1.3). The interviewees did not seem to share the interpretation put forward in the literature that **taxonomic** activities would possibly not qualify as research. However, some did emphasise the (purely) fundamental nature of such activities, which would be unlikely to (directly) lead to development (no R&D dimension). In other words, taxonomic research only describes the resource to increase scientific knowledge and would therefore possibly not be considered as *use*. Interviewees made similar observations regarding **phylogeny**, the mapping of evolutionary trees, an area of fundamental research that is underexplored in the legal literature. Likewise absent from the legal analyses is the distinction that was emphasised by the interviewees between taxonomic and/or phylogenetic research that is phenotype-based and such research that is genotype-based (see also in more detail section 4.1.2.2). Some interviewees believed that purely morphological descriptions and comparisons (research on the bases of, e.g., colours, hairs and structures) are more likely to fall outside the EU ABS Regulation's scope, as it does not involve the study of the organism's genetic make-up (section 5.1.1.3). However, these interviewees also acknowledged that purely morphological research is becoming increasingly rare and most basic research combines such research with fundamental genomics.

The discrepancies between the definition of R&D that follows from the legal analysis above (section 2.3), whereby only upstream activities without *any* research component would fall outside the scope, and the interpretation of some interviewees who indicated that everyday conservation activities and possibly particular breeding activities and fundamental research could be excluded from the scope, may, however, not only be attributed to a different understanding of R&D and use. Practical considerations were frequently put forward, notably interviewees' concerns about the need to refuse genetic resources for which it would be more difficult to ensure due diligence, to the detriment of their conservation (section 5.1.1.1) and the administrative burdens that would derive from highly frequent activities of conservation, breeding for conservation, taxonomy and phylogeny (sections 5.1.1.1, 5.1.1.2, 5.1.1.3 and also section 2.4 above). These practical concerns, rather than a clear-cut understanding of the nature (research and/or R&D) of their conservation and fundamental research activities, appear more significant in explaining the position of interviewees with limited resources (mostly collections).

The interviews confirm that questions regarding the subject-matter scope of the EU ABS Regulation (and thus the definition of utilisation) are mainly raised by actors that perform everyday conservation activities and fundamental research activities as their main activities and not merely as a basis for more advanced, applied research (section 4.1.2.1, 4.1.2.3 and 4.2.2, but also section 2.3). Those actors are primarily collections, although the distinction between collections and research institutions can be blurred, as collections are often – although not always – hosted or closely linked to research institutions and are often involved in basic research activities that can be similar to the research activities conducted by (biological) research departments (section 3.1 and 3.2). However, generally, research departments, e.g. in the field of plant sciences and pharmacology, rely on fundamental data (e.g. DNA sequences) of more targeted characterisation (functional genomics), modification and pre-breeding (sections 4.1.2.3 and 4.2.2). This also explains why research institutions were less inclined to suggest that (basic) research activities could fall outside of the R&D definition (section 5.1.1.4). This seems to confirm the finding from the legal analysis about the increasingly blurred lines between non-commercial/commercial, basic/applied research (sections 4.2.2 and 4.2.3), so that it may be virtually impossible for upstream actors to pinpoint activities without any (potential) commercial value. When distinctions were drawn, they seem to be based on the interviewees' awareness of, and active involvement in, the direct application and exploitation of their research results for commercial purposes (section 4.2.2). Commercial exploitation may be done by third parties through licensing agreements that allow for the use of IPRs that are sought by research institutions. However, practical and legal considerations may also be important reasons why IPRs are or are not sought. One interviewee indicated that he seeks IPRs to prevent others from privatising research findings: he was therefore seeking IPRs to ensure widespread use (section 4.2.2). The data thus confirms that the existence of IPRs may not be a sufficient basis for determining whether research is commercial or non-commercial (also section 2.4).

## **6.2 Current Practices**

Another aim of this consultancy was to investigate how the EU ABS Regulation, notably its due diligence obligation (article 4) and the due diligence declaration (article 7), is likely to impact on, by changing standard procedures of, upstream actors, in light of their existing practices related to due diligence and benefit-sharing . With regard to current practices, it has emerged that information on the origin of the genetic resource and its (genetic) make-up is often shared, whereas information sharing is far more limited with regard to PIC and MAT (section 4.3). In the case of collections, the absence of sharing of particular types of information, e.g. on the permit, may be related to the practical, administrative issues in light of the large number of exchanges between collections and the fact that hundreds of specimens may be collected under a single agreement, raising problems of document management. In the case of research institutions, the limitations in amount and type of information shared is more likely to be connected to the general lack of awareness about ABS obligations among researchers (section 4.3).

Some interviewees, however, held that they already exercise due diligence (voluntarily) or are actively working towards exercising due diligence (section 5.1.1.4). They are under pressure to do so by their commercial partners that demand from all actors in the value chain to comply with ABS laws, namely to keep and transfer all necessary paperwork. This finding emphasises the importance for all actors to work together to preserve the chain of information (also section 2.4 above), to preserve for themselves and their partners freedom to operate. Although collections are currently, to some extent, operating as entities that are separated from the downstream sector, they indicated that they cannot predict future uses (section 5.1.1.4). Like universities, they are increasingly relying on the applied value of their research to attract (public and private) funding streams (section 3.4 and 4.2.2). Collections thus acknowledge that they also exercise (voluntarily) due diligence to allow themselves freedom to operate and cooperate with others in the near and distant future. In addition, most interviewees also indicated that they are already involved in benefit-sharing practices (section 4.3). Such practices are based upon long-lasting collaborations with partners in countries of origin, which follow a win-win logic: the exchange of resources upon the exchange of (mostly non-monetary) benefits.

## **6.3 Issues in Relation to Compliance**

Overall, questions on the subject-matter scope of the EU ABS Regulation appear likely to become increasingly less important in the future in the upstream section of the value chain, as dividing lines between the upstream and downstream sector, non-commercial and commercial research, or fundamental and applied research, are becoming even more blurred (section 5.1.1.4). Nevertheless, this consultancy also sought to identify the particular challenges that upstream actors face with regard to EU-level implementation of the Nagoya Protocol on the basis of the EU ABS Regulation (section 5.2 and 5.3). Interviewees focused on practical issues experienced or foreseen in exercising due diligence (section 5.2.2), such as the standard of proof of due diligence (section 5.2.2.1), in absence of clear, step-by-step guidance on how to follow national ABS laws, as well as the administrative burdens arising from the setting up

or redesigning of document management systems and from the implementation of reporting requirements (section 5.2.2.2).

To facilitate compliance and to ease administrative burdens, the interviewees asked for guidance on the standard of proof for due diligence, taking into account the current difficulties in obtaining proper information on national ABS legislations in provider countries, including on the international ABS Clearing House (section 5.2.2.1). Moreover, recognition of best practices and capacity building (with national or EU funding) is considered needed to ease the pressure on document management systems and to (possibly) implement reporting requirements (section 5.2.2.2). Interviewees therefore asked for detailed guidance for compliance that takes account of their limited financial and human resources.

A final area where more clarity would be helpful concerns traditional knowledge: although few interviewees indicated that they are very actively involved in the use of traditional knowledge associated with genetic resources, the majority uses traditional knowledge on an occasional, non-systematic basis (section 4.1.3). In absence of a clear definition in the Nagoya Protocol and the EU ABS Regulation of traditional knowledge associated with genetic resources, the interviewees differ in their understanding of what traditional knowledge relevant for the purposes of complying with the Nagoya Protocol is.

## **Annex A – Guide for Semi-Structured Interview**

### **Part I Upstream Actors and their Activities**

1. Briefly describe your institution and your own role within the institution.
2. How are genetic resources (GRs) and/or associated traditional knowledge (ATK) of significance for the work and daily activities of your institution?
3. From whom and where does your institution obtain GRs and ATK and related information? Do you share and/or are you required/solicited to share GRs and ATK? With whom? How? Why? Which information about ATK and GRs is communicated to other persons?
4. Which activities does your institution carry out on GRs and/or ATK? Which of the activities have a research or R&D dimension to it?
5. Does your institution expect to make any commercial use of its work on GRs and ATK and does it seek intellectual property protection? Are you aware of others that may use your work on GRs and ATK for commercial innovation purposes? Do you know how do they access your work?
6. Does your institution disseminate the results of its work on GRs and ATK? Which information about ATK and GRs is shared when you divulge these results?
7. What happens to the GRs and/or ATK after your institution concludes work on them? And to the information that accompanied them when you obtained them?
8. What kind of funding (public/private) is sought out to carry out the work?

### **Part II The Nagoya Protocol and the EU ABS Regulation**

9. Is your institution subject to the rules of the Nagoya Protocol, as implemented by the EU ABS Regulation?
10. What are your institution's obligations, if any, under the EU ABS Regulation?  
  
[If due diligence and the due diligence declaration are not identified as specific obligations, the interviewer will inform the interviewee about these obligations].
11. Do the obligations stemming from the EU ABS Regulation change your institution's standard procedures with regards to access to GRs and ATK?
12. Do you experience any uncertainties with regard to your obligations under the EU ABS Regulation that could benefit from further clarification?

**13.** Do you foresee any other issues in the implementation of your obligations under the Nagoya Protocol and the EU ABS Regulation.