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**THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING: WHAT IS NEW AND WHAT ARE THE IMPLICATIONS FOR PROVIDER AND USER COUNTRIES AND THE SCIENTIFIC COMMUNITY?**

Evanson Chege Kamau, Bevis Fedder and Gerd Winter

ARTICLE



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## ARTICLE

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# 1

## FROM RIO TO NAGOYA

As widely known, the three main objectives of the Convention on Biological Diversity (CBD) of 1992 are conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of benefits.<sup>1</sup> The latter is also considered as a key element of measures necessary for realisation of the other two objectives. Thus, for permitted access, users of genetic resources are obliged to share benefits arising from the utilisation of such resources with the providers; benefits, which help providers to develop their own sustainable uses and to preserve biodiversity.

Article 15.1 and 15.7 of the CBD acknowledge the sovereign rights of resource states to regulate access to genetic resources as well as their right to stipulate the sharing of benefits from the utilisation of genetic resources. Article 15.2 places a caveat requiring resource providing states not to impose restrictions that hinder access to genetic resources and thereby restrain conservation and sustainable use of biodiversity. Article 15.7 of the CBD implies that users of genetic resources are obliged to share benefits arising from the utilisation of genetic resources with resource states. According to Article 8(j) Parties have an obligation to share benefits from the utilisation of traditional knowledge, innovations and practices of indigenous and local communities associated with genetic resources.

Seventeen years have elapsed since the CBD entered into force. The Conference of the Parties (COP) met ten times with one extraordinary meeting held in two parts to adopt the Cartagena Biosafety Protocol. Although much has transpired and tremendous work done in relation to biodiversity protection, barely are there any effectively and efficiently functioning measures/regimes for access and benefit sharing (ABS).

Only a few countries (mostly provider states) have enacted thorough legislations on ABS.<sup>2</sup> The Philippines

was the first country to develop a stand-alone ABS regime, the Executive Order 247 (EO 247) of 18 May 1995, one and a half years after the CBD had entered into force. The EO 247 has been the most quoted regime for its extremely restrictive approach to access.<sup>3</sup> It created a procedure that turned out to be very long, exhaustive and costly resulting to delay, uncertainty and high transaction costs for the users. The consequence was that basic research and bioprospection projects were frustrated.<sup>4</sup> According to Cabrera Medaglia and Dutfield, only one from eight applications for commercial research and only one from seventeen for academic research was approved by the year 2004,<sup>5</sup> almost ten years after the enactment of the EO 247.

Several countries that enacted ABS regimes after the Philippines basically followed the same trend.<sup>6</sup> What are the reasons leading to such a reaction and development?

Many countries of the South had welcomed the CBD as the panacea against rampant biopiracy that existed

1 Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, 31 *Int'l Leg. Mat.* 818 (1992), Article 1.

2 Lyle Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources* 23ff (Gland: IUCN, 1998). See Country Reports in Evanson Chege Kamau and Gerd Winter eds., *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit Sharing* (London: Earthscan, 2009).

3 Paz Benavidez, 'Philippines: Evolving Access and Benefit-sharing Regulations', in Santiago Carrizosa et al, eds., *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*, 153-176 at 160-167 (Gland: IUCN, 2004); Krystyna Swiderska et al. *Developing the Philippines' Executive Order No. 247 on Access to Genetic Resources* (London: IIED, 2001).

4 Marcio de M. Santons and Maria Nunes O. Sampaio, Relatório sobre análise dos artigos 12 e 18 da Convenção da Biodiversidade Biológica (Paper presented at the workshop estratégia Nacional de Biodiversidade organised by PROBIO, São Paulo 1998) and Jorge Cabrera Medaglia, *A Comparative Analysis of the Implementation of Access and Benefit-Sharing Regulations in Selected Countries* (Bonn: IUCN, 2004).

5 See Medaglia, note 4 above at 192 and Graham Dutfield, Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experience in Selected Developing Countries (Paper presented at the UNCTAD Expert Meeting on Systems and Experiences for Protecting Traditional Knowledge, Innovations and Practices, Geneva, 30 October-1 November 2000), available at [http://r0.unctad.org/trade\\_env/docs/dutfield.pdf](http://r0.unctad.org/trade_env/docs/dutfield.pdf).

6 See the reports by Juliana Santilli on Brazil, Anne Angwenyi on Kenya and Rachel Wynberg and Mandy Taylor on South Africa in Kamau and Winter eds., note 2 above. More recently, Australia heralded a more streamlined approach, see Geoff Burton, 'Australian ABS Law and Administration - A Model Law and Approach?', in Kamau and Winter eds., note 2 above at 271.

and persisted long before it.<sup>7</sup> They also saw the opportunity to share benefits as a new way of earning great and quick wealth.<sup>8</sup> The user states could have helped them to develop a more realistic stance by introducing benefit sharing regimes on their side, but they failed to do so.<sup>9</sup> The ABS regimes of provider states therefore remained the lone tool against abuse and as a means of trying to enforce the sharing of benefits. No wonder conditions for access became very restrictive.

Against that background, in order to assist parties and stakeholders with developing a more balanced solution, COP 5 (2000) established the **Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (WG-ABS)** with mandate to develop guidelines and other approaches (Decision V/26). The WG-ABS was also mandated to work jointly with the **Working Group on Article 8(j) and Related Provisions**.

The WG-ABS developed the so-called Bonn Guidelines,<sup>10</sup> which were adopted by COP 6 in 2002. The Bonn Guidelines are intended to guide users and providers inter alia in developing mechanisms and arrangements for ABS with the participation of relevant stakeholders and based on their prior informed consent (PIC) and mutually agreed terms (MAT). They also provide an indicative list of MAT, and possible monetary and non-monetary benefits. Although the Bonn Guidelines have played a vital role mainly in the

development of provider measures, they did not achieve the envisaged ground-breaking success as far as the obligations of users are concerned as their implementation was on voluntary basis.

At the World Summit for Sustainable Development in Johannesburg in August 2003, the megadiverse countries argued that the lack of clear international rules on access to genetic resources might prompt them to restrict access for researchers, business and private investment.<sup>11</sup> Towards the close of the summit, an agreement was reached to push for an international regime to be negotiated within the framework of the CBD and its Bonn Guidelines.<sup>12</sup>

Following these developments, the WG-ABS was given a new mandate at COP 7 (2004) (COP Decision VII/19) to elaborate and negotiate, together with the **Working Group on Article 8(j)**, an international regime on access to genetic resources and benefit-sharing in order to effectively implement Article 15 and Article 8(j) of the CBD. COP 8 (2006) requested the WG-ABS to continue its work and complete it at the earliest possible time before COP 10. In line with these decisions, the WG-ABS held its fifth meeting in Montreal, Canada (8-12 October 2007), and its sixth meeting in Geneva, Switzerland (21-25 January 2008). The report of its sixth meeting (UNEP/CBD/COP/9/6), which is an output of the two meetings, contained possible elements<sup>13</sup> – with options – for an international instrument as recommendations for consideration as well as elaboration by COP 9.<sup>14</sup> These recommendations were consolidated by COP 9 (2008) and taken up in Annex I of its decision on ABS (Decision IX/12) as the basis for further elaboration and negotiation of the international regime.<sup>15</sup> The COP instructed the WG-

7 The Brazilian State of Acre, for example, passed its Acre State Law N° 1235/97 in response to a single case of 'biopiracy' involving an NGO that was cataloguing the native use of medicinal plants. See Jordan E. Erdos, *Current Legislative Efforts in Brazil to Regulate Access to Genetic Resources* (1999), available at [http://www.sustain.org/biotech/library/admin/uploadedfiles/Current\\_Legislative\\_Efforts\\_in\\_Brazil\\_to\\_Regul.htm](http://www.sustain.org/biotech/library/admin/uploadedfiles/Current_Legislative_Efforts_in_Brazil_to_Regul.htm).

8 Evanson Chege Kamau, 'Facilitating or Restraining Access to Genetic Resources? Procedural Dimensions in Kenya', 5/2 *Law, Environment and Development Journal* (2009), available at <http://www.lead-journal.org/content/09152.pdf>. See also Darrell A. Posey, (Re)Discovering the Wealth of Biodiversity, Genetic Resources, and the Native Peoples of Latin America, available at [http://gupea.ub.gu.se/bitstream/2077/3240/1/anales\\_5\\_posey.pdf](http://gupea.ub.gu.se/bitstream/2077/3240/1/anales_5_posey.pdf).

9 See Gerd Winter, 'Towards Common Pools of Genetic Resources – Improving the Effectiveness and Justice of ABS', in Kamau and Winter eds., note 2 above at 19.

10 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, in Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, UN Doc. UNEP/CBD/COP/6/20 (2002).

11 Evanson Chege Kamau, 'Disclosure Requirement – A Critical Appraisal', in Kamau and Winter eds., note 2 above at 28.

12 Plan of Implementation of the World Summit on Sustainable Development, Johannesburg 2002, Paragraph 42(o).

13 UNEP/CBD/COP/9/6: The main components include fair and equitable benefit sharing, access to genetic resources, compliance, traditional knowledge and capacity. Others include the objective and scope. The proposals on objective, scope and nature were neither negotiated nor agreed.

14 The scope and nature of the International Regime, for example, had to be elaborated.

15 See Access and Benefit Sharing, COP decision IX/12, Decision adopted by the Conference of the Parties to the Convention on Biological Diversity at its ninth meeting, UN Doc. UNEP/CBD/COP/DEC/IX/12 (2008).

ABS to meet three times<sup>16</sup> between 2009 and 2010 to ensure that it submits a draft protocol for adoption at COP 10.

The final text of the last three meetings of the WG-ABS<sup>17</sup> before COP 10 was born in Cali, Colombia.<sup>18</sup> The negotiated text was adopted by the Plenary on 29 October 2010 at Aichi-Nagoya, Japan.<sup>19</sup> Many issues remained contentious until the last minute, when in night-long sessions a bargain was struck between provider and user states. The resulting text is summarised below.

## 2

### THE SUBSTANTIVE CONTENT OF THE NAGOYA PROTOCOL

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity [hereinafter the Protocol] is structured into 27 preambular paragraphs, 36 articles, and one annex. This section examines and summarises the core provisions of the Protocol.

#### 2.1 Objective

Stating its objective the Protocol repeats verbatim the third objective of the CBD, but adds to it that ABS shall contribute 'to the conservation of biological diversity and the sustainable use of its components'.<sup>20</sup> Thereby ABS is linked to the other two objectives of the CBD.

#### 2.2 Access Requirements

Access provisions under the Protocol reiterate that, under reaffirmation of sovereign rights over natural resources, access to genetic resources for their utilisation is subject to prior informed consent of the providing party.<sup>21</sup> Given experiences with over-bureaucratic and intransparent access procedures the Protocol is very elaborate on the procedural facilitation of access. For this purpose, provider states shall provide for 'legal certainty, clarity, and transparency' of their domestic ABS legislation, 'fair and non-arbitrary rules and procedures' on access to genetic resources', 'information on how to apply for prior informed consent', clear, cost-effective and timely decision-making, recognition of a permit or its equivalent as evidence of PIC, criteria and procedures for the involvement of indigenous and local communities, and clear rules and procedures for requiring and establishing MAT.<sup>22</sup> Parties on the provider side that must be involved by giving consent and agreeing on mutual terms include the provider state itself<sup>23</sup> and – according to domestic legislation – indigenous and local communities that hold genetic resources<sup>24</sup> and/or associated traditional knowledge.<sup>25</sup> Responsible for advising on PIC and MAT are national focal points and competent national authorities.<sup>26</sup> The latter are also responsible for granting access.<sup>27</sup> One

16 *Seventh meeting*. Negotiation of operational text on the objective, scope, compliance, fair and equitable benefit sharing, access; *Eighth meeting*. Negotiation of operational text on nature, traditional knowledge associated with genetic resources, capacity-building, compliance, fair and equitable benefit sharing, access; *Ninth meeting*. Consolidation of all operational text developed at the seventh and eighth meetings of the Working Group (see COP decision IX/12).

17 *Seventh meeting*. Paris, France 2-8 April 2009; *Eighth meeting*. Montreal, Canada 9-15 November 2009; *Ninth meeting*. Cali, Colombia 22-28 March 2010.

18 Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, UNEP/CBD/COP/10/5/ADD5, available at <http://www.cbd.int/cop10/doc/> (accessed 30 December 2010).

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

20 *Id.*, Art. 1.

21 *Id.*, Art. 6.1. The providing party is either the country of origin or a party that acquired the genetic resources in accordance with the Convention.

22 *Id.*, Art. 6.2(a)–(b) and (f). According to Art. 6.3(g)(i)–(iv), MAT include, among others, dispute settlement clauses and terms on benefit sharing, including intellectual property rights; subsequent third-party use; changes of intent; and sharing information on implementation of MAT.

23 *Id.*, Art. 6.1.

24 *Id.*, Art. 6.2.

25 *Id.*, Art. 7.

26 *Id.*, Art. 13.1 and 13.2.

27 *Id.*, Art. 13.2.

single entity may be designated to fulfil the functions of both focal point and competent national authority.<sup>28</sup>

### 2.3 Benefit Sharing

Concerning benefit sharing, each party is obliged to take legislative, administrative, or policy measures to ensure that benefits arising from the utilisation of genetic resources as well as subsequent application and commercialisation are shared fairly and equitably with the providing party.<sup>29</sup> Benefits listed under the Protocol include monetary and non-monetary benefits and are almost a verbatim repetition of benefits listed in the Bonn Guidelines.<sup>30</sup> Additionally, the Protocol prescribes collaboration and cooperation in technical and scientific research and development (R&D) programmes, which preferably take place in and with participation of provider parties.<sup>31</sup> In this regard, access to technology by, and transfer of technology to, developing country parties should be encouraged.<sup>32</sup> The basic paradigm that maintaining the potential of discovering valuable genetic resources stimulates conservation and sustainable use is now explicitly complemented by the obligation to encourage the flow of benefits towards conservation and sustainable use.<sup>33</sup>

Finally, the Protocol introduces extensive measures on improving capacities.<sup>34</sup> Capacity is one of the core benefits under the Protocol,<sup>35</sup> and parties must cooperate in capacity-building, capacity development, and strengthening of human resources and institutional capacities.<sup>36</sup> Therefore, developing country parties should conduct capacity self-assessments to identify their national needs and priorities.<sup>37</sup> Key areas identified by the Protocol that require capacity-building include implementation of the Protocol, negotiation of MAT,

development and enforcement of domestic legislation, and endogenous research capabilities.<sup>38</sup>

### 2.4 Utilisation of Genetic Resources

Any utilisation of genetic resources generating benefits is a ground for benefit sharing. For this reason, the definition of the term is crucial. Utilisation of genetic resources is defined as 'research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention'. The Protocol does not contain a list of kinds of R&D as was envisaged in prior deliberations.<sup>39</sup> Those lists can however still be used as indications. The one resulting from the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches contained a non-exhaustive list consisting of the following activities:

- Genetic modification
- Biosynthesis (use of genetic material as a 'factory' to produce organic compounds)
- Breeding and selection
- Propagation and cultivation of the genetic resource in the form received
- Conservation
- Characterisation and evaluation
- Sequencing genes or genomes
- Production of compounds naturally occurring in genetic material (extraction of metabolites, synthesis of DNA segments and production of copies)

It is of high importance that R&D on the biochemical composition of the genetic resource is covered. This means that, for instance, drugs based on the extraction

<sup>28</sup> *Id.*, Art. 13.3.

<sup>29</sup> *Id.*, Art. 5.1 and 5.5.

<sup>30</sup> *Id.*, Art. 5.4 and Annex (Monetary and Non-Monetary Benefits). *See also* Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, note 10 above, Appendix II.

<sup>31</sup> Nagoya Protocol, note 19 above, Art. 23.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*, Art. 9.

<sup>34</sup> *Id.*, Art. 22.

<sup>35</sup> Nagoya Protocol, note 19 above, Annex (Monetary and Non-Monetary Benefits), 2(g)-(j).

<sup>36</sup> *Id.*, Art. 22.1.

<sup>37</sup> *Id.*, Art. 22.3.

<sup>38</sup> *Id.*, Art. 22.4. Exemplary measures to improve capacities are listed in Art. 22.5.

<sup>39</sup> *See* Access and Benefit Sharing, note 15 above, Section B of Annex II and WG-ABS official document 7/2, Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UN Doc. UNEP/CBD/WG-ABS/7/2 (2008).



of chemicals from biological resources are subject to benefit sharing.

## 2.5 Indigenous and Local Communities and Traditional Knowledge

Communities that hold genetic resources and traditional knowledge associated to genetic resources enjoy extensive consideration within various provisions of the Protocol. First, where communities have the domestic right to grant access to genetic resources or hold traditional knowledge, parties should adopt measures ensuring that PIC and involvement for access is obtained from such communities.<sup>40</sup> Second, benefits derived from the utilisation of genetic resources or traditional knowledge held by communities must be shared in a fair and equitable way with such communities.<sup>41</sup> Third, parties, with effective participation of communities, shall establish mechanisms to inform users of traditional knowledge about their obligations.<sup>42</sup> Such obligations can be laid down in community protocols, minimum requirements for MAT, and model contractual clauses as developed by communities with the support of the party.<sup>43</sup> Fourth, in order to increase awareness of genetic resources and traditional knowledge held by communities, parties shall organise meetings of communities, establish a help desk for communities, and involve communities in the implementation of the Protocol.<sup>44</sup> Fifth, in order to enable effective participation of communities in implementation of the Protocol, capacities of communities need to be improved as well. In this regard, the Protocol emphasises the need to increase capacities of women,<sup>45</sup> owing to their vital role in ABS processes, policy making, and implementation of biodiversity conservation.<sup>46</sup>

40 See 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, note 19 above, Art. 6.2 and 7. Additionally parties specify criteria and/or processes for obtaining PIC and involving communities, Art. 6.3(f).

41 *Id.*, Art. 5.2 and 5.5.

42 *Id.*, Art. 12.2.

43 *Id.*, Art. 12.1 and 12.3.

44 *Id.*, Art. 21(b)–(c) and (h).

45 *Id.*, Art. 22.3 and 22.5(j).

46 *Id.*, Eleventh preambular paragraph.

## 2.6 Compliance

The Protocol contains provisions on compliance but leaves it primarily to parties to decide on appropriate, effective, and proportionate measures to make sure that genetic resources and traditional knowledge have been accessed in accordance with PIC and that MAT have been established.<sup>47</sup> Similarly elusive are those provisions addressing situations of non-compliance,<sup>48</sup> and in cases of alleged violations, parties have a weak obligation to cooperate.<sup>49</sup> These shortcomings will be addressed at the next COP though, where cooperative procedures and institutional mechanisms to promote compliance with the Protocol will be considered and approved.<sup>50</sup>

Concerning the resolution of future disputes, parties are encouraged to agree, before access takes place, on the jurisdiction to which disputes will be submitted, applicable laws, and options for alternative resolution, such as mediation or arbitration.<sup>51</sup> Additionally, parties shall take effective measures on access to justice and mutual recognition and enforcement of foreign judgments and arbitral awards.<sup>52</sup>

## 2.7 Monitoring

The Protocol applies several novel approaches to monitor compliance on the utilisation of genetic resources. The most prominent approach is ‘checkpoints’ designated by each party.<sup>53</sup> Checkpoints would require users to submit information related to PIC, MAT, as well as the source and utilisation of the genetic resource.<sup>54</sup> That information is then submitted to relevant authorities, the provider party, and the ABS Clearing-House Mechanism (CHM).<sup>55</sup> Other

47 *Id.*, Art. 15.1 and 16.1.

48 *Id.*, Art. 15.2 and 16.2.

49 *Id.*, Art. 15.3 and 16.3.

50 *Id.*, Art. 30.

51 *Id.*, Art. 18.1.

52 *Id.*, Art. 18.3.

53 *Id.*, Art. 17.1(a). Although parties are free to designate checkpoints, they should be relevant to utilization or collection of information on utilization of genetic resources, e.g., to any stage of research, development, innovation, pre-commercialisation, or commercialisation, Art. 17.1(a)(iv).

54 *Id.*, Art. 17.1(a)(i)–(ii).

55 *Id.*, Art. 17(a)(iii). The ABS CHM is established by Article 14 and is responsible for sharing of information on national ABS measures, focal points and relevant authorities, permits, etc.

monitoring mechanisms include the sharing of information through reporting requirements, cost-effective communication tools and systems, and a mandatory, internationally recognised certificate of compliance.<sup>56</sup>

A certificate of compliance is basically a permit made available to the ABS-CHM and contains non-confidential information on the issuing authority, date, provider, person to whom PIC was granted, genetic resources, use, a unique identifier, and confirmation that PIC was obtained and MAT were established.<sup>57</sup> Finally, it is the obligation of each party to monitor the implementation of the Protocol and report regularly to the COP.<sup>58</sup>

Despite above measures to monitor utilisation of genetic resources, any similar monitoring mechanisms mentioning explicitly the utilisation of traditional knowledge are lacking under the Protocol.<sup>59</sup> Considering the clear distinction the Protocol draws between the utilisation of genetic resources and the utilisation of traditional knowledge, this might constitute an omission with far-reaching consequences.

## 2.8 Transboundary Situations

Although the Protocol reaffirms sovereign rights of parties over their genetic resources, its provisions on transboundary cooperation, in case the same genetic resources or traditional knowledge straddle national boundaries, constitute a kind of, though weak, derogation of absolute state sovereignty. In such cases, parties shall 'endeavour to cooperate' with a view to implement the objectives of the Protocol.<sup>60</sup>

Worth mentioning in this regard is a prospective 'global multilateral benefit-sharing mechanism' for genetic resources and traditional knowledge that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.<sup>61</sup> Such a mechanism would direct the benefits derived from utilisation of genetic resources and traditional knowledge

towards global supporting of conservation of biological diversity and sustainable use of its components.

# 3

## EVALUATION OF THE ACCESS AND BENEFIT-SHARING RESULT

### 3.1 Overview

In some respects the Protocol was uncontroversial because it only reiterates or specifies what was already rather precisely laid out in the CBD, or because the obligations do not really hurt any side. This is true, for instance, for many definitions, for the recognition of sovereign rights of provider countries (Art. 6.1), compliance with mutually agreed terms and the provision of dispute resolution mechanisms (Art. 18), the elaboration of model contractual clauses and codes of best practices (Art. 19, 20), awareness raising (Art. 21), capacity building (Art. 22), technology transfer (Art. 23), and the financial mechanism (Art. 25).

Many other issues however remained controversial until the last minutes of bargaining. They concerned:

- a) The scope of the Protocol
  - whether it should apply to genetic resources accessed before the CBD
  - whether it should apply to genetic resources accessed before the Protocol if no benefit-sharing agreement existed according to the requirements of the CBD
  - whether it should apply to continuing and new uses of genetic resources and traditional knowledge accessed before the CBD
  - whether it should apply to traditional knowledge accessed before the Protocol
  - whether it should have a broad application covering biological resources or be restricted to genetic resources
  - whether it should apply to biochemicals/derivatives

<sup>56</sup> *Id.*, Art. 17.1(b)–(c) and 17.2.

<sup>57</sup> *Id.*, Art. 17.2–4.

<sup>58</sup> *Id.*, Art. 29.

<sup>59</sup> *Id.* Only Art. 17.4(g)–(i) on PIC and MAT can be interpreted to not only include providers and users, but also communities holding genetic resources and traditional knowledge.

<sup>60</sup> *Id.*, Art. 11.

<sup>61</sup> *Id.*, Art. 10. The need for and modalities of such a mechanism will be considered by the parties.

- b) Fair and equitable benefit sharing
    - whether benefits from traditional knowledge associated with ex situ genetic resources should be subjected to Article 8(j) of the CBD
    - whether the scientific community should be allowed a simplified procedure of access for purposes of basic (non-commercial) research
  - c) Access to genetic resources
    - whether access to genetic resources should be subjected to the PIC and MAT of indigenous and local communities where access to associated traditional knowledge is not requested
    - which measures should parties put in place to ensure compliance with access legislations
  - d) Compliance
- These issues were settled as indicated in the table below. *Yes* denotes who proposed or supported the idea and *No* vice versa.

Table 1: Most contentious issues and final results

A\ Scope	Issue(s)	Position of parties		Articles in ABS draft Protocol	Articles reflecting or maintaining issue in Nagoya Protocol	Variation Comment
		Providers	Users			
Retroactivity I	Benefits from genetic resources accessed pre-CBD	Yes	No	In previous deliberations	Abandoned	None
Retroactivity II	Benefits from genetic resources accessed pre-ABS Protocol where no benefit-sharing agreement has been established in accordance with the CBD	Yes	No	Art. 3	Abandoned	None
Retroactivity III	Benefits from continuing & new uses of genetic resources & traditional knowledge accessed pre-CBD	Yes	No	Art. 3	Abandoned	None
Retroactivity IV	Benefits from traditional knowledge accessed pre-ABS Protocol	Yes	No	Art. 3	Abandoned	None
Biological/genetic resources	Should ABS Protocol also apply to biological resources?	Yes	No	Deduced from Art. 2, <sup>62</sup> Definitions & Art. 6, Special considerations <sup>63</sup>	Abandoned	None
Biochemicals/derivatives	Benefits from biochemicals/derivatives from entry into force of ABS Protocol	Yes	No	Art. 3	Art. 2 (c), (d), (e)	Maintained through definition of utilisation of genetic resources
B\ Fair & equitable benefit sharing	Benefits from traditional knowledge associated with ex situ genetic resources	Yes	No	Preamble	Abandoned	None
Ex situ collections						

<sup>62</sup> 'Utilization of genetic resources' means to conduct research and development on the genetic and biochemical composition of genetic material/biological resources/genetic resources ....'

<sup>63</sup> 'Pay due regard that the domestic access and benefit-sharing laws, policies or measures will not affect biological resources that are traded and used as commodities'.

C\ Access to genetic resources						
Ownership of genetic resources	PIC, approval & involvement of indigenous & local communities needed in access to genetic resources	Yes	Yes/No?	5.1 <i>bis</i>	6.2	PIC required where such communities have established right to grant access to such resources
National ABS measures	Provide for legal certainty, clarity & transparency	No/Yes	Yes	Art. 5	Art. 6.3(a)	Providers have repeatedly demanded compliance measures in user countries in return
Non-commercial research	Provide simplified access	No/Yes	Yes	Art. 5.2(c <i>bis</i> ) & Art. 6(a)	Art. 8(a)	Abandonment of draft Art. 5.2(c <i>bis</i> )
<b>D\ Compliance</b>						
Checkpoints	Identification & establishment of checkpoints to enhance monitoring, tracking & reporting utilisation of genetic resources, derivatives & traditional knowledge	Yes	No	Art. 13.1(a) <sup>64</sup>	Art. 17(a)	List of likely check points abandoned. Instead duty to establish authority with checking function
Certificate	Internationally recognised certificate should be evidence of compliance with PIC & MAT requirements	Yes	No	Art. 13.2, 13.3, 13.4 <sup>65</sup>	Art. 17.2, 17.3, 17.4	Draft Article 13.4 has 12 types of minimum information, Art. 17.4 Nagoya Protocol has 9
Disclosure of origin/source	Should be made mandatory: -Failure to disclose: user should be given fixed time to comply/remedy -Refusal to disclose: application shall not be further processed	Yes	No	Art. 13 <i>bis</i> Art. 13 <i>bis</i> (a) Art. 13 <i>bis</i> (b)	Abandoned	None The duty to disclose is so-to-say vaguely incorporated in Art. 17

### 3.2 Temporal Scope

The provider side entirely lost on the issue of temporal application of the ABS regime. As shown in the table four variants had been proposed: The most demanding was to extend the scope to benefits from genetic resources accessed before the entering into force of the CBD, i.e. 1993. Less ambitious was the variant which only included benefits from continuing and new uses of genetic resources and traditional knowledge accessed pre-CBD, and even less the one only including benefits from genetic resources accessed pre-ABS Protocol where no benefit-sharing agreement had been established in accordance with the CBD.

The fact that the agreed Protocol is tacit on temporal scope does not however imply that benefit sharing only relates to benefits from genetic resources and traditional knowledge accessed post-CBD or even post-ABS

Protocol. The question must be answered according to general international law. Drawing on the Vienna Convention on the Law of International Treaties, the provisions of the CBD and the new Protocol 'do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party'.<sup>66</sup> Clearly, this means that any genetic resource or traditional knowledge accessed before that date cannot retroactively be made subject to PIC requirements. Likewise, any benefits obtained before that date cannot retroactively be subjected to a benefit-sharing obligation. However, it can be argued that the generation of benefits after that date is a new act in terms of Article 28 Vienna Convention, or that the holding of the genetic resource or traditional knowledge is a situation which has not ceased to exist.<sup>67</sup>

64 Draft Article 13.1(a) also possesses a non-exhaustive list of likely checkpoints.

65 Draft Article 13.4 has a list of minimum information an internationally recognised certificate should contain.

66 Vienna Convention on the Law of Treaties, Vienna, 23 May 1969, 1155 UNTS 331 (1980), Article 28.

67 See Heintschel von Heinegg, 'Die völkerrechtlichen Verträge als Hauptrechtsquelle des Völkerrecht', in Knut Ipsen ed., *Völkerrecht* § 12 No. 15 (München: Beck Verlag, 2004).

### 3.3 The Range of Utilisation

The provider states were successful concerning the extension of benefit sharing to benefits from biochemical compounds resulting from genetic expression or metabolism of biological or genetic resources. Biochemicals that do not contain hereditary traits clearly do not fall under the term 'genetic resource'; they are hence not subject to sovereign rights of provider states and, more specifically, to the PIC requirement. They can however – and were now indeed – be captured by the term 'utilisation of genetic resources'. This term triggers benefit-sharing duties.<sup>68</sup>

Still, it is far from clear how the limits of technological applications of biochemicals shall be drawn. In a way any product made out of crops – such as flour from cereals – can be regarded as a derivative in the definition of the Protocol. Formulas delineating bulk uses from biotechnical uses are still to be developed. As the Protocol does not solve the question, this is now up to national legislation.

### 3.4 Simplified Conditions on Prior Informed Consent for Basic Research

The transnational research community was successful in lobbying for a clause on facilitating basic research. The providers had been concerned about the likelihood of simplified access (initially 'fast track') being abused, especially because there are no clear boundaries between basic and commercial research, and also since basic

research can easily turn to commercial.<sup>69</sup> In addition, the results of basic research may be used by third parties for commercial purposes. However, providers have been willing to ease access for such research trusting that contractual clauses can be agreed to curb violations, for example, the use of come-back clauses requiring the partner to obtain a new consent for commercial R&D, and contractual specifications of the transfer of genetic resources to third parties. In this regard both the draft and adopted ABS Protocol maintained a very loose language under Articles 5.2 (f) (iii), (iv) and 6.3 (g) (iii), (iv), respectively, of possible measures for establishing clear rules and procedures for MAT. It will be a task for drafters of model ABS agreements to cope with this question.

### 3.5 User State Measures

Until now, hardly any user state has introduced legislation, administrative or policy measures ensuring compliance with access conditions and the duty to share benefits. The new provisions on compliance now call them to task, albeit only half-heartedly. Four problems had to be solved: What agency should be in charge, at what point in the valorisation stream of genetic resources shall the checking occur, what documents shall count as evidence, and what substantive issue shall be checked.

As for the responsible agencies the Protocol only requires that user states must designate them. Other than the Draft Protocol which had envisaged a list of checkpoints such as research institutions, patent offices and regulatory agencies, the agencies are not specified

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68 See Morten Walloe Tvedt and Tomme Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD* (Gland: IUCN, Environmental Policy and Law Paper No. 67/2, 2007), at 65 for this very useful change of *sedes materiae*. The legal technique of capturing biochemicals is somehow tricky. The term biotechnology was introduced as one kind of utilization of genetic resources. This term, which embraces technological applications of derivatives such as biochemical compounds, is employed in the CBD but only outside the realm of the ABS regime. The Protocol now draws biotechnology including applications of biochemicals into the scope of ABS.

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69 Other CBD sources characterise non-commercial research by a) public availability, b) purely non-commercial intentions, c) results benefit providers, conservation, ecosystem analysis, and characterisation of organisms, and d) generation of near-term, non-monetary benefits. Examples include a) conservation, b) taxonomy, c) production of natural compounds, and d) DNA synthesis. In contrast, commercial research a) often restricts access, b) generates market products; c) primarily benefits users, and d) generates long-term, monetary benefits. CBD GTLE information document 1/INF/2, Concepts, Terms, Working Definitions and Sectoral Approaches Relating to the International Regime on Access and Benefit Sharing, UN Doc. UNEP/CBD/ABS/GTLE/1/INF/2 (2008) at 5 and CBD WG-ABS official document 7/2, Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UN Doc. UNEP/CBD/WG-ABS/7/2 (2008), Paragraphs 13 and 43–44.

anymore. This is probably wise because states may decide to nominate just one agency for this purpose.

With regard to the point of disclosure the Protocol is very broad including 'any stage of research, development, innovation, pre-commercialisation and commercialisation'.<sup>70</sup> Using a 'should' the provision leaves discretion for user states to identify strategic points. The mandatory disclosure requirement at the state of patenting of inventions from genetic resources which had widely been discussed in the run-up to COP10 was not included in the Protocol.

In relation to documents accepted as proof of compliance the Protocol refers to the provider state permit and an internationally recognised certificate of compliance the contours of which are only partially outlined. More resolutions of the contracting parties will be required to make it functional.

The main problem however is the material issue that shall be checked. Articles 15 and 17 very much concentrate on compliance with access conditions the primary concern apparently being the prevention of biopiracy. In addition, checkpoints shall also collect information related to the establishment of mutually agreed terms and to the utilisation of the genetic resource.<sup>71</sup> By contrast, there is no specified obligation of user states to ensure benefit sharing. As before, the enforcement of benefit-sharing duties is left to contractual means, with all the difficulties of forum, litigation costs, and prosecution of titles. The fact that the Protocol does not go further in that direction constitutes a major disappointment for the provider side.

### 3.6 Multilateralism

While ABS is largely conceived as a bilateral undertaking between provider and user states of genetic resources, and also of traditional knowledge,<sup>72</sup> there are various reasons for more multilateral concepts.<sup>73</sup> Regional pools

of certain genetic resources and traditional knowledge may emerge because the genetic resource or traditional knowledge is indigenous in more than one state.<sup>74</sup> Networks of ex situ collections exist that exchange biological material among themselves and with researchers fostering taxonomic research, but excluding commercialisation and, in consequence, the regulation of benefit sharing.<sup>75</sup> Worldwide pools of certain genetic resources or traditional knowledge – such as the Multilateral System of the International Treaty on Plant Genetic Resources – may evolve because the genetic resource or traditional knowledge is felt to be a common good of mankind which must jointly be improved and at the same time be designed to share any monetary benefits with states of primary origin. Taxonomic and genomics data bases exist and spring up in rich variety. Many of them allow for free feeding-in of and free access to data, considering themselves as public domain.<sup>76</sup> Even the pooling of benefits, for instance, of intellectual property rights on inventions based on genetic resources and traditional knowledge are imaginable.

The Protocol gives leeway for such endeavours at various points. In relation to regional pools it encourages the establishment of such pools for genetic resources and/or traditional knowledge.<sup>77</sup> Multilateral systems on a global scale are furthered by Article 10 for genetic resources and traditional knowledge that occur in transboundary situations or for which PIC cannot be

70 See Nagoya Protocol, note 19 above, Art. 17(1)(a)(iv).

71 *Id.*, Art. 17(1)(a)(i).

72 There is a difference between traditional knowledge associated with genetic resources and genetic resources as such in the domestic realm: While the CBD does not touch upon potential rights of citizens to genetic resources, it does set out rights and obligations of traditional knowledge holders vis-à-vis their state. See Convention on Biological Diversity, note 1 above, Art. 8(j).

73 See Winter, note 9 above.

74 Regine Anderson and Tone Winge, Success Stories from the Realization of Farmers' Rights Related to Plant Genetic Resources for Food and Agriculture 33-52 (Lysaker: Fritjof Nansen Institute, Report No. 4/2008).

75 See Bert van den Wollenberg et al., Konsortium Botanischer Gärten in der EU, available at <http://www.hortus-botanicus.info/assets/files/HHH-IPEN-de.pdf>; Marliese von den Driesch et al., 'The International Plant Exchange Network (IPEN): An Instrument of Botanic Gardens to Fulfil the ABS Provisions', in Ute Feit, Marliese von den Driesch, Wolfram Lobin eds, *Access and Benefit-sharing of Genetic Resources. Ways and Means for Facilitating Biodiversity Research and Conservation While Safeguarding ABS Provisions* (Bonn: BfN, 2005), available at [http://www.abs.bfn.de/fileadmin/ABS/documents/Gesamt\\_163.pdf](http://www.abs.bfn.de/fileadmin/ABS/documents/Gesamt_163.pdf).

76 For microbial research see Tom Dedeurwaerdere, Self-governance and International Regulation of the Global Microbial Commons: Introduction to the Special Issue on the Microbial Commons, 4/1 *International Journal of the Commons* 390 (2010).

77 See Nagoya Protocol, note 19 above, Art. 11.

granted or obtained. They could also cover genetic resources or traditional knowledge that was obtained prior to the entering into force of the CBD, for instance for ex situ collections. If specialised international agreements are concluded to that purpose they have, according to Article 4, priority over the Protocol insofar as they do not run counter to the objectives of the CBD and the Protocol. In relation to benefit sharing this means that parties can agree not to establish duties in such agreements that ask for benefit sharing with individual provider states. One example is the already cited International Treaty on Plant Genetic Resources, which can now be copied for more genetic resources and extended to certain types of traditional knowledge.

## 4 IMPLICATIONS FOR MAJOR ACTORS AND STATES

The provisions of the Protocol need to be implemented by actors (holders of genetic resources and traditional knowledge, researchers, etc.) and by states. Actors and states can wait for the Protocol's formal entering into force which presupposes the ratification by at least 50 states.<sup>78</sup> But they can as well start right away taking it as a not yet binding guidance. This is preferable because clear conditions for access, utilisation and benefit sharing are urgently needed.

When transposing the Protocol, actors and states will have to decide if they take the provisions as maximum or minimum standards. We believe it is advisable to establish regimes based on reason rather than slavishly copy the provisions. Provider states, for instance, may decide not to make use of the full set of rights granted by the Protocol, while user states may, in an effort to build trust, choose to go further than required in ensuring benefit sharing.

In the following we will discuss implications for the individual or institutional R&D activities concerning genetic resource and traditional knowledge, and for provider states and user states.

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<sup>78</sup> *Id.*, Art. 33.

### 4.1 Research and Development by Individuals and Institutions

When a R&D activity qualifies as access to or utilisation of genetic resources and/or associated traditional knowledge, information on rules and procedures on obtaining consent by the state and local communities as well as on contracts to be concluded must be gathered. To date, the primary means to obtain such information have been CBD websites concerning national ABS legislation and country profiles.<sup>79</sup> In due time, the ABS-CHM, as established by the Protocol, will constitute the primary node for retrieving information. More specific information on national access rules and procedures can be searched from national focal points and competent national authorities designated by provider parties.

On the user side, research organisations have sometimes produced advisory texts<sup>80</sup> and model agreements<sup>81</sup> that can be suggested by researchers if provider states do not operate on their own models.

In the normal case a researcher seeking access to genetic resources or traditional knowledge in a provider state will be confronted with the following requirements:

- research cooperation contract if R&D shall be conducted in collaboration with institutions within the provider state; mind that the inclusion of provider state measures in projects is a core means of capacity building in provider states<sup>82</sup>

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<sup>79</sup> Convention on Biological Diversity, 'ABS Measures', CBD Website, available at <http://www.cbd.int/abs/measures>, listing 54 parties and six regional instruments, and Convention on Biological Diversity, 'Country Profiles', CBD Website, available at <http://www.cbd.int/countries/contacts.shtml>, listing national focal points.

<sup>80</sup> German Research Foundation, Guidelines for Funding Proposals Concerning Research Projects Within the Scope of the Convention on Biological Diversity (CBD) 19 (Bonn: DFG, 2008), available at <http://www.abs.bfn.de/fileadmin/ABS/documents/guidelines.pdf>.

<sup>81</sup> See the model ABS agreement proposed by the Australian government, reprinted in Kamau and Winter eds., note 2 above at 455.

<sup>82</sup> See Nagoya Protocol, note 19 above, Art. 22(4)(d) which states that one way of capacity building is the 'capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources', and Art. 23, according to which 'the Parties shall collaborate and cooperate in technical, scientific research and development programmes', and 'such collaborative activities shall take place in and with a Party or the Parties providing genetic resources'.

- administrative authorisation for access by the competent state body; depending on the legislation of a given provider state it may suffice to notify the authorities of a project if this is non-commercial. In many states a research authorisation and – if the case may be – an authorisation to enter protected areas can in addition be required
- authorisation by a local community if local traditional knowledge shall be accessed or genetic resources shall be accessed that, according to provider state legislation, belong to a local community
- conclusion of an ABS contract specifying the conditions of access, the allowed utilisations, the benefit-sharing obligations (the so-called mutually agreed terms); and – if the case may be – the conditions of transfer of the biological material to another state (the so-called material transfer agreement); part of these conditions will also be contained in the access permit.

As said before, the Protocol asks provider states to allow for simplified procedures for non-commercial research, although, in fact, a sharp line can hardly be drawn. In practice, there will be clear-cut cases of non-commercial and of commercial research, but also cases where the line between the two goals is blurred. The best means is to insert a come-back clause in the ABS contract in cases of change of intent. But we suggest researchers aiming at non-commercial research do not run a risk if they agree to a contract which also covers duties to share monetary benefits they obtain. If they sign such contract the pertinent clauses are of no avail if benefits do not accrue. Accepting such clauses can even be helpful when the types of allowed utilisations of the genetic resource or traditional knowledge are specified. The stricter the obligation to share benefits the broader the list of allowed R&D activities a provider state will be willing to grant.

More than in simple contracts basic researchers will be interested in simplified versions of administrative authorisation requirements and consent requirements by landowners and local communities. But that is up to the national legislation of the provider state and cannot be influenced by the individual or institution searching access (see sect. 4.2 below).

How to handle the transfer of biological material to third parties is another intricate question which must be settled by the ABS contract. It is a common feature of research that the material is freely exchanged among befriended research teams. In order to retain the necessary flexibility, contract clauses could be introduced requiring that any new user shall be subjected to the same contact terms, especially to the reporting and benefit-sharing duties.

A third problem is how to specify benefit-sharing obligations. The Protocol has in its Annex a long list of non-monetary and monetary benefits from which a given contract may choose the most appropriate ones. Core are the duty to make available research results and name in publications the country of origin and possible co-authors residing in the same country, as well as the duty to share a certain percentage of the net monetary return from royalties and sales of products.

In order to ensure utilisation of genetic resources in accordance with PIC and MAT requirements once the genetic resource has left the provider state, user states must have adopted measures on monitoring. These measures include primarily ‘checkpoints’ designated by the user state, which monitor legitimate uses of genetic resources and traditional knowledge. Those checkpoints can be the front institutions that are responsible for the individual research project, such as universities, companies, and scientific journals, as well as administrative supervisory bodies that supervise the supervisors. This means that besides the rules of the provider state the researcher will also have to inquire about the relevant rules of the user state where his or her research is conducted.

## 4.2 Provider States

As mentioned above, in meeting their Protocol obligations, we suggest that provider states cautiously consider how to transpose it. There is an advantage in not waiting for it to enter into force, but rather starting on implementation activities now, especially on the establishment of PIC and MAT. Previous ABS legislative activities show that grave errors often occur as a result of implementation in a rush. Early beginners on the other hand often gain early experience.

### 4.2.1 Formal Requirements

The Protocol itself does not make PIC mandatory but rather obliges parties to respect PIC if required by the



provider state. It is the provider state's discretion to either require PIC or allow access without prior control.<sup>83</sup> This is important to note because many states – and in particular the industrialised states which normally appear on the user side – may opt for free access to their genetic resources and traditional knowledge.

If a state however opts for controlling access, the access regime must provide legal certainty. Information on how to apply must be easily accessible.

The provider state will wish to lay out the legal forms and procedures of access. These will comprise:

- an authorisation by the competent administrative body granting access and setting basic terms for access, utilisation, and benefit sharing
- a contract between the same body and the research institution which specifies the terms of access, utilisation and benefit sharing
- in relation to traditional knowledge, the consent of its holder
- in relation to genetic resources, according to domestic legislation, the consent of private or communal landowners or owners of the genetic resources

These legal instruments contain what the CBD and the Protocol call PIC, MAT and material transfer agreements (MTA) (if a transfer is foreseen).

The Protocol requires each party to designate one or more competent national authorities on ABS with responsibility for granting access or, as applicable, issuing written evidence that access requirements have been met.<sup>84</sup> The competent national authority(ies) is/are to be notified to the Secretariat together with information on its/their respective responsibilities.<sup>85</sup>

Provider state legislation may require further authorisations besides the ABS regime, such as a licence for research, entering into national parks, the collection of produce from forests, seas, etc. It is suggested that in such cases procedures should be streamlined in order not to deter researchers and increase transaction costs.

<sup>83</sup> See Nagoya Protocol, note 19 above, Art. 6.3.

<sup>84</sup> *Id.*, Art. 13.2.

<sup>85</sup> *Id.*, Art. 13.4.

Two ways could be taken in that regard: procedural and full integration.<sup>86</sup>

Procedural integration means that the competent agencies coordinate their procedures and conditions of granting access permits to avoid any contradiction of requirements as well as a protracted waiting period. That makes it possible for the applicant to file requests for PIC at the same time, the agencies to handle them simultaneously and to coordinate their decisions and conditions attached to the permit. This may be done most appropriately by designating one of the agencies with competencies to coordinate and combine the publication of the application, receive comments, hold hearings and draft decisions.

Full integration of licensing means combining the relevant permits into one permit. That implies that the applicant would be required to file only one application with the competent authority, but with the requirement that s/he submits all data and documents necessary for other permits (in line with the relevant agencies' regulations) to the competent authority. Whilst giving the other responsible agencies an opportunity to comment on the application and respecting the material criteria they would normally apply, the competent authority will have the exclusive competence to take the decision which also includes any other permit.

#### 4.2.2 Substantive Requirements

Concerning substantive criteria of PIC and MAT neither the CBD nor the Protocol provides much guidance. The Protocol requires that access shall be 'fair and non-arbitrary'<sup>87</sup> and benefit sharing 'fair and equitable'.<sup>88</sup>

Provider states will first of all specify cut-off criteria that must be fulfilled unless the application for access is denied from the outset. Setting such conditions is embedded in the sovereign rights of provider states as laid down in Article 15.1 CBD and confirmed by Article 6 (1) of the Protocol. They may include the following considerations:

- environmental: Proposed uses of genetic resources are environmentally unsound

<sup>86</sup> See further Evanson Chege Kamau and Gerd Winter, 'Streamlining Access Procedures and Standards', in Kamau and Winter eds., note 2 above at 371-373.

<sup>87</sup> See Nagoya Protocol, note 19 above, Art. 6.3(b).

<sup>88</sup> *Id.*, Art. 5.

- security considerations concerning the territory where access is proposed
- compliance: No compliance measures in user state
- morality: Proposed uses, collection methods etc. are incompatible with beliefs and practices of indigenous and local communities
- economic considerations: Bioprospection activities without foreseeable non-monetary or monetary benefits
- previous violations: Applicant has previously violated ABS requirements and agreements

Besides cut-off criteria of this sort provider state legislation should also sketch out points to consider when conditions of the ABS authorisation and contract clauses shall be fixed. Such points may include:

- kinds and quantity of biological material accessed
- modalities of access
- right of transfer of material
- objectives and kinds of utilisation
- change of objectives and utilisation
- reporting on utilisations
- sharing of non-monetary benefits
- sharing of monetary benefits

The concrete results will widely depend on the bargaining positions and tactics of the parties. The provider state may sometimes be able to push for favourable terms that go beyond its rights under the Protocol, for instance, by including new uses of genetic resources obtained prior to the CBD.

In addition to shaping access requirements provider state legislation should also look at the implementation phase of authorised access. It may lay down basic obligations that any user of the accessed genetic resource and traditional knowledge is bound to respect the terms of the authorisation and contract, and that, even if no authorisation or contract was obtained, or if these documents do not specify the rights and duties of users, any user must still share non-monetary and monetary benefits. A minimum list of such benefits may be

provided, for instance requiring that research results must be forwarded and a certain percentage of net revenues shall be paid. This is important to determine because it will be the standard guiding the necessary user state compliance and monitoring duties. It is conceivable that a provider state may even waive authorisation and contracting requirements if a user is subject to well developed compliance control by his/her home state.<sup>89</sup>

### 4.3 User States

Should the Protocol enter into force, user states will need to enact their own ABS measures. We suggest as outlined above that they should not wait for the Protocol becoming binding, and that they should take measures which follow reason and not establish the minimum which is absolutely commanded by the Protocol. Those who go further will build trust in provider states and from that benefit in the long term. In any way, times seem to be over when user states could do without any legislation on their side.

In the European Union (EU) questions of competence will have to be clarified. The EU has powers to set up its own research programmes. In relation to third countries it is called and empowered to 'promotion of cooperation in the field of Union research, technological development and demonstration with third countries and international organisations'.<sup>90</sup> This implies setting conditions for funding projects involving ABS. However, the EU lacks explicit competences to legislate in this field. Another competence basis to be considered is the one for environmental legislation.<sup>91</sup> This would however require that ABS is primarily conceived as a means to protect biodiversity, while in fact it is rather regarded as an undesired obstacle to free R&D. External trade<sup>92</sup> may be considered as a third basis. However, trade is not the core of the ABS transactions. It is the valorisation of genetic resources and traditional knowledge.

The competence basis for EU legislation on ABS being weak, member states will have to step in. Considering the user states' obligations under Articles 15 and 16 to ensure compliance with provider state legislation, user

<sup>89</sup> See Tvedt and Young, note 68 above, Ch. 6.

<sup>90</sup> Treaty on the Functioning of the European Union, Rome, 25 March, 1957, OJ C 115/47 (9 May, 2008), Art. 180(b).

<sup>91</sup> *Id.*, Art. 193.

<sup>92</sup> *Id.*, Art. 207.

state legislation should first of all lay out the basic duties of domestic users of genetic resources and traditional knowledge. These are that provider state legislation must be respected. Due diligence rules as laid down in EU Regulation No 995/2010 concerning timber imports may be considered in that relation.<sup>93</sup> If no authorisation was obtained or no contract concluded the competent administrative body must have powers to impose remedial measures or sanctions, maybe after having consulted the provider state.

It is not mandated by the Protocol that the user state takes administrative law measures to ensure the implementation of contractual obligations. This can be left to the initiative of the contract partner on the provider side. Of course, his action must be receivable at and enforceable by user state courts.<sup>94</sup>

In addition, according to Article 17 of the Protocol, user state legislation must establish some kind of monitoring of R&D activities. First of all user states should mandate the institutions and companies directing R&D to operate a monitoring system themselves. In addition, administrative bodies should be identified that have the power of inquiring R&D actors about their utilisation of genetic resources or traditional knowledge and respect for provider state legislation. Moreover, disclosure requirements may be established at certain stages in the valorisation chain. Disclosure at the patenting stage is widely recommended and was introduced by some states. However, as many products are brought to the market without implying patents and only 0.2 per cent of all patents are commercially viable at all,<sup>95</sup> user states that take their monitoring obligation seriously should rather require disclosure of origin concerning any new genetic resource or traditional knowledge based product placed on the market. The alternative – linking disclosure to product licensing – would leave out the many products which are not subject to licensing, such as, for instance, cosmetics.

Although according to the Protocol the user states do not have a self-standing duty to ensure benefit sharing, they do if provider state legislation lays out such duties of users. In that case a competent administrative body must be empowered to order remedial action.

## 5 CONCLUSIONS

The Protocol constitutes the latest ambitious approach to develop an international instrument complementing critical aspects of previous ABS instruments. In this regard, some major achievements were reached: the binding nature, a clear definition of 'utilisation of genetic resources' integrating the use of biochemicals (despite omission of an indicative list of possible uses), obligations to ensure legal certainty, facilitation of non-commercial research, obligations to ensure compliance supported by monitoring, stronger involvement of local and indigenous communities holding genetic resources and traditional knowledge, measures on increasing capacity and awareness, additional obligations on technology transfer, specific obligations on dispute settlement, the establishment of an ABS Clearing House Mechanism, and encouragement of multilateral approaches in transboundary situations.

However, the Protocol also suffers from several drawbacks such as: ample use of debilitating qualifiers ('as appropriate', 'where applicable', 'as far as possible', and 'if available') and weak language ('endeavour', 'encourage', 'consider', and 'promote') in central provisions, no clarification of the question of retroactivity, and no self-standing obligation of user states to ensure benefit sharing.

Considering positive and negative features, the Protocol probably reflects what could be reached at all given the clash of interests behind it. It therefore deserves to be swiftly ratified by all states interested in the research and valorisation of genetic resources and traditional knowledge with the final goal of protecting biodiversity. The actual utility of the Protocol will only become visible during the implementation phase. It is suggested that states start introducing their own ABS regimes without waiting any longer.

<sup>93</sup> Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market, OJ L 295/2010/23, Art. 4(2).

<sup>94</sup> See Hiroji Isosaki, 'Enforcement of ABS Agreements in User States', in Kamau and Winter eds., note 2 above at 439.

<sup>95</sup> 'Avoiding the Inventors Lament', Business Week, November 10, 2005, cited in the submission of Canada to the Group of Technical and Legal Experts on Compliance in the Context of the International Regime on Access and Benefit-Sharing, UNEP/CBD/ABS/GTLE/2/2, 19 December 2008 at 11.

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