

**Miriam Dross and Franziska Wolff**

**New Elements of the International  
Regime on Access and Benefit-  
Sharing of Genetic Resources  
- the Role of Certificates of Origin -**



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# 1 Introduction

The current debate on an international regime for access and benefit-sharing is rapidly gaining momentum. The enthusiasm among many countries is high,<sup>1</sup> both due to the limitations of national legislation for the realization of benefit-sharing and because of the high expectations with regard to the expected benefits.

Perceptions differ with respect to the second point. On the one hand, a Western research institute holds:

*“One key point of erroneous but established dogma is that pharmaceutical companies pay huge amounts of money for access to biodiversity, and that by holding back this access the quantum of “access fees” can be increased. This is not the reality. Bioprospecting is a high cost, high risk process with no guarantee of any financial returns at all. If access controlling agencies try to push the stakes even higher, industry will simply find alternative sources of chemical innovation for the bioproduct discovery process.”*<sup>2</sup>

On the other hand, it was recently reported that

*“[t]he Kenya Wildlife Service (KWS) is seeking a share of the hundreds of millions of dollars generated from the sales of a popular detergent and a bleaching agent manufactured in the US whose active ingredients were acquired in Kenya illegally.”*<sup>3</sup>

Obviously, provider and user countries as well as stakeholders have diverging expectations regarding the benefits of bioprospecting and differing views on sharing them.<sup>4</sup> A view shared by many stakeholders is that the current national provisions are not sufficient for regulating access and benefit-sharing in a comprehensive way.

An ongoing ABS project came to the preliminary conclusion that:

*“national and international law does not include the tools and concepts necessary to address ABS in a systematic, coherent and legally consistent way. The most important conclusion of our initial research is that there is no framework in national or international law that is currently able to address the legal rights relating to genetic resources. [...] Lacking basic legally accepted principles, it is not possible for countries to depend on normal contractual processes, documents and provisions, to protect their rights under ABS Agreements.”*<sup>5</sup>

Seen from a user’s perspective, this assessment is equally valid. Scientists and companies have been reported to find processes set out in access laws cumbersome, time consuming

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<sup>1</sup> Ruiz 2004, p. 1.

<sup>2</sup> Evans-Illidge/Murphy 1999, p.6.

<sup>3</sup> Mbaria 2004.

<sup>4</sup> It is reported that “Many pharmaceutical companies have withdrawn from the field for a variety of reasons, including doubts about its commercial benefits.” Dalton 2004, p.598.

<sup>5</sup> IUCN, 2004a.

and costly to follow.<sup>6</sup> Even worse, in the opinion of such experts access laws are “fine in theory, [but] there is no practical way to implement, monitor and enforce them.”<sup>7</sup>

Thus, a common goal of all those involved in access and benefit-sharing of genetic resources should be to contribute to a regime that provides an effective means of promoting access and benefit-sharing in a fair and equitable way, offers legal clarity and certainty, and thereby protects both users and providers. What could be gained would be the building of trust between the provider and user side. A third goal of an international ABS regime should be to contribute to the conservation and sustainable use of biodiversity. While it is disputed whether this can be attained by means of mere monetarization of genetic resources,<sup>8</sup> a position that will not be discussed in depth here, there might be additional possibilities for an international regime to reach this goal.

This study is concerned mainly with the design of an international ABS regime and specifically with the question which role certificates of origin, source or legal provenance could play in such a regime. In analyzing this question we are indebted to researchers who have studied this issue for years and made valuable suggestions upon which we have based our study, especially Brendan Tobin of the United Nations University (UNU).

We would like to thank all people who have supported this research. Most of all we thank the German Federal Agency for Nature Conservation (BfN), specifically Ute Feit, but also all people whom we interviewed and with whom we discussed pertinent questions including Dietrich Jelden (BfN), Marceil Yeater (CITES Secretariat), Tomme Young (IUCN), Sarah Laird and John Caldwell (WCMC), as well as numerous representatives of companies, universities, ex-situ collections, patent offices and NGOs for their help. Our special thanks are due to our colleague Ruth Brauner from the Öko-Institut for making sure that we got the scientific facts right.

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<sup>6</sup> Ten Kate/Laird 1999, p.

<sup>7</sup> Ibid, p. 297.

<sup>8</sup> Perrings/Gadgil 2002, Heineke/Wolff 2004.

## 2 Access and benefit-sharing under the Convention on Biological Diversity

The Convention on Biological Diversity (hereinafter: the CBD or the Convention) was signed at the World Summit in Rio de Janeiro in 1992 by 157 states and entered into force in December 1993. As of September 2004 the CBD has 188 parties, including the European Union.<sup>9</sup> The Convention is thus binding for almost all countries of the world, the important exception being the U.S.

The objectives of the Convention on Biological Diversity are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Art. 1 of the Convention). Compared to earlier international conventions on nature conservation, the CBD is, on the one hand, more comprehensive and integrated, and also more practice-oriented than the drafts for the international treaty that were presented by UNEP and NGOs.<sup>10</sup>

With respect to the third pillar of the Convention – benefit sharing regarding genetic resources, i.e. genetic material or, respectively, material of plant, animal, microbial or other origin containing functional units of heredity, with an actual or potential value (cf. Art. 2 CBD) – the CBD represents a paradigm shift: Until the CBD entered into force in 1993, access to genetic resources was unrestricted.<sup>11</sup> Art. 3 and Art. 15 para. 1 of the CBD recognize the sovereign rights of states over their natural resources and grant them the authority to regulate access to genetic resources, which is the responsibility of the national governments and is subject to national legislation. Unrestricted access to genetic resources had generally been based on an understanding that genetic resources were a “common heritage of mankind”. This concept derives from the law of the sea designating the status of the deep seabed and the ocean floor, which are (unlike genetic resources) outside of national territory. During the negotiations of the CBD, industrialized countries and NGOs alike (though for different reasons) advocated the concept of a “common heritage of mankind”.<sup>12</sup> While the exact content of the “common heritage” concept was unclear, the countries of the South rejected the idea, because they feared for their national sovereignty over the diversity on their national territory.<sup>13</sup> As a compromise, the conservation of biological diversity was finally referred to as “a common concern of humankind” in the preamble to the Convention.<sup>14</sup>

The industrialized countries favored an approach to access regulation that so far was embodied in the International Undertaking for Plant Genetic Resources. It was “based on the universally accepted principle that plant genetic resources are a heritage of mankind” (Art.

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<sup>9</sup> <http://www.biodiv.org/world/parties.asp>.

<sup>10</sup> Henne 1997, p. 109 – 113.

<sup>11</sup> This, however, is contended. As Stoll points out natural resources under the jurisdiction of a state were considered their sovereign property before as well. Stoll 2004, p. 77/78.

<sup>12</sup> Henne 1997, p. 119-121.

<sup>13</sup> Ibid, p. 120.

<sup>14</sup> However, Godt points out that biological resources have never been “common heritage” in the sense of “open access resources”. Godt 2004, 202.

1). Consequently, these resources were to be available “without restrictions”. The industrialized countries thus wanted access to genetic resources under the Convention to be “fair and equal”, “free” or “open”, while initially opposing benefit sharing obligations.<sup>15</sup> However, the idea of free access was rejected early on in the negotiations. As a compromise, according to Art. 15 para. 2 of the CBD, contracting parties are under obligation to create conditions which facilitate access to genetic resources and which do not impose restrictions that contradict the objectives of the Convention. The new concept of the CBD combines the access to genetic resources with sharing with the provider, i.e. the country of origin, the fruits resulting from using the resources. In this way, genetic resources were attributed a commodity value, and genetic information became a tradable object.

The Convention states three crucial prerequisites of access to genetic resources:

First, Art. 15 para. 4 of the CBD requires that the party providing genetic resources gives prior informed consent (PIC, Art. 15 para. 5). The providing party, however, can abstain from requiring PIC if it “determines otherwise” (Art. 15 para. 5).

A second prerequisite deems that access to genetic resources shall be granted on mutually agreed terms (MAT). The Convention calls for a framework in which the exchange of genetic resources can occur as opposed to a unilateral regulated administration of the access to genetic resources.<sup>16</sup>

Third, access is linked to the fair and equitable sharing of benefits. On the one hand, this involves the results of research and development, thus also covering joint research with provider countries (Art. 15 para. 6) and access and transfer of technology (including biotechnology) (Art. 16, 19). On the other hand, this idea of access affects benefits arising from the commercial and other uses of genetic resources to which the providing party is entitled. Benefit sharing, too, shall be agreed upon according to mutually established terms (Art. 15 para. 7, in conjunction with Art. 16, 19).

For years, access and benefit-sharing (ABS) has been one of the most disputed issues in the framework of the Convention.<sup>17</sup> Besides the economic relevance and distributive dimension of the topic, its importance can also be attributed to the complexity of the subject matter and its’ overlaps with other important fields of international policy such as patent law and agricultural policy.

In 1995, at the second Conference of the Parties (COP), delegates considered a compilation of the parties’ views regarding possible options for implementing Art. 15.<sup>18</sup> At its fourth meeting in May 1998, the Conference of the Parties addressed the equitable sharing of benefits resulting from genetic resources as a separate agenda item. In this context, the Swiss delegation presented a survey among Swiss companies and research institutes that recommended for the implementation of the CBD’s ABS regulations among others the development of Guidelines.<sup>19</sup> Decision IV/8 on access and benefit-sharing established a panel

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<sup>15</sup> Ibid, p. 123.

<sup>16</sup> Henne 1997, p. 150.

<sup>17</sup> Stoll 2004, p. 73.

<sup>18</sup> CBD 1996, Access to Genetic Resources, UNEP/CBD/COP/3/20.

<sup>19</sup> UNEP/CBD/COP/4/Inf., p. 16.

of experts appointed by governments and composed of representatives from the private and public sectors as well as representatives of indigenous and local communities. The mandate of the expert panel was to develop a common understanding of basic concepts of ABS and to explore all options for ABS on mutually agreed stipulations. The panel of experts met in October 1999 in Costa Rica and reached “broad conclusions” on a number of terms regarding ABS. At this meeting, draft Guidelines that had in the meantime been developed by Swiss government institutions were presented. They were tabled again at a subsequent Expert Panel Meeting and on COP 5, thus becoming building blocks of the later Bonn Guidelines.<sup>20</sup> Decision V/26 of COP 5 which was taken in May 2000 established an Ad Hoc Open-Ended Working Group with the mandate of developing guidelines for access and benefit-sharing. The Ad Hoc Working Group met in Bonn in October 2001 and developed the Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Subsequently, these guidelines were adopted at the sixth meeting of the Conference of the Parties which were part of Decision VI/24 (see infra at 3.).

At the World Summit in Johannesburg in 2002, delegates adopted a Plan of Implementation, which under Paragraph 44 not only called for the wide implementation of and the continued work on the Bonn Guidelines (Para. 44 (n)). It also recommended “negotiat[ing] within the framework of the CBD an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources (Para. 44 (o)). This commitment, which stresses the dimension of benefit sharing (as opposed to access), resulted mainly from the initiative of the so-called Group of Like-Minded Megadiverse Countries, which was founded in February 2002 to pursue the objective of creating an international and binding regime on ABS.<sup>21</sup> Many countries from the South felt that while the Bonn Guidelines elaborated on access, they had left the benefit-sharing aspect relatively unspecified.

In March 2003, the Intersessional meeting on the Multi-Year Programme of Work of the Convention up to 2010 recommended that the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing should consider the process, nature, scope, elements and modalities of such a regime. Against this background, the second meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing in Montreal in December 2003 resulted in recommendations on the terms of reference for the negotiation.<sup>22</sup> These recommendations were submitted to the Conference of the Parties at its seventh meeting in February 2004 in Kuala Lumpur, which in turn mandated the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing to elaborate and negotiate an international regime.<sup>23</sup>

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<sup>20</sup> Swiss Draft Guidelines on Access and Benefit Sharing (UNEP/CBD/COP/5/INF/21).

<sup>21</sup> Cancun Declaration of Like-Minded Megadiverse Countries. The Group consists of Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela.

<sup>22</sup> CBD, 2004, Report of the ad hoc open-ended working group on access and benefit-sharing on the work of its second meeting, UNEP/CBD/COP/7/6.

<sup>23</sup> CBD, 2004, COP- Decision VII/19, Access and benefit-sharing as related to genetic resources (Art. 15).

Before analyzing and commenting on the mandate terms of reference *infra* the Bonn Guidelines are discussed in detail in the following paragraph as a major point of reference for a future ABS regime.

### 3 The Bonn Guidelines

The Bonn Guidelines (BG) derived from a survey conducted among Swiss companies and research institutions. Switzerland presented the results at COP 4 and subsequently developed guidelines which were again presented at two meetings of the Panel of Experts on Access and Benefit-sharing. The Swiss draft for voluntary guidelines on access and benefit-sharing was circulated in 2000 by the Executive Secretariat to the Parties of the Convention and tabled at COP 5 in April 2000.<sup>24</sup> These draft guidelines were the ‘ foundation’ on which the Bonn Guidelines were developed. At the first meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing,<sup>25</sup> held in October 2001 in Bonn, the guidelines were almost finalized and subsequently adopted as Decision VI/24 at COP 6 in The Hague in April 2002.

The Bonn Guidelines set up a voluntary framework for legislative, administrative or policy measures on access and benefit-sharing as well as ABS contracts and agreements. Due to this broad approach and their non-binding nature, the guidelines represent recommendations which leave room for choice and interpretations. On the other hand, it has been pointed out that the Bonn Guidelines further harmonized the steps for adequate access and benefit-sharing and clarified and complemented existing obligations under the CBD.<sup>26</sup> The Guidelines substantiate Art. 15 para. 2, para. 2, para. 5 and para. 7 of the CBD as well as Art. 8 lit. j and Art. 10 lit. c and Art. 16 to 19 of the CBD.<sup>27</sup> A number of provisions are borrowed from existing national ABS provisions.<sup>28</sup>

The Bonn Guidelines contain five chapters. The General Provisions (I.) include objectives, the scope and definitions. The core of the Guidelines is contained in chapter II, which clarifies roles and responsibilities. The participation of stakeholders is detailed in chapter III. Part IV describes the steps of the access and benefit-sharing process. The Other Provisions (V.) are followed by two appendices that suggest elements for material transfer Agreements (Appendix I) and exemplify monetary and non-monetary benefits (Appendix II).

The Guidelines assign different responsibilities to the countries of origin of genetic resources, providers, users and countries with users of genetic resources under their jurisdiction.

#### 3.1 Roles and responsibilities

Countries of origin should designate both a national focal point and competent national authorities (13. and 14. BG.). The former shall inform applicants for genetic resources on

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<sup>24</sup> CBD, 2000, Access to Genetic Resources, Draft Guidelines on Access and Benefit-sharing regarding the Utilization of Genetic Resources, UNEP/CBD/COP/5/INF/21.

<sup>25</sup> CBD, 2001, Report of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, UNEP/CBD/COP/6/6.

<sup>26</sup> Vivas 2003.

<sup>27</sup> Godt 2004, p. 202/203.

<sup>28</sup> Namely, provisions from Peru, Brazil, India and the Philippines.

procedures for access, i.e. the requirements for prior informed consent and entering into mutually agreed terms. This information should be made available by means of the CBD clearing house mechanism.

The latter are responsible for the negotiations and approval of ABS agreements, prior informed consent and mutually agreed terms and their monitoring and enforcement. They are also responsible for the conservation and sustainable use of the genetic resources accessed (14.f BG). The countries of origin should make sure that environmental consequences of the access activities are taken into consideration and that indigenous communities are able to represent their interests during negotiations.

Private providers – as opposed to provider countries - are addressed separately by the Bonn Guidelines (16.c BG).<sup>29</sup> They should act in accordance with the CBD, i.e. only supply genetic resources or traditional knowledge if they are entitled to do so and not impose arbitrary restrictions on access.

Users, i.e. private entities such as enterprises, universities and research institutions, are addressed in-depth in the Guidelines (16.b BG).<sup>30</sup> When implementing MAT, users should seek prior informed consent, share benefits arising from the use of the resources, respect customary traditions and values of indigenous communities and use genetic resources only for purposes consistent with the MAT. The users are also required to maintain proof of PIC and information on the benefits arising from the use of the resources. If the resources are used for different purposes, new PIC and MAT have to be acquired. Principles for contractual agreements are described in point 43.<sup>31</sup>

There are only a few stipulations set out in the CBD concerning user countries, i.e. countries with users of genetic resources under their jurisdiction (16.d BG). User countries could consider measures which call for among other things, informing potential users about their obligations, supporting compliance with PIC and MAT and preventing the use of genetic resources obtained without PIC. These measures are to encourage user countries to disclose the country of origin and the origin of traditional knowledge when filing applications for intellectual property rights. User countries should also consider introducing voluntary certification schemes for institutions abiding by rules on access and benefit-sharing.

Part III of the Bonn Guidelines relates to the participation of stakeholders, which encompass indigenous and local communities (17.-21. BG). Stakeholders are to be consulted throughout all steps of the process of access negotiations. In addition, they should be kept informed and capacity-building is envisaged as a way to facilitate their active involvement. However, their exact degree of involvement, especially whether they are to profit from access agreements and whether they are partners in contractual agreements, is left to the discretion of user countries.

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<sup>29</sup> Generally provisions of international law do not oblige individuals private entities (individuals or corporations). Obligations have to be transposed into national law in order to create rights and obligations of private entities.

<sup>30</sup> Godt 2004, p. 204.

<sup>31</sup> See infra.

### 3.2 The access and benefit-sharing procedures

Part IV of the Bonn Guidelines outlines the steps of the access and benefit-sharing process. Countries should aim to introduce an overall strategy at the national or regional level on which a prior informed consent system that provides legal certainty and clarity is to be based. The Guidelines propose possible elements of a prior informed consent system as well as procedures (24.-40. BG). The system administering access to genetic resources should be implemented and managed at minimum costs and restriction should not run counter to the objectives of the Convention, i.e. the goal of facilitating access to genetic resources. While consent of the competent authority of the provider country is necessary, consent of stakeholders such as local communities should only be obtained “as appropriate to the circumstances and subject to domestic law”. The prior informed consent is envisaged to be obtained for a specific use. In case the applicant wants to use the resources for other purposes later or transfer them to third parties, a new application for prior informed consent may be required. Decisions on applications for access to genetic resources are to be reached within “a reasonable period of time.”

Under Art. 15 para. 7 of the CBD, mutually agreed terms (41.-45. BG) facilitate agreement on the sharing of benefits, which may arise for commercial and other uses of genetic resources. Mutually agreed terms shall also include provisions regarding the sharing of benefits arising from commercial and other utilization of genetic resources and their derivatives and products. The Bonn Guidelines stress the importance of legal certainty, the minimization of transaction costs as well as efficient and time-saving negotiations. The basic requirements for contractual agreements according to the Bonn Guidelines (43. BG) are:

- regulation of the use of resources in order to take into account ethical concerns;
- provisions that ensure the continued customary use of genetic resources;
- provisions on intellectual property rights that include e.g. joint research and provision of licenses by common consent;
- the possibility of joint ownership of intellectual property rights.

The Guidelines enumerate possible elements that could form part of a contractual agreement in detail in annex I, such as type and quantity of genetic resources, geographical area of activity, the treatment of confidential information etc.

With regard to benefit-sharing, the Bonn Guidelines cautiously state that mutually agreed terms could cover conditions, procedures and types of benefits to be shared, depending on what is regarded as fair and equitable in the given case (45.-50. BG). Annex II of the Guidelines provides examples of monetary and non-monetary benefits. These benefits can be long, medium and short-term. A balance should be achieved between the different forms of benefits. Possible benefits are to be distributed between all those that have contributed to the research and resource management, such as government, academic institutions and indigenous communities. The Guidelines also stipulate that benefits should be “directed in such a way as to promote conservation and sustainable use of biological diversity”.

The relationship between intellectual property rights and genetic resources has been set out in a number of provisions of the Bonn Guidelines. Parties concluding contracts with users of genetic resources under their jurisdiction should consider measures to encourage the disclosure of origin of the resources and the associated traditional knowledge in applications for intellectual property rights. In addition, the joint ownership of intellectual property rights is considered a basic requirement of contractual agreements.

Numerous provisions concern traditional knowledge and the role of indigenous and local communities. Generally, indigenous and local communities are regarded as part of the stakeholders, which should be included in the ABS process, but whose appropriate involvement can only be determined on a case by case basis. However, the consent of relevant stakeholders should be obtained in the framework of prior informed consent, especially where established legal rights of indigenous and local communities are concerned. The competent national authority is responsible for mechanisms for the effective participation of indigenous and local communities. The communities' traditions, values and customary practices are to be respected and the countries of origin should seek to ensure that the use of genetic resources does not prevent their traditional use. Indigenous and local communities are also mentioned as possible recipients of benefits if they have contributed to the resource management, scientific and/or commercial process.

### **3.3 Further provisions**

The “other provisions” (V.) of the Bonn Guidelines involve incentives (such as the removal of perverse incentives that act as obstacles for the conservation of biological diversity), accountability (reporting and disclosure of information) and national monitoring and reporting. The Guidelines also recommend implementing a voluntary certification system at the national level in order to promote compliance with the CBD's and national ABS provisions. Finally, they contain recommendations on the settlement of disputes and remedies.

Pertaining to other regimes, the Guidelines are to be applied “in a manner that is coherent and mutually supportive” with other international agreements and institutions, such as the FAO International Treaty for Plant Genetic Resources (ITPGR) and the World Intellectual Property Organization (WIPO).

### **3.4 The ecological dimension**

The Bonn Guidelines provide little guidance on the environment and on biological diversity. Although one of the objectives calls for the contribution to the conservation and sustainable use of biological diversity, ecology does not play an important role in the Guidelines. Generally, an access and benefit-sharing strategy, which should be set up by the contracting parties, should aim at the conservation of biodiversity. An application for access to genetic resources should include an evaluation of how the access activity may impact on conservation and sustainable use of biodiversity. Access approvals should facilitate envi-

environmentally sound uses and ABS provisions should establish a duty to minimize environmental impacts of collecting activities.

### 3.5 Summary

Interestingly, the Guidelines address predominantly private users who are theoretically not bound by international law.<sup>32</sup> While the stipulations for the users are rather detailed, the Guidelines only briefly deal with the so-called “user measures”, i.e. measures to promote compliance by users of genetic resources and traditional knowledge with obligations concerning PIC, MAT and benefit-sharing.<sup>33</sup>

Since the adoption of the Bonn Guidelines by the COP 6, they have been criticized on various accounts.<sup>34</sup> Foremost, the voluntary nature of the Guidelines has been judged as insufficient for implementing the ABS provisions of the CBD.<sup>35</sup> Representatives of indigenous peoples have criticized above all the use of the term “stakeholder”, viewing themselves as rights holders rather than as stakeholders.<sup>36</sup> They judged the voluntary guidelines as too weak and as providing insufficient protection of the knowledge and natural wealth of local people. They also reiterated previously voiced concerns that national governments rather than indigenous peoples would benefit from the commercial exploitation of TK.<sup>37</sup> NGOs commented that negotiators could pick and choose from different elements of ABS contracts without implementing conservation-oriented measures.<sup>38</sup> Furthermore, the Guidelines were too focused on the access side and neglected benefit-sharing since they would not contain any obligations for the user countries.<sup>39</sup>

It has been said, that the Bonn Guidelines are rather vague with regard to the protection of biodiversity. No explicit provision exists which would link access and benefit-sharing to the conservation of biological diversity. The Draft Guidelines on Access and Benefit-sharing regarding the Utilization of Genetic Resources, which were presented by Switzerland in 2000, had included in their Annex C as possible elements of benefit-sharing the transfer of knowledge and technology that are relevant to the conservation and sustainable use of biodiversity as well as trust funds, without specification of their function and use. The Bonn Guidelines do not address the idea of trust funds.

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<sup>32</sup> Godt 2004, p. 206.

<sup>33</sup> For the definition, compare Barber/Johnston/Tobin 2003, 20.

<sup>34</sup> There exists also a position, which fundamentally condemns the CBD approach of access and benefit-sharing. The exponents of this position claim that it results in commodifying genetic resources, which contributes to the destruction of biological diversity. Local and indigenous communities would be bound to lose through the commercialisation of genetic resources, either because they no longer have access to the resources or by pushing them to “sell out” their traditions and traditional knowledge. *See*, ETC Group 2004; Friends of the Earth International 2004; Brand/Görg, 2001.

<sup>35</sup> Stoll 2004, p. 86.

<sup>36</sup> IIFB 2001.

<sup>37</sup> ITCSD 2002.

<sup>38</sup> ETC Group 2004, p. 9.

<sup>39</sup> Meyer/Frein 2004.

Also, regarding the regulation of private users, according to NGOs, the Guidelines would not go far enough. In particular, the explanation of the role of so-called “intermediaries” was too vague. Intermediaries, such as universities, scientific institutions and botanical gardens would have proven indispensable in bioprospecting contracts. Currently, intermediaries have no obligation to extend their contractual obligations to third parties when passing on material.<sup>40</sup> In general, the Guidelines do not include measures for addressing infringements.<sup>41</sup>

One primary merit of the Bonn Guidelines is the naming of the different interests, legal positions and procedural elements.<sup>42</sup> If imparted by the users, this information provides helpful guidance on ABS contracts. Thus, the Bonn Guidelines also represent a valuable basis for a more detailed international regime on ABS.

So far, experiences with the Bonn Guidelines are very limited. It is still too early to decide what they have achieved in regard to fair and equitable access and benefit-sharing.

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<sup>40</sup> Godt 2004, p. 2006.

<sup>41</sup> Barber/Johnston/Tobin 2003, p. 35-37.

<sup>42</sup> Stoll 2004, p. 86.

## 4 Overview of some existing national and regional ABS laws and policies

At the outset, access and benefit sharing agreements were mainly concluded between companies on the one side and governments in biodiversity rich countries and/or indigenous communities on the other side without a national ABS legal basis for these arrangements being in force. Hence, initially practical experiences with ABS primarily concerned agreements which were not based on legislation.<sup>43</sup> In response to the bilateral agreements, in the meantime many governments have developed or are developing ABS legislation. Glowka<sup>44</sup> describes five types of legislation:

- Provisions contained in general environmental framework laws,
- Framework laws on sustainable development, nature conservation or biodiversity,
- Stand-alone national laws or decrees on ABS,
- Modifications of existing laws and regulations,
- Regional level regulation.

On the regional level, several framework laws and policies were agreed on. The counterparts of the biodiversity rich countries, like botanical gardens, research institutes and companies making use of genetic resources have adopted voluntary guidelines or policies. Access to genetic resources is regulated not only by specific legal frameworks but also by means of indirect regulation with laws on land ownership as well as laws regulating conditions to access and exploit State-owned land and natural resources, the law of contracts, etc.<sup>45</sup>

The number of countries and regions that have adopted ABS policies and legislation or draft legislation is increasing.<sup>46</sup> Regional frameworks have been implemented in Latin America, Africa and Asia. The Andean Community of Nations (Venezuela, Colombia, Ecuador, Peru and Bolivia) adopted the Common Regime on Access to Genetic Resources with Decision 391 taken in 1996. Of the Andean Community countries, some have chosen to further implement Decision 391 with national laws while others have limited themselves to directly applying Decision 391. In Africa, the Organization of African Unity, which consists of 53 countries, agreed on the so-called African Model Law.<sup>47</sup> Finally, with regard to regional approaches, the draft ASEAN Framework Agreement on Access to Biological and Genetic resources provides a common context for ASEAN member states (Brunei, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam, Laos, Myanmar and Cambodia).

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<sup>43</sup> Compare Columbia University 1999; Laird /Lisinge 1998; Aalbersberg et al. 1998; Guerin-McManus et. al. 1998; Baruffol; Iwu/Laird 1998; Henne et al. 2003; Moran 1998.

<sup>44</sup> Glowka 2004.

<sup>45</sup> COM(293) 821, p.13.

<sup>46</sup> Databases of ABS laws in different countries are available at <<http://www.grain.org/brl/abs-brl-en.cfm>> (8 July 2004) and <[http://wwwuser.gwdg.de/~ujvr/wirtschaft/forschung/access.htm#\\_National\\_legislation](http://wwwuser.gwdg.de/~ujvr/wirtschaft/forschung/access.htm#_National_legislation)> (8 July 2004).

<sup>47</sup> African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources, 1998.

Countries from the Global South that have implemented legislation or are in the process of doing so include Argentina,<sup>48</sup> Bangladesh,<sup>49</sup> Belize, Brazil,<sup>50</sup> Bhutan,<sup>51</sup> Cambodia, Cameroon,<sup>52</sup> Colombia, Costa Rica,<sup>53</sup> Ecuador,<sup>54</sup> El Salvador, Ethiopia, Eritrea, Fiji, The Gambia,<sup>55</sup> Ghana, Guatemala, Honduras, India,<sup>56</sup> Indonesia, Kenya,<sup>57</sup> Korea, Laos,<sup>58</sup> Lesotho, Malawi,<sup>59</sup> Malaysia,<sup>60</sup> Mexico,<sup>61</sup> Mozambique, Nepal,<sup>62</sup> Namibia,<sup>63</sup> Nigeria, Niue, Papua New Guinea, Pakistan,<sup>64</sup> Panama,<sup>65</sup> Peru,<sup>66</sup> Philippines,<sup>67</sup> Samoa, Seychelles, Solomon Islands,<sup>68</sup> South Africa,<sup>69</sup> Tanzania, Thailand, Turkey, Vanuatu, Venezuela, Yemen and Zimbabwe. So, while only 18 countries have actually implemented legislation, many more are in the process of doing so.

Industrialized countries that have adopted ABS legislation or regulated aspects of ABS such as disclosure requirements in patent law include Canada,<sup>70</sup> Australia,<sup>71</sup> the Nordic countries,<sup>72</sup> and the US.<sup>73</sup>

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<sup>48</sup> Draft law on access to genetic resources of biological diversity, 2000.

<sup>49</sup> Draft Biodiversity and Community Knowledge Protection Act, 1998.

<sup>50</sup> Medida Provisoria 2.186-16 on access to genetic resources and traditional knowledge, 2001; Acre State Law, 1997; Amapá State Law on Access to Genetic Resources, 1997.

<sup>51</sup> Biodiversity Act of Bhutan, 2003.

<sup>52</sup> Biosafety Law, 2003

<sup>53</sup> Biodiversity Law, Law 7788, 1998.

<sup>54</sup> Proposed Access to Genetic Resources Act, 2004. <http://www.elaw.org/resources/text.asp?id=2403>.

<sup>55</sup> The National Environmental Management Act, 1994. [http://www.sisei.net/gambia/article.php3?id\\_article=39](http://www.sisei.net/gambia/article.php3?id_article=39).

<sup>56</sup> Biological Diversity Act 2002; Biological Diversity Rules, 2004.

<sup>57</sup> [http://www.gbf.ch/Session\\_Administration/upload/agenda\\_access\(1\).PDF](http://www.gbf.ch/Session_Administration/upload/agenda_access(1).PDF).

<sup>58</sup> Draft Decree on Biological Resources and Related Traditional Knowledge. <http://archive.idrc.ca/books/reports/1996/37-01e.html>.

<sup>59</sup> Considerations on an ABS law: <http://www.sdn.org.mw/~esaias/nrcm/policies/guideline4.htm>.

<sup>60</sup> Draft Access and Benefit Sharing Law

<sup>61</sup> The environmental law can be found under: [http://www.semarnat.gob.mx/dgeia/web\\_ingles/indice.shtml](http://www.semarnat.gob.mx/dgeia/web_ingles/indice.shtml).

<sup>62</sup> Draft Policy on Access to Genetic Resources and Benefit Sharing, 2001.

<sup>63</sup> Draft Access to Biological Resources and Traditional Associated Knowledge Act. <http://www.dea.met.gov.na/met/programmes/legislation/legislation.htm>

<sup>64</sup> Draft law on access and community rights (no date).

<sup>65</sup> Special intellectual property regime upon collective rights of indigenous communities for the protection of their cultural and traditional knowledge, 2000.

<sup>66</sup> Law introducing a protecting regime for the collective knowledge of indigenous peoples derived from biological resources, 2002.

<sup>67</sup> Executive Order 247, Prescribing Guidelines and Determining a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By Products and Derivatives, for Scientific and Commercial Purposes and Other Purposes, 1996.

<sup>68</sup> Workshop on the design of a national ABS law: [http://www.field.org.uk/PDF/Sol\\_Report.pdf](http://www.field.org.uk/PDF/Sol_Report.pdf)

<sup>69</sup> Biodiversity Act, 2004.

<sup>70</sup> Canada Wildlife Act, – National Parks Act, – Migratory Birds Convention Act and Regulations, – Department of Fisheries and Oceans Act, – Department of the Environment Act, – Wild Animal and Plant Protection and Regulation of International and Inter-provincial Trade Act (WAPPRIITA), – Convention on International Trade in Endangered Species (CITES), – Oceans Act, – Canada Environmental Assessment Act.

Taken from second national report presented by the Canadian Government according to Art. 26 of the CBD.

<sup>71</sup> Australia, Queensland, The Biodiscovery Bill of Queensland

<http://www.legislation.qld.gov.au/Bills/51PDF/2004/BiodiscoveryB04.pdf>

<sup>72</sup> Denmark: Law for the revision of the patent law (Lov om ændring af patentloven, varemærkeloven, lov om brugsmønstre m.v., lov om mønstre og lov om plantenyheder). Norway: § 8 b of the Norwegian Patent Act (Lov om patenter).

## 4.1 Andean Community

In 1996, the Andean Community, consisting of Bolivia, Colombia, Ecuador, Peru and Venezuela, enacted Decision 391: Common Regime on Access to Genetic Resources.<sup>74</sup>

The Decision provides in Art. 1 a detailed list of definitions. On the basis of the definition of “access” it becomes clear that the decision covers genetic resources *in-situ* as well as *ex-situ*. Furthermore, the by-products are included and the potential use of the genetic resources is understood extensively: It concerns purposes of research, biological prospecting, conservation, industrial application and commercial use. According to Art. 3, human genetic resources, their by-products and the exchange of the resources among local communities for their own consumption based on their customary practices, are excluded from the scope of the Decision.

The Decision is built upon the following principles (title IV):

- sovereignty of the member countries over their genetic resources,
- recognition of know-how, innovations and traditional practices of the local communities,
- training, research, development and the transfer of technology,
- sub-regional cooperation,
- national reciprocity,
- precaution,
- free sub-regional traffic in biological resources,
- and juridical security and transparency.

The access procedure is ruled by title V. It provides that all access procedures require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of a corresponding resolution and the declarative registration of the acts connected with that access (Art. 16). The content of the application for access and of access contracts is explained in Art. 17. It predominantly reflects the interests of the member countries of origin and those of the local communities, e.g. their participation in research, the transfer of know-how, the deposit of duplicates of collected material and the obligation to inform the countries about the research results. All documents connected with the access should be kept in a public file unless confidential treatment is required (Art. 18, 19).

Art. 26 et. seq. establish rules for the application for access to genetic resources. The application must be addressed to the Competent National Authority, designated by the member

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<sup>73</sup> Access to genetic resources with in the Federal National Parks: The National Parks Organic Act regulations under the US Code of Federal Regulations (36 CFR 1).

<sup>74</sup> The text of the Decision 391 can be found on: <http://www.sice.oas.org/trade/JUNAC/decisiones/DEC391e.asp>. For further analysis of the Andean Pact *compare* Chaves, in: Stoianoff 2004. For an in-depth analysis of access and benefit-sharing in Colombia *compare* Ferreira-Miani, in: Carrizosa et. al. 2004, p. 79 et. seq.

countries (see fifth temporary provisions; functions of the Competent National Authority are scheduled in Art. 50). If the Competent National Authority accepts the application, taking into account the national environmental provisions in effect, the access contract between the State (represented by the National Competent Authority) and the applicant can be negotiated. The stipulation of an annex, as an integral part of the contract, is necessary when the requested access covers intangible components. The annex must be signed by the supplier of the intangible component and the applicant for the access and shall regulate the fair and equitable distribution of the profits from the use of that component. The Decision itself does not regulate the benefit-sharing. The subject matter of the benefits-sharing arrangement is not specified. Once the access contract has been adopted and signed, an extract of it must be published in a newspaper that has wide national circulation (Art. 38).

In addition to stipulating the access contract, the Decision also provides ancillary contracts which facilitate the implementation of activities related to the genetic resources (Art. 41 et. seq.). These contracts do not authorize access to genetic resources.

Art. 24 of the Decision contains restrictions on the use of genetic resources: The use of genetic resources in biological weapons and for practices that are harmful to the environment or to human health are forbidden. In addition, the member countries are empowered to establish, by means of an express legal rule, further limitations on access to genetic resources in specific cases, e. g. danger of extinction of species or undesirable environmental effects of access activities on the ecosystems (Art. 45).

Art. 46 seq. deal with the enforcement of the provisions. In the event that genetic resources are accessed without authorization, the Competent National Authority may apply administrative sanctions. Those sanctions shall be applied without interfering with the suspension of the access, the payment of compensation and civil and criminal sanctions that may be in order.

At the end of the Decision, in the complementary provisions, the member countries of the Andean Community are requested to set up funds financed by the profits generated by the access in order to promote compliance with the aims of the Decision, which are described in Art. 2 (e.g. promote the conservation of biological diversity and the sustainable use of biological resources).

Furthermore, it has been established, that no rights, including intellectual property rights, over genetic resources shall be acknowledged in cases in which they were obtained by means of an access activity that does not comply with the provisions of the Decision. When the Competent National Office on intellectual property sees reasonable indications for the use of genetic resources in connection with the requested right, it shall ask for the access contract. The Decision does not contain other restrictions concerning intellectual property rights. It only clarifies that the national provisions regulating that area have to be respected (Art. 26). With respect to intellectual property rights, Decision 391 is complemented by Decision 486: Common Intellectual Property Regime. Decision 486 establishes in Art. 3 that the granting of patents on inventions that have been developed on the basis of genetic material shall be subordinated to the acquisition of that material in accordance with international, Andean Community and national law. Consequently, the applications for a patent in

connection with biological resources must include a copy of the contract for access (Art. 26).

Finally, it has to be noted that Decision 391 does not contain provisions concerning prior informed consent.

#### **4.2 The ASEAN Framework Agreement on Access to Biological and Genetic Resources**

In 2000, the member states of the Association of South East Asian Nations, ASEAN, (Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Viet Nam) adopted the Framework Agreement on Access to Biological and Genetic Resources, which is still only a draft.<sup>75</sup>

One of the principles of the Framework Agreement is the sovereignty of the member states over biological and genetic resources within their territories (Art. 1). Access to biological and genetic resources is understood as the acquisition and use of biological and genetic resources as well as the derivatives thereof, as applicable, intangible components, for purposes of research, bioprospecting, conservation, industrial application or commercial use, among others (Art. 3). According to Art. 4, the Framework Agreement also covers traditional knowledge associated with biological and genetic resources. Access to traditional knowledge shall be explicitly indicated in the application for access. Materials of human origin and the traditional use of resources by the local communities in accordance with their customary practices and traditions are outside the scope of the framework.

Art. 4 of the Framework Agreement maintains that the member states shall not allow the patenting of plants, animals, micro-organisms or any parts thereof, and traditional and indigenous knowledge.

Before genetic resources can be accessed, the prior informed consent of the member state has to be obtained (Art. 10). Although the procedures concerning prior informed consent shall be determined by the competent national authority designated by the member state, the Framework Agreement sets out some rules for it: indigenous peoples and local communities shall be actively involved in the procedures and the PIC shall comply with their customary laws, practices and protocols. The application for the prior informed consent must necessarily contain specified information (e.g. potential environmental impact and specific purposes of the activity).

Art. 11 stipulates that the member states shall establish legal procedures to ensure the fair and equitable sharing of benefits arising from the use of resources and traditional knowledge. Indigenous peoples and local communities must participate actively in the negotiations of the benefits. The benefit-sharing arrangement shall contain a minimum set of requirements, such as the sharing of results, a complete set of all vouchers specimens left in national institutions as well as financial benefits.

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<sup>75</sup> The text of the Framework Agreement can be found on: <http://www.grain.org/brl/asean-access-2000.cfm>. (9 August 2004).

As set out in Art. 12, the Framework Agreement creates a Common Fund for biodiversity conservation. This fund shall be endowed by a share of the revenues derived from any commercialization of the use of resources, from a portion of the charges and fees on access application imposed by the member states and a portion of negotiated financial benefits.

Finally, Art. 13 stipulates that the various environmental and social impacts of access to genetic resources shall be taken into consideration in accordance with national, regional and international guidelines.

### **4.3 Australia/Queensland**

In 2004, Queensland adopted the Biodiscovery Act, “an act about taking and using State native biological resources for biodiscovery, and for other purposes.”<sup>76</sup>

The purposes of the Biodiscovery Act are (Art. 3.1):

- To facilitate access to native biological resources for biodiscovery,
- To encourage the development of value added biodiscovery,
- To ensure the State obtains a fair and equitable share in the benefits of biodiscovery,
- To ensure biodiscovery enhances knowledge of the State’s biological diversity, thus promoting conservation and sustainable use of biological resources.

This Act envisages setting up a regulatory framework for taking and using biological resources, a contractual framework for benefit-sharing agreements, a compliance code for taking resources and ensuring monitoring and enforcement of the Act (3.2).

The so-called schedule of the Act contains definitions. In this schedule, “biological diversity” is defined as “natural diversity of native biological resources” and shall encompass regional diversity (diversity of landforms, soils and water), ecosystem diversity, species diversity as well as genetic diversity. Thus the term “biological diversity” is defined in a very broad manner.

The Act introduces “collection authorities”, which are permits to take biological material and use it for biodiscovery (Art. 10). An application for such an “authority” must contain a description of what material the applicant intends to collect and for what purposes. The authority is valid for a maximum time period of three years. The applicant may only make use of the collection authority if a benefit-sharing agreement concerning the material has been concluded (Art 17.1). The user of biological material is required to take minimum quantities which are necessary for conducting his activities and which will have only minor impacts on biological diversity.

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<sup>76</sup> The Biodiscovery Bill of Queensland <http://www.legislation.qld.gov.au/Bills/51PDF/2004/BiodiscoveryB04.pdf>. For more information on Australia’s national approach to ABS *see* Stoianoff/Fox in: Stoianoff 2004 and for a case study of ABS in Queensland/Australia *compare* Jones in: Stoianoff 2004. For an analysis of Australia’s draft regulations on ABS *compare* Petherbridge in: Carrizosa et. al. 2004, p. 201 et. seq.

The Environmental Protection Agency, which is in charge of issuing the permits must maintain a register of the “collection authorities”, which is partly publicly accessible (Art. 27). The user must give samples of the collected material to the state (Art. 30). Holders of “collection authorities” are required to give so-called “material disposal reports” to the Queensland administration which specifies what biological material has been taken and whether it has been transferred to someone else.

Part 5 of the Act pertains to benefit-sharing agreements. The user and the state are the parties that shall enter into benefit-sharing agreements. “Benefits of biodiscovery” are defined in the schedule as those including any economic, environmental or social benefits for the State of Queensland. This encompasses among other benefits the transfer of technology to state-based entities, the creation of employment in the state, other commercial activities in the state (conducting research, undertaking production), improved knowledge of the state’s biological diversity, and payments to the state.

The user of the resource must prepare a biodiscovery plan, which will be approved by the administration. The plan shall contain the commercialization activities that the user intends to carry out and these must be approved by the administration. It shall include all commercial activities, a timetable for them, the activities that are to be carried out outside as well as inside the State of Queensland and the benefits that will be provided to the state. Benefit-sharing agreements that are entered into subsequently must be recorded in a register.

The EPA will set up a compliance code, which requires minimum standards for biodiscovery activities, such as environmental impacts (Part 6). Each provision of the Act regulates penalties for infringements against them. The Act does not envisage prior informed consent by local or indigenous communities.

#### **4.4 Brazil**

Brazil holds one of the World’s highest concentrations of biodiversity. It also was the first nation to sign the CBD. With the passage of Legislative Decree No. 2 in 1994, Brazil ratified the CBD, thus adopting its articles as national law. Prior to the Convention, the access to genetic resources and traditional knowledge was unregulated for Brazilian nationals except for the export of material.

The work of foreign researchers in this field was regulated by Decree 98.830 of 15 January 1990. One limitation of the decree is the absence of protection for indigenous or traditional knowledge.<sup>77</sup>

Apart from that, Art. 225 of the Constitution of 1988 contains a number of environmental provisions. It deals exclusively with environmental protection, including specific references to the preservation of diversity and the integrity of genetic patrimony. After Brazil ratified the Convention, several acts concerning genetic resources and traditional knowledge were presented and discussed in Congress. The proposal of two amendments to the Federal Pat-

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<sup>77</sup> Columbia University, environmental policy studies 1999, p.24

ent Bill concerning the rights of indigenous people and local communities marked a first attempt to establish equitable benefit-sharing. However, this attempt failed and the Patent Law passed in 1996 did not include the two amendments. Instead, reliance on the international standards of the Uruguay round of the TRIPS agreement relevant to indigenous people and local communities was seen as more favorable.<sup>78</sup>

Subsequently, three federal bills regulating access to genetic resources and their derived products, the protection of the associated knowledge and the sharing of benefits derived from resource use were proposed.<sup>79</sup> In June 2000 the Federal Executive issued its own version of the law by decree, in the form of a Provisional Measure.<sup>80</sup>

The Provisional Measure provides for the benefits, rights and obligations concerning the access to components of genetic heritage on the national territory, on the continental shelf and in the exclusive economic zone for purposes of scientific research, technological development or biological prospecting; the access to traditional knowledge relating to genetic heritage that is relevant to the conservation of biological diversity, the integrity of the country's genetic heritage and the use of its components; the fair and equitable sharing of the benefits deriving from exploitation of components of the genetic heritage and the associated traditional knowledge; and access to and transfer of technology for the conservation and use of biological diversity.

The regulations of the Provisional Measure exclude human genetic resources; the exchange and dissemination of components of genetic heritage and associated traditional knowledge practiced within indigenous and local communities for their own benefit and based on customary usage are preserved. The Provisional Measure does not mention biochemical properties or biological material in general.

The legal system does not, however, state clearly who is the owner of the genetic resources. The ownership depends basically on the general legal system of Brazil at the federal or state level. There is a Proposal for Constitutional Alteration to include genetic patrimony as a Union good.<sup>81</sup>

When the Federal Government first published the Provisional Measure in 2000, it was criticized by the public. It was claimed that the Provisional Measure only serves immediate

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<sup>78</sup> Ibid, p.25

<sup>79</sup> The first proposal for a law was brought to Congress by Senator Marina Silva and dates back to 1995 (Senate proposal no. 306). It was followed by proposal no. 4579 made by Congressman Jaques Wagner in 1998 and a little later by proposal no. 4751 that was submitted by the Government. The difference between these proposals is that the government proposal is of a more general nature, leaving specific details of regulations such as Terms of Responsibility, to be developed further and implemented by means of a regulatory mechanism, whereas the other proposals clearly define these details. Another major difference between the proposed bills is the way that they regulate benefit sharing. The Marina Silva and Wagner bills deal with benefit-sharing and compensation in a rather unspecific way, the bill of the Government on the other hand states that the economic exploration of a product or process resulting from access to patrimonial genetic resources must be shared in a fair and equitable manner with the union comprising indigenous or local communities, national, state, municipal or private owners. In June 2000, while Congress was discussing the proposed bills, the Government published a Provisional Law (PL no. 2.052) on access to genetic resources, protection and access to traditional knowledge, benefit-sharing and access and transfer of technology for its conservation and use". Its content was similar to that of the former proposal to Congress. Guedes/Sampaio 2000, p.2.

<sup>80</sup> The current version has the status of 23 August 2001.

<sup>81</sup> Cabrera 2004, p. 65.

special interests and overruns the legitimate legislative process, especially since Brazil has no legislation in force to guarantee its sovereignty over its own genetic resources. Until mid 2001, these measures were only valid for 30 days, and could be republished and amended every month.<sup>82</sup> At the time of writing, the Congress had passed no version of federal ABS legislation.

Meanwhile, two states in the Amazon region have passed ABS legislation: Acre, in the northwest corner of the country bordering Bolivia and Peru, and Amapá, near the border to French Guiana.

#### 4.4.1 Acre

In the case of Acre the legislation was passed responding to a particular case of “bio-piracy” involving an NGO that was cataloguing the native use of medicinal plants.<sup>83</sup> Acre State Law N° 1235/97, defines access to genetic resources as including the knowledge of indigenous and local communities. It places the responsibility to preserve the diversity, integrity and sustainable use of Acre’s genetic patrimony on the state executive power. The Acre law explicitly calls for three scenarios to require the prior informed consent of the local communities and indigenous peoples: (1) activities relating to access to genetic resources in areas that they occupy; (2) their domesticated agricultural crops; and (3) the traditional knowledge that they hold.

The decision to grant access to genetic resources is made by the State Council on the Environment, Science and Technology (CEMAT) and by a commission of representatives from the state government, municipal governments, state research entities, the scientific community, and entities representing the local communities and indigenous populations. The law protects the rights of local communities to benefit collectively and to receive compensation for the use of their rights. It also includes a provision for the local communities to deny permission to collect biological and genetic resources, as well as to deny access to traditional knowledge if it can be demonstrated that “these activities threaten the integrity of their natural or cultural patrimony”.

Due to the still recent nature of the law it is not yet clear what impact the Acre law will have on the region.<sup>84</sup>

#### 4.4.2 Amapá

The Amapá legislation resulted from a larger program aimed at sustainable development. Like Acre, Amapá has not experienced a large scale of environmental destruction, with less than 2% of its area being deforested. Concerns about the pristine forests led to the adoption

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<sup>82</sup> Marina Silva 2002, p.2.

<sup>83</sup> Erdos 1999, p. 2.

<sup>84</sup> Erdos 1999, p.17.

of the Sustainable Development Program of Amapá (PDSA) in 1995, which laid the foundation for a law regulating access to genetic resources.

In response to growing concerns about “bio-piracy”, Amapá Law N° 388/97 was passed at the end of 1998. In June of the following year, Decree N° 1624 was issued, which implemented the new biodiversity law, outlining further regulations in detail.

The law itself is far more concise than its Acre counterpart. Article 1 establishes the participation of local communities and indigenous peoples in decisions relating to the access to genetic resources in the areas in which they live, as well as their participation in the economic and social benefits resulting from access to genetic resources.

Decree N° 1624 contains 49 terms related to access to genetic resources, thereby reducing deviating interpretations of key concepts. The State Secretary of the Environment, Science and Technology (SEMA) is given the authority to "plan, coordinate, supervise, control, license, authorize and evaluate the development of activities of genetic resource access," as well as to guarantee and facilitate the participation of local communities and indigenous peoples in decisions on access to genetic resources. A permit granting access to genetic resources will be awarded by the Access to Biodiversity Resources Commission (CARB), which is to be composed of the following representatives: the regional office of Embrapa, SEMA, the State Attorney General's Office, IEPA, the Legislative Assembly, the regional office of IBAMA, the Federal University of Amapá, the municipality involved, the Secretary of Health, the Secretary of Justice, the community organization involved, the indigenous population involved, local environmental NGOs, the extractivist organization, the workers' union, the forest engineers, the fishers, the Organization of Cooperatives (OCEAP), the GTA, the Federation of Industries and the Pastoral Land Commission (CPT).<sup>85</sup>

#### 4.4.3 The question of jurisdiction

It is not clear whether the states have the right to regulate access to the genetic resources found within their borders, or whether only the federal government can decide on ABS policy. Genetic resources are not mentioned expressly in the Constitution as belonging to the Federal Union. The union, the states, and the federal district have the legislative right to regulate all questions concerning forests, hunting, fishing, fauna, nature conservation, preservation of the soil and natural resources, protection of the environment, and pollution control. It appears that the states may regulate access, at least until the passage of federal legislation.<sup>86</sup>

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<sup>85</sup> Erdos 1999, p. 19-20.

<sup>86</sup> Ibid, p. 21.

#### 4.4.4 The current situation in Brazil

Brazilian policy makers have not yet been able to establish regulations on access to genetic resources since they are confronted with many obstacles such as difficulties in establishing ownership of the genetic resources and insufficient legal, institutional and scientific capacities as well as opposing interests among the different stakeholders.

Some of the regulations drafted are comprehensive and will require extensive participation by state agencies to process requests for access and to monitor compliance with the terms of the agreements. Many conflicts of interest among stakeholders could come to an end, once a Brazilian law for access to genetic resources enters into force.<sup>87</sup>

### 4.5 Costa Rica

Costa Rica was one of the first countries to implement access and benefit-sharing legislation. Biodiversity Law No. 7788 dates back to 1998.<sup>88</sup> In December 2003 the Minister for Environment and Energy and the President of the Commission for the Management of the Biodiversity published the Access Regulations that function as a bylaw to the Biodiversity Law.<sup>89</sup> Before the entry into force of the Biodiversity Law several other laws regulated the field of biodiversity. Some chapters of the Wildlife Conservation Law addressed flora and fauna collection permits. Apart from that bylaws also existed that dealt with investigation, specifically with regard to national parks. But no regulations on agricultural matters existed until the implementation of the Biodiversity Law.

The approval process for the Biodiversity Law was a long and time consuming one and many stakeholders participated in the process of drafting the law.<sup>90</sup>

The overall objective of the Biodiversity Law is the conservation of biodiversity, the sustainable use of resources, and the fair distribution of the derived benefits and costs. It covers all the issues raised in the CBD including biosafety, conservation and sustainable use of ecosystems and species, access to genetic and biochemical elements of biodiversity, prior informed consent, protection of scientific and traditional biodiversity-related knowledge with intellectual property rights and/or *sui generis* systems, education and public awareness, technology transfer, environmental impact assessment and incentives.<sup>91</sup>

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<sup>87</sup> Columbia University, Environmental Policy Studies 1999, p.33.

<sup>88</sup> For an in-depth analysis *compare*: Jorge Cabrera-Medaglia in: Carrizosa et. al. 2004, p. 101 et. seq.

<sup>89</sup> Cabrera 2004, p. 183.

<sup>90</sup> The first draft appeared in 1996. It set off a negative reaction from many sides, which considered it to be too restrictive and contrary to national reality and scientific research. In January 1997 a second version of the bill was presented, which did not respond to the main objections made towards the first draft and therefore met with the same opposition. By this time, it seemed impossible to unify the opposing sides, therefore a commission was created in order to draft a new bill, which was to take into account the views of both sides. The Commission consisted of the National University, the main political parties, the Advisory Commission of Biodiversity, the Farmers Board, the Indigenous Board, the Union of National Chambers, the University of Costa Rica and the National Biodiversity Institute (INBio). At the end of 1997 a new draft of the project was completed, which was approved by the Congress with some changes in May 1998. Dutfield 2000, p. 20.

<sup>91</sup> Train for Trade 2000, p.46.

The regulations of the law exclude three sectors, which include human genetic and biochemical material, non-commercial exchanges between indigenous peoples and local communities of biochemical and genetic resources and associated knowledge derived from their practices, uses and customs, and the autonomy of universities with respect to field investigations and teaching for non-commercial purposes.<sup>92</sup>

The law regulates the ownership of genetic and biochemical resources of wild or domesticated biodiversity. According to Article 2 the state will exercise total and exclusive sovereignty over the components of biodiversity.

Art. 6 of the Biodiversity Law declares these resources to be in the public domain and all biodiversity elements per se are subject to the exclusive sovereignty of the State (Article 2) The state authorizes the exploration, research, bio prospecting and use of the components of biodiversity which constitute part of the public domain, as well as the utilization of all the genetic and biochemical resources (Article 6). Therefore, while the resources are under sovereignty of the State, private landowners or local communities, nobody, not even those who discover or may be aware of these properties, can own the properties of these elements.<sup>93</sup>

On 18 September 1998, the Office of the Attorney General of the Republic of Costa Rica instituted proceedings in the Constitutional Court to establish the unconstitutionality of certain articles of the Biodiversity Law. According to Articles 81 and 82 of the Law of the Constitutional Jurisdiction No. 7135, the legal action does not suspend the execution of the Biodiversity law, which is thus still in force.<sup>94</sup>

#### 4.5.1 Certificate of origin

Costa Rica has implemented a certificate of origin in its Biodiversity Law. Accordingly, Art. 77-85 are dedicated to the subject of intellectual and industrial property rights. They recognize that there is a need to protect knowledge and innovations through appropriate legal mechanisms.<sup>95</sup>

Any research program or biodiversity prospecting on genetic or biochemical material from biodiversity which will be carried out in Costa Rica requires an access permit. According to Art. 71 of the law, the access permit shall also stipulate the certificate of origin. This certifi-

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<sup>92</sup> Ibid, p.47.

<sup>93</sup> Ibid.

<sup>94</sup> The arguments of the Office of the Attorney General were that the Law admits far too much power to the CONAGEBIO (National Commission for the Management of the Biodiversity; Article 14) and SINAC (National System of Conservation Areas; Article 22). Article 14 creates the CONAGEBIO and gives it among other things the competence to define the national policies for biodiversity, including access to genetic resources. Articles 19 and 20 of the Law gives CONAGEBIO the right of independent management of public funds, which is contrary to Articles 121, 176 and 180 of the Constitution where it is written that the competence to decide over public finances is elsewhere. Article 22 creates SINAC with its own legal identity, it gives it the competence to lay down policies, plan and execute processes aimed at achieving sustainability in the management of Costa Rica's natural resources. The sections dealing with access to genetic resources have not been questioned, as a consequence if the action succeeds it would only have an effect on the legal competences of CONAGEBIO and SINAC but not the rest of applicable dispositions. Cabrera 2004, p.185.

<sup>95</sup> Dutfield 2000, p. 21.

cate is issued by the Technical Office of the Commission.<sup>96</sup> Both the National Seed Office and the Registers of Intellectual Property are required to consult with the Commission's Technical Office before granting protection for intellectual or industrial property involving biodiversity components. Those seeking protection must always provide the certificate of origin issued by the Technical Office of the Commission and proof of prior informed consent (Art. 80 of the Law). So far, few practical experiences have been gained with regards to the Costa Rican certificate of origin.

#### 4.5.2 Experience with the Costa Rica ABS legislation

Because the legal framework is still relatively new and due to the slow implementation process, firm conclusions as to the implementation of ABS cannot yet be drawn. The constitutional challenge surrounding the Biodiversity Law did not prevent the implementation process of the law, but had the effect of slowing down many of the necessary decisions to make the law operational. Neither CONAGEBIO nor SINAC was able to issue final decisions or receive funding. To date, Constitutional Chamber has not resolved the action.

If the legal proceedings turn out to be successful CONAGEBIO could be changed from a public policy setter to a simple adviser.<sup>97</sup> No draft text has been formally submitted as of yet, but some of the points that will be subject to review concerned IPR protection, particularly the form and limits of protection and licenses.<sup>98</sup>

Costa Rica has made an attempt to link the use of genetic resources to conservation in making a bargain with the pharmaceutical company Merck (INBio-Merck Agreement) in 1991 before ABS legislation went into force. This was one attempt to create mechanisms to help maintain Costa Rica's Conservation Areas by making them economically viable. Merck provided US \$ 1.0 million during the first two years for the purchase of laboratory equipment and materials to operate INBio's processing laboratory. INBio provided 10 % of this budget for reinvestment in conservation.<sup>99</sup> This, however, has to be juxtaposed with the costs of Costa Rica's conservation efforts, which amount to US \$ 1.0 billion for 10 years of maintaining the national parks.

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<sup>96</sup> Rivera/Cordero 1999, p.7.

<sup>97</sup> Cabrera 2004, p. 186.

<sup>98</sup> Train for Trade 2000, p.48.

<sup>99</sup> Columbia University 1999, p.18.

## 4.6 India

India signed the Convention on Biological Diversity in December 1993. Afterwards a long and time-consuming process started in order to develop India's draft biodiversity law, which took place between 1994 and 2002.<sup>100</sup> The India Biological Diversity Bill entered into force in 2002<sup>101</sup>.

According to section 2 "biological resources" are plants, animals, and micro-organisms or parts thereof, their genetic material and by-products with actual or potential use or value, but does not include human genetic material. Chapters III to V establish a National Biodiversity Authority, which is able to approve access activities. Generally speaking, all persons who are not citizens of India need a previous approval of the National Biodiversity Authority to obtain any biological resource or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization (section 3). Prior approval is also necessary for the transfer of biological resources, associated knowledge, the results of any research and for the application for intellectual property rights relating to biological resources (sections 20, 4 and 6). Citizens of India who want to use biological resources have to inform the State Biodiversity Board in advance, except with regard to activities in connection with indigenous medicine (section 7). "While granting approvals", the National Biodiversity Authority shall also ensure that benefits are equitably shared. Section 21 details the possible benefits, which include the joint ownership of intellectual property rights, technology transfer, inclusion of Indian nationals in R&D as well as other monetary and non-monetary benefits not further specified. The National Biodiversity Fund may also profit from benefit sharing, with an order from the National Biodiversity Authority. The Fund shall be used for channeling benefits to the "benefit claimers", the conservation of biological resources, the development of biodiversity-rich areas and the socio-economic development of these areas (section 27).

Biodiversity Management Committees are to be established at the local level (Chapter X). They shall be responsible for promoting conservation, sustainable use and documentation of biodiversity and are to be consulted by the National Biodiversity Authority before taking decisions which concern their territory. The Committees can levy fees for access in their territory. In addition to the National Biodiversity Fund, local funds will also be established, which shall be used for conserving local biodiversity and shall benefit the local community if such use is consistent with preserving biodiversity. Sections 55-57 contain penalties for violations of the provisions of the bill.<sup>102</sup>

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<sup>100</sup> It included the establishment of a drafting group of representatives from different ministries of the Government and the non-governmental side including experts from NGOs and research institutes in 1994; the circulation of a discussion paper prepared by the drafting group; a national consultation seminar to discuss possible elements of the law in 1997; the circulation of the proposed regulations to relevant experts and organizations; a second consultation seminar in 1998 and further discussions with NGOs and research institutes. The level of consultation in the development of the law has been unique in the history of the legal drafting of laws in India. Swiderska 2001, p. 18.

<sup>101</sup> The text can be found at: <http://www.grain.org/brl/india-biodiversityact-2002.cfm>. (9 August 2004).

<sup>102</sup> The text can be found on: <http://www.grain.org/brl/india-biodiversityact-2002.cfm>. (9 August 2004).

#### 4.6.1 The Biodiversity Action Plan

In 1994, together with the initiative to develop a Biodiversity Law, the Ministry of Environment and Forests held consultation meetings with representatives from ministries, government agencies, NGOs and academics to discuss the need for a national action plan on biodiversity. Even though this is not a legally binding instrument, the goal was to provide a policy guide for the government, administrators and the judiciary which they consider criteria for the direction that a law should take. The first proposed Action Plan was discussed as early as 1994. However, a time-lag of a couple of years followed and only in 1997 did discussions begin again. These resulted in the publication of the National Policy and Macro-level Action Strategy on Biodiversity in 1999.<sup>103</sup>

#### 4.6.2 Biodiversity Registers

The State of Kerala has initiated a process of local participation in biodiversity management by means of a number of local self-governance initiatives including the development of a People Biodiversity Register (PBR). The PBR was started as a pilot project in the district of Ernakulam in Kerala in 1997 and was followed by a second PBR in the village of Panchayat.

These registers are considered to be necessary in order to recognize the range of local knowledge identifying and promoting the use of traditional knowledge, skills, techniques and conservation practices. It is also believed that the register could be used to protect biodiversity and local knowledge from being privatized by commercial interests, which could patent modified products, processes and biological materials developed while using local resources and knowledge.<sup>104</sup>

On the other hand there is also concern that the registers could be misused by third parties. To date there is a legal vacuum with regard to biodiversity registers since no authority has been named to control the access to the registers.

A draft of a national law addressing the problem stipulates that the State Biodiversity Committee would have the jurisdiction over access by a domestic entity; whereas the national authority would decide on access by a foreign entity. However, in both instances local Biodiversity Management Committees have to be consulted.<sup>105</sup>

In the State of Karnataka an initiative by NGOs and individuals led to the establishment of PBRs. They even formulated a law governing these efforts, which however is to date not yet in force. The method of creating the PBR was similar to the one taken in Kerala, except that it had greater emphasis on aspects such as the economic potential of resources.<sup>106</sup>

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<sup>103</sup> Anuradha/Taneja/Kothari 2001, pp.20-21.

<sup>104</sup> Ibid, p. 32.

<sup>105</sup> Ibid, p. 36.

<sup>106</sup> Ibid, p. 41.

The process of developing PBRs has led to the affirmation of the belief that only in a decentralized system can biological resources be conserved effectively.

The government's response to the PBRs is widely positive; part of the funding for the register process of the PBRs was provided by the Federal Ministry of the Environment and Forest. The Government has never opposed attempts to formulate registers; however, there has been no response or action of taking up the efforts on a larger scale.<sup>107</sup>

#### 4.6.3 Summary

The level of consultation in the development of India's biodiversity law has been unique in the history of legal drafting in India. The process included well-informed stakeholders, which were consulted on numerous occasions. The stakeholders consisted of an assembly of NGOs, research and academic institutes and industry. Even though local communities were not part of the direct decision-making process, NGOs and researchers were able to provide the perspectives of the communities with which they were involved.<sup>108</sup>

Experiences with PBRs in the states of Kerala and Karnataka have revealed that these examples are a potentially valuable tool for the conservation and sustainable use of biodiversity and the preservation of related knowledge. PBRs may also provide means to enhance community control over local genetic resources and related knowledge and to promote community involvement in ABS partnerships as well as an effective system of benefit sharing. However there is concern that without a proper legislation the PBRs could be used to facilitate unapproved access to genetic resources.<sup>109</sup>

### 4.7 Organization of African Unity

The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources was formally endorsed and recommended in 2000 by all OAU Heads of State.<sup>110</sup>

According to Art. 1 access means the acquisition of biological resources – including genetic resources – their derivatives, community knowledge, innovations, technologies or practices as authorized by the National Competent Authority. Both in situ as well as ex situ biological resources are covered, but the local communities' traditional systems of access are not affected (Art. 2).

Art. 3 seq. establish the rules for access to biological resources. It is determined that any access activity – in a protected area or not - shall be subject to an application for the necessary prior informed consent and written permit (Art. 3). Art. 5 regulates the prior informed

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<sup>107</sup> Ibid, p. 45.

<sup>108</sup> Swiderska 2001, p. 18.

<sup>109</sup> Ibid.

<sup>110</sup> The text of the model legislation can be found at: <http://www.grain.org/brl/oau-model-law-en.cfm>. (9 August 2004).

consent, Art. 7 the written permit. Both of them require that the competent national authority as well as the concerned local communities accept the application. In order to provide the necessary information for indigenous people(s), the application for access shall be placed in a public registry or published in a newspaper (Art. 6). According to Art. 8 the agreement which grants the access permit shall contain, *inter alia*, the guarantee to deposit duplicates of each specimen of the biological resource collected, provisions for the sharing of benefits and the obligation to submit to the National Competent Authority a regular status report of research and development on the resource concerned. The permit can be an academic research permit, a commercial research permit, or a commercial exploitation permit (Art. 13, see also Art. 11). Art. 9 declares expressly that patents on life forms and biological processes are not recognized and cannot be applied for.

Concerning the sharing of benefits, as set out in Art. 12, the Model Legislation requires that a payment be made before the commencement of collection. Its amount depends on whether or not the collection is to be used for commercial purposes, the number of samples, the area of collecting, the duration of collection and whether or not the collector is granted exclusive rights. Furthermore, the member state and the local communities shall be entitled to a share of the earnings derived from the use of the biological resource collected in a production process.

Restrictions on the access to biological resources are set out in Art. 15. They affect, for example, rarity, adverse effects upon human health, undesirable environmental impacts and non-compliance with rules on biosafety or food-security.

In addition to the general provisions regarding the prior informed consent and the written permit, Art. 16 seq. establish specific rights for local communities, which include the right to refuse and to withdraw the consent (Art. 18, 19), and the right to participate in the benefits arising from the commercialization of the biological resource at least up to 50 %.

Art. 67 stipulates enforcement provisions, such as written warning, fines, confiscation of collected material and a permanent ban on access to biological resources.

#### **4.8 Philippines**

The Philippines ratified the Convention on Biological Diversity (CBD) in May 1993, making the country the 31st state to ratify the CBD. Shortly thereafter it implemented national ABS legislation and was the first country in the world to do this.<sup>111</sup>

The Philippines' ABS System does not contain a single law, but consists of the following elements:

- Executive Order No. 247 (1995)
- Administrative Order No. 96-20 Implementing Rules and Regulations (1996)
- The Indigenous Peoples Rights Act (1997)

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<sup>111</sup> For an in-depth analysis compare Benavidez II in: Carrizosa et. al. 2004, p. 153 et. seq.

- The Wildlife Law (2001).

In May 1995, Executive Order No. 247 “Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their Products and Derivatives for Scientific and Commercial Purposes and other Purposes” was adopted for implementing the CDB’s provisions. The Department of Environment and Natural Resources (DENR) subsequently issued Administrative Order No. 96-20 (A.O. 96-20) to implement Executive Order No. 247, which together provided a framework for access to genetic resources and benefit-sharing.

Executive Order No. 247 is based on the constitutional principle that the state bears the ultimate responsibility to preserve and protect the environment. Various problems occurred during the implementation process of the Administrative Order. In response to these problems the Philippine enacted the Wildlife Law in 2001. It is unclear, whether and to what extent the two orders were repealed by this law, which diverges from the framework on important points.<sup>112</sup> No authorized opinion on that has yet been issued and the Draft Regulation to the Wildlife Law has not been approved.

However, one has to take into account that the regulations in the Administrative Order and the Executive Order are far more specific and detailed than the rather wide and unspecific regulations in the Wildlife Law. The Wildlife Law contains only two articles (Art. 14 and 15) that relate directly to the subject of bioprospecting. Thus a total revocation of the Administrative Order and the Executive Order by the Wildlife Law cannot have been the aim of the enactment of the Wildlife Law. It has to be assumed that certain provisions which do not contradict the Wildlife Law are still in force. Hence, all the regulations will subsequently be outlined.

#### 4.8.1 Executive Order No. 247

The Executive Order regulates the prospecting of biological and genetic resources in order to ensure that these resources are protected, conserved, developed and put to sustainable use in the national interest. It also aims to develop local capacity in science and technology in order to achieve technological self-reliance in specific areas.

Executive Order No. 247 covers the prospecting of all biological and genetic resources in the public domain. Traditional uses by indigenous and local communities, however, are exempted from the regulation. Definitions of biological and genetic resources and material are the same as in the CBD. The Order envisages research agreements between the government and the “collectors”. An agreement shall include a payment of royalties if commercial uses are derived from the resources but can also foresee other forms of compensation where “appropriate and applicable”. In general, Philippines’ scientists shall be involved in all research and collection processes as well as in the technological development of products derived from the resources.

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<sup>112</sup> Cabrera 2004, p. 188, 191.

While implementing the Executive Order various problems occurred:

- The Executive Order covers “bioprospecting” of all kinds. It applies to all commercial bioprospectors as well as to all activities of academic and scientific institutions. This was considered undesirable, because these institutions are the main actors in biodiversity conservation work. For example, maintaining scientific inventories to conserve biodiversity is considered bioprospecting under the Executive Order because collecting is involved. It was said that the Executive Order is hindering and restricting this kind of work unjustifiably.<sup>113</sup>
- Traditional uses of biological and genetic resources are excluded from the Executive Order. Difficulties arise, however, in identifying traditional users.
- The application process is considered to be too time consuming. It is estimated that it takes at least 5 months for an application to be approved.
- Still, no inter-agency body exists, which means e.g. that an applicant who wishes to execute bioprospecting activities at 12 sites might need 12 certificates, with the possibility that each affected community will put forth different terms and conditions.
- The Executive Order allows bioprospecting only with the prior informed consent (PIC) of the indigenous and local communities concerned. A PIC certificate is issued only after a 60 day period has elapsed, during which time the affected groups have to be notified and consulted. The costs of this notification process have to be borne by the researchers. There are complaints that the described procedure is too exhausting, long and costly.<sup>114</sup>
- The Executive Order regulates the use of traditional knowledge and benefit-sharing. This includes local information, practices and techniques that have been developed and used by local peoples of all cultural backgrounds.
- The types of traditional knowledge have not yet been attributed to one or numerous indigenous communities and a database of existing traditional knowledge will be developed. Up to now, information about traditional knowledge is still scattered and patchy and it is not clear what exactly is considered to be traditional knowledge. It may often be that some genetic resources that are considered to be the gifts of nature are in fact the results of many generations of selective crop breeding and landscape management.<sup>115</sup> A definition process has yet to be started; until then lack of information can lead to numerous controversies.

#### 4.8.2 Wildlife Law

To respond to the problems outlined above, in 2001 the Philippines enacted the Wildlife Law, which contains two articles (Art. 14 and 15) directly related to the subject of bio-

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<sup>113</sup> Liebig 2002, p.36.

<sup>114</sup> Cabrera 2004, p. 187

<sup>115</sup> Dutfield 2000, p. 8.

prospecting and also establishes criminal sanctions concerning the violation of the restrictions for the exploitation of any kind of wildlife resources (Sec. 27). The Wildlife Law also establishes a wildlife fund (Sec 29).

The key changes introduced by means of the Wildlife Law are the following:

- The access authorization for bioprospecting on shore shall be granted by the Department of the Environment and Natural Resources (DENR) when plants and animal species, all turtles, tortoises and wetland species are involved. The Department of Agriculture (DA) has the jurisdiction over all declared aquatic critical habitats and all aquatic resources. In the province of Palawan, the Palawan Council for Sustainable Development (PCSD) is authorized to grant permissions.
- Bioprospecting is limited to research with commercial purposes only. The research with a scientific or non-commercial purpose does not require an Academic Research Agreement. Nonetheless, in the case of scientific or non-commercial research a prior permission in the form of a clearance has to be obtained.<sup>116</sup> In order to obtain this, the applicant has to sign an undertaking or agreement with the government.

#### 4.8.3 The Indigenous Peoples Rights Act

The Indigenous Peoples Rights Act was introduced in 1997 in order to ensure the intellectual rights protection of local and indigenous cultural communities with respect to the development of genetic resources and the conservation of the country's biological diversity.

To respond to the specific needs of indigenous cultural communities and indigenous peoples, the act states that these groups are entitled to the full ownership, control and protection of their cultural and intellectual rights. They shall have the right to take special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seed, including derivatives of these resources, traditional medicines, medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts.

Because the Act has only recently gone into force, it is still impossible to evaluate how effective it is in conveying property rights. However, it can be stated that up to now it was not capable of fully meeting the goal of protecting traditional knowledge. Article XII of the Philippines Constitution states that the Philippine government owns and has full control and supervision of the wildlife, flora and fauna within its territory. However, according to Executive Order 247 and the Intellectual Property Rights Act, the Philippine government also recognizes the "rights of indigenous cultural communities/indigenous peoples and other Philippine communities to their traditional knowledge and practices." This leads to confusion when determining the ownership of genetic resources. On the other hand, it is due to the complex nature of the subject. Due to the intangible character of information about the

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<sup>116</sup> Cabrera 2004, p. 189.

historical ownership of the rights, defining who should have rights over the genetic resources is a critical issue that is difficult to resolve.

Many traditional communities have their own view on ownership, which does not correspond to private and public property rights enforced by the state. Many traditional tenure systems regarding genetic resources are grounded on collective ownership or heritage and, sometimes, religious and mystical considerations.<sup>117</sup> The existing Act has not managed to cope with these problems.

#### 4.8.4 Experience with the Philippines ABS legislation

##### 4.8.4.1 Executive Order and Wildlife Law

Since the Philippines' ABS legislation was the first introduced, it was somewhat of a test case. The Executive Order defines bioprospecting very broadly.<sup>118</sup> It applies to the activities of all bio-prospectors, including the activities of academic and scientific institutions. Still, under the Wildlife Law a prior clearance has to be obtained by a scientific or non-commercial researcher. The latter are the main actors in biodiversity conservation work. Therefore, their inclusion in the Order and Wildlife Law is an issue of discussion. The regulation of ABS and especially the requirement to obtain local PIC has generated some controversy.<sup>119</sup> There is the concern that the rules and regulations are too complex and bureaucratic.<sup>120</sup> On the one hand, it is regarded as indispensable to involve local communities, on the other some scientists feel that the provisions on local PIC are too cumbersome and costly.<sup>121</sup> Scientific organizations offered criticism that the ABS regime will deter foreign partners, or even hinder scientific progress.<sup>122</sup> Local scientists view the benefit-sharing requirements under the EO as too demanding. According to Cabrera, up to 2004, only eight applications for commercial research agreements have been submitted in the Philippines, of which only one was approved. 17 applications were submitted for academic research agreements, of which also a single one was approved.<sup>123</sup>

##### 4.8.4.2 Intellectual Property Rights

Because the legal framework for intellectual property rights (IPR) has emerged only recently, firm conclusions as to its implementation cannot be drawn yet. It has, however, failed to recognize the more informal, communal system of innovation through which farmers and indigenous communities produce, select, improve, and breed a diversity of crop and livestock varieties – a process which takes place over a long period of time.<sup>124</sup> The existing

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<sup>117</sup> Columbia University 1999, p. 10.

<sup>118</sup> Molinyawe 1998, p. 104.

<sup>119</sup> Swiderska et. al. 2001, p. 8.

<sup>120</sup> Dutfield 2000, p. 17.

<sup>121</sup> Swiderska et. al. 2001, p. 8.; Molinyawe 1998, p. 104.

<sup>122</sup> Swiderska et. al. 2001, p. 8.

<sup>123</sup> Cabrera 2004, p. 192.; Dutfield 2000, p. 19.

<sup>124</sup> Explanatory note Community Intellectual Property Protection Act (2001, draft).

IPR framework effectively sidesteps the traditional knowledge of indigenous communities even if it is widely acknowledged that without the input of indigenous knowledge, many products used extensively throughout the modern world would not exist today.

For example, a World Health Organization bulletin reports that of the 120 active compounds currently isolated from the higher plants and widely used in medicine today, 74% show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they were derived.<sup>125</sup>

Therefore, a new bill is needed in order to attenuate and prevent the exploitation of the country's genetic resources by major multinational companies (especially those working in the areas of drugs and agriculture). A proposal for new legislation on intellectual property rights is still pending.

#### **4.9 South Africa**

In June 2004, South Africa signed the National Environmental Management: Biodiversity Bill;<sup>126</sup> chapter 6 deals with bioprospecting and access to genetic resources and benefit-sharing.

According to section 80 in conjunction with section 1, "indigenous biological resources" are resources consisting of organisms of indigenous species, including any derivative and genetic material of such organism. The coverage of the Biodiversity Bill is extended to specified exotic animal, but human genetic material is excluded.

Section 81 establishes that a permit is necessary for bioprospecting and exporting indigenous biological material. According to section 82, in addition to the permit, the prior informed consent of the stakeholders must be obtained as well when their interests are affected. A stakeholder is the person providing the access to the indigenous biological resources and the indigenous community whose traditional uses or knowledge is relevant for the proposed activity. Furthermore, as a condition for the permit, the stakeholder and the applicant have to make arrangements, which are to be approved by the Minister, concerning material transfer (i.e. export of biological resources) and benefit-sharing. The content of these arrangements are described, in a very general way, in section 83 and 84 and include e.g. the type of biological material to be collected, the area of collection, the use, quantity as well as traditional and present potential use.

The permit itself is regulated by sections 87 seq. The issuing authority has to assure that the permit is consistent with national and international law (section 88). When a specimen of an alien species or of a listed invasive species is involved, the permit shall only be issued after extensive examination of the potential impacts and the potential benefits associated with the activity (section 91).

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<sup>125</sup> Explanatory Note; Community Intellectual Rights Protection Act (2001, draft).

<sup>126</sup> The text can be found on: <http://www.grain.org/docs/south-africa-biodiversity-act-2004.pdf>. (9 August 2004).

Chapter 9 deals with offences and penalties. Section 102 stipulates that a person convicted of an offence pursuant to section 101 (e. g. performing an access activity without a permit) is liable to be fined or imprisoned for a period not exceeding five years.

#### 4.10 Summary

The analysis of the selected examples of ABS legislation allows for a number of conclusions. First, the ABS laws examined generally reveal a very broad range of interpretations regarding key concepts such as “access to genetic resources”, “users”, “owners” if they define them at all. This leads to a rather uncertain situation regarding the regulations worldwide with differences in terms/definitions between countries as well as in the application of the ABS law within a country. Especially concerning the term “genetic resources” definitions differ. Derivatives (sometimes referred to as by-products) are included in some of the laws. Many provisions contain only a definition of derivatives/by-products which is not mentioned further in the substantive provisions, e.g. in Costa Rica and in the Philippines.<sup>127</sup>

Second, rules concerning prior informed consent are also not uniform. This concerns the competent authorities, procedure as well as the question, whose consent has to be obtained. Not all countries require the prior informed consent of local communities/indigenous peoples. Sometimes it is sufficient to inform them. Sometimes, they are not mentioned at all.

Third, in regard to benefit-sharing, a wide range of regulations exist. Major differences can be seen with regard to who is participating in the benefit-sharing, whether local communities are involved and if funds have been allocated or not. Only few regulations stipulate obligatory monetary benefits. More and more, non-monetary benefits are playing an important role.<sup>128</sup>

Fourth, as an overall approach it can be stated that, in order for it to be effective, a national ABS legislation needs a broad acceptance among the country’s population. This acceptance can be gained with the participation of a broad variety of stakeholders in the drafting process, and ongoing consultation on the local and regional levels. As shown in the case studies of Brazil and India, new developments also point to the fact that there could be a potential need for regulation on the local and regional levels.

Some ABS regulations were drafted due to a fear of “bio-piracy” or a reaction to cases which were seen as such, e. g. in Acre in Brazil.<sup>129</sup> Subsequently, sometimes an overregulation of the issue has occurred, as in the example of the Philippines, where in the original Executive Order No. 247 commercial and non-commercial “bioprospecting” was covered by similar rules, thereby strictly limiting the research of academic and scientific institutions, which led to an amendment of the Executive Order. Still, in the case of the Philippines research institutions have withdrawn their applications. The reasons for that were not stated but could be due to the time-consuming application process or the overall transaction costs.

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<sup>127</sup> Ten Kate/Laird 1999, p. 18.

<sup>128</sup> See Annex 3: Comparative table of ABS agreements.

<sup>129</sup> Erdos 1999, p. 2.

Furthermore, for a number of years, industry has complained about the lack of legal certainty and clarity of national ABS legislation.<sup>130</sup> Overall, there are not many agreements that have been entered into worldwide. This could undermine one of the efforts of ABS legislation, which was to derive concrete benefits from the commercial and industrial use of the countries' genetic resources.

It has been stated that

*“it is strongly believed and supported that simpler and more flexible legislative provisions and administrative processes will foster ABS. Research indicates that this statement is not supported by fact. A country's ability to get ABS contracts bears no relation to the simplicity of its legislation – between neighbouring countries, the one with the most regulatory flexibility may not be chosen.”*<sup>131</sup>

Whether this assessment can be supported following the research of the national legislations above, seems questionable. In general, complicated legislation and especially the practice of countries (based on the latter) of rejecting access applications have proven to result in fewer ABS agreements and companies collecting resources in fewer countries.<sup>132</sup> Especially time-consuming procedures are held responsible for this.<sup>133</sup> While regulatory flexibility is probably not an inherent goal of ABS legislation, it should not be overlooked that those countries with a comprehensive, easy to handle system with clear national competences will profit from greater transparency. Even though users will not automatically choose a country with a simpler legislation, they could otherwise most certainly choose a country with no ABS legislation.

At the same time, the existing provisions are enforced poorly. While it is difficult to obtain an access permit or to enter into ABS agreements, once this has happened, no one is monitoring whether genetic resources leave the country.<sup>134</sup>

As a consequence of the analysis, it is evident that an international ABS regime could be helpful if it were to result in more consistent national legislations for both providers and users and provider and user countries for a number of reasons:

- If mandated by an international regime more uniform conditions could reduce transaction costs for users by leveling national requirements for access to genetic resources,
- If an ABS regime were to promote 'best practices' internationally, time-consuming and costly procedures could be streamlined,
- Users could no longer use differences between national legislations in order to avoid benefit-sharing agreements,

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<sup>130</sup> Ten Kate/Laird 1999, p. 197-198.

<sup>131</sup> IUCN 2004a, p.3.

<sup>132</sup> Ten Kate/Laird 1999, p. 301.

<sup>133</sup> Ibid.

<sup>134</sup> Ibid.

- Better monitoring and enforcement could be implemented throughout the flow of genetic resources,
- Provider countries could benefit from each other's experiences due to more uniform legislations.

Interestingly, most ABS legislations analyzed provide for a fund of some sort. This issue will be further discussed *infra*,<sup>135</sup> however, as a general conclusion national ABS laws seem to indicate the need for biodiversity funds to be introduced by means of an international regime.

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<sup>135</sup> See chapter 5.3.12.



## 5 The international regime on access and benefit-sharing of genetic resources

### 5.1 The Terms of Reference for further negotiations of the international ABS regime

The Annex to COP Decision VII/19 contains the Terms of Reference for the Working Group on Access and Benefit-Sharing. They relate to the process of negotiation, the nature of the regime, its scope and elements. The mandate of the Ad hoc Working Group was not intended to result in the development of a legally binding regime, but rather to set in motion a process to reach a decision on the nature of the regime and its contents.

With regard to the process, the Working Group received a broad mandate for the negotiations. It has been called upon to draw on experience with access and benefit-sharing to date by analyzing national, regional and international instruments. Existing access contracts and experiences with their implementation should be assessed as well as compliance and enforcement mechanisms. The Working Group shall conduct a gap analysis with regard to the content of existing instruments to explore which of the possible elements of a regime identified by Decision VII/19 are currently not contained in the existing instruments.

The nature of the international regime is quite vague under the mandate: it could consist of one or more instruments, be legally binding or non-binding, “within a set of principles, norms, rules and decision-making procedures.” Thus, all options were left open with regard to the legal nature of the regime. The EU, Canada and Switzerland had encouraged prioritizing the implementation of the Bonn Guidelines to help identify problems and gaps but committed to negotiating building a regime based on these experiences. The African Group and others supported a legally binding regime that balances access with benefit-sharing concerns, and includes technology transfer.

Concerning the scope, there was disagreement about whether the regime was to cover only benefit-sharing or access to genetic resources as well. According to the Terms of Reference it is to encompass both, as well as the issue of traditional knowledge, innovations and practices under Art. 8 (j).

Concerning the elements of an international regime a list is to be considered by the ABS Working Group includes, *inter alia*:

- measures ensuring: collaborative scientific research and sharing of its results; sharing of benefits arising from the utilization of genetic resources and their derivatives and products; compliance with national legislations on ABS, PIC and MAT; and compliance with PIC of indigenous and local communities holding associated traditional knowledge;
- measures preventing unauthorized access to genetic resources;
- the issue of derivatives;
- certificates of origin/source/legal provenance;
- disclosure requirements in IPR applications;

- protection of community rights over their traditional knowledge and customary law;
- instruments to ensure benefit-sharing with communities;
- monitoring, compliance and enforcement;
- dispute settlement and/or arbitration; and
- relevant elements of existing instruments and processes.

In this regard many aspects were difficult to agree on. Industrialized countries opposed the idea that the mandate should cover derivatives as well, while the megadiverse countries like Indonesia wanted to include them. The most contentious elements were the question of disclosure requirements in patent applications, the role of certificates of origin/source/legal provenance, the relevance of national ABS legislations, possible measures to ensure that bioprospecting beyond the jurisdiction of countries of origin is in compliance with the CBD, the issue of monitoring, compliance and enforcement and dispute settlement.

The EU insisted on the negotiation mandate comprising existing instruments and processes, which they attributed to the endeavor to avoid duplication and overlap, to save resources and to prevent the establishment of new structures where they are not necessary. The Terms of Reference for the Ad Hoc Open-ended Working Group on Access and Benefit-sharing contained in Decision VII/19 are drafted in a very broad language, which leaves open all options for the negotiations. Conflicts concerning the design of the international regime have been postponed until the negotiation stage within the Working Group and later negotiations.

At the same time, the political momentum for the further development of the international regime is very strong.<sup>136</sup> After its inclusion into the Plan of Implementation in Johannesburg, there has been an express political commitment to international negotiations.

The elements of the TORs cover a broad range of aspects. However, a couple of points, which are further outlined below were not included, even though they might be helpful for further progress in negotiating the ABS regime.

## **5.2 (New) elements of the international ABS regime**

COP Decision VII/19<sup>137</sup> contains in its Annex the Terms of Reference of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing for the elaboration of an international regime on access to genetic resources and benefit-sharing. The ABS Working Group accordingly shall consider the process, nature, scope and elements of the international regime. It has been claimed that it is impossible to identify the components of the international regime realistically, since no parameters of the proponents' expectations have been made public yet.<sup>138</sup> However, the past experience with national/regional ABS laws and frameworks as

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<sup>136</sup> It has rightly been pointed out that an international ABS regime – consisting among other things of the ABS provisions of the CBD and the ITPGR, guidelines and policies well as both regional and national implementation measures - already exist, Young 2004c.

<sup>137</sup> UNEP/CBD/COP/7/21.

<sup>138</sup> IUCN 2004b, p. 14.

well as with the Bonn Guidelines and individual access contracts allows one to draw conclusions on probable further elements of the international regime and different options for these elements.

Even though the mandate for the negotiations indicates what should be discussed during the negotiations for the ABS regime, the question remains, what needs to be regulated at the international level and what should remain in the national realm.<sup>139</sup> As the CBD itself contains only very general parameters regarding the design of ABS agreements,<sup>140</sup> this question can only partly be answered by the CBD, which clearly points towards national competencies in regulating specific questions.<sup>141</sup> An example is Art 15 itself, which states that the “authority to determine access to genetic resources rests with the national governments and is subject to national legislation“.<sup>142</sup> However, it cannot be inferred from this and similar provisions, that the Parties to the CBD are prevented from agreeing on additional norms that limit their national rights.

The CBD is an international convention. As such it addresses states. However, the obligations that the CBD puts forward concerning e.g. the sharing of benefits or the transfer of technology are often addressed to private entities – in particular the users of genetic resources. The states therefore have the duty to “guide” private organizations and economic actors in a way that makes sure that the cooperation intended by the Convention can be attained.<sup>143</sup> On the one hand, states thus have a responsibility to implement the provisions of the CBD, for there are obligations that can only be fulfilled by the states themselves.<sup>144</sup> After the provider states have increasingly adopted ABS legislation in the last years, now the focus is shifting more and more towards so-called “user measures”, which the user states shall adopt to make sure that private entities under their jurisdiction follow the obligations of the CBD.<sup>145</sup> The provisions of the CBD can in fact be interpreted to provide for an obligation of user states to do that.<sup>146</sup> A number of “user measures” are currently being discussed. An instrument that receives increased attention is the certificate of origin/source/legal provenance, which is a user measure in that it potentially regulates the user side but requires regulation both from the provider and the user countries.

Since the focus of this analysis is on the proposed certificates of origin/source/legal provenance, a separate chapter 6 is devoted to the analysis of their function, legal aspects and economic implications.

### 5.3 Definitions

It has been noted that a broad range of terms is either not defined in the Convention or even if defined in the Convention is not clear enough and can thus be interpreted differently by

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<sup>139</sup> Henne et. al. 2003, p. 39.

<sup>140</sup> WBGU 2001b, p. 341.

<sup>141</sup> Ibid.

<sup>142</sup> Ibid.

<sup>143</sup> Stoll 2004, p. 81.

<sup>144</sup> Ibid.

<sup>145</sup> Barber/Johnston/Brendan 2003.

<sup>146</sup> Ibid, p. 15.

the Parties.<sup>147</sup> One of the consequences is the invitation to parties in COP-Decision VII/19, governments and stakeholders to submit information on existing national definitions on a number of terms including access to genetic resources, benefit sharing, commercialization, and derivatives. In the following, possible definitions of the terms “genetic resources” and “access to genetic resources” will be discussed since they are of pivotal importance for the international regime.

With regard to German law, no relevant definition were found that could illustrate the use of terms in a future ABS regime. Pertinent terms found in German law and their use are contained in Annex I.

### 5.3.1 Genetic resources

Of crucial importance for the scope of the international regime is the definition of the term “genetic resources” (GR), which in the Convention is based on the term “biological resources”. The latter includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. Genetic resources are defined in the Convention as genetic material of actual or potential value, with genetic material meaning any material of plant, animal, microbial or other origin containing functional units of heredity (Art. 2 CBD). According to the definition of Art. 2, genetic resources thus have to contain functional units of heredity. The distinction between genetic resources governed by an ABS agreement and biological material not covered by the ABS framework is not always clear.<sup>148</sup> It has been claimed that the lack of clarity of this definition does complicate the implementation of access and benefit-sharing.<sup>149</sup> This is true insofar as most biological material potentially contains functional units of heredity. At the same time the actual value of the genetic material can be difficult to determine, while a potential value can generally not be excluded.

Concerning the definition of genetic resources, it has thus been pointed out that it depends not only on the genetic code of the material in question but can also refer to the specific use that is being made of a sample, i.e. of their DNA, genes etc.<sup>150</sup> In other words, the same resource can represent a genetic resource, if its genetic components are of interest, or it can be a biological resource if the whole plant, animal etc. is used for other purposes.<sup>151</sup> A definition of ‘genetic resource’ should thus refer to the intended use of the material to which the scope of Art. 15 of the CBD is confined.<sup>152</sup> Such a definition would also avoid the difficulties that arise from the very broad definition of the CBD, which in fact results in minimum

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<sup>147</sup> IUCN 2004b, p. 8.

<sup>148</sup> Henne et. al. 2003, p. 42.

<sup>149</sup> Chishakwe/Young 2003, p. 5. This opinion is not shared by everybody, *see* Henne et. al. 2003, who propose to simply refer to the definitions in the CBD, p. 42.

<sup>150</sup> IUCN 2004b, p. 8.

<sup>151</sup> *Ibid.*

<sup>152</sup> Ten Kate/Laird 1999, p. 17.

quantities of biological material being taken out of a country for no purpose being potentially GR. The export of fruits would be covered as well.<sup>153</sup>

The use of biological resources is not to be covered in the access and benefit sharing regime. As a consequence, there is no obligation to facilitate access to biological resources.<sup>154</sup> However, provider countries can include biological resources in national legislation and do so in order to ensure that prior informed consent and benefit-sharing provisions apply to these as well.

With regard to the international ABS regime, it is debatable whether the regime has to contain a more precise definition than that of the CBD. On the one hand, this could be helpful in order to ensure that the same material is covered by the new regime in all countries. On the other hand, it might be difficult to agree on a more precise definition, which might limit the Parties' ability to regulate ABS.

Concerning a possible definition, a reference to the use of the resources seems convincing because it would provide a clear distinction between biological and genetic resources. It would present problems, however, when the final use of the resource is not clear at the time of the access activity.<sup>155</sup>

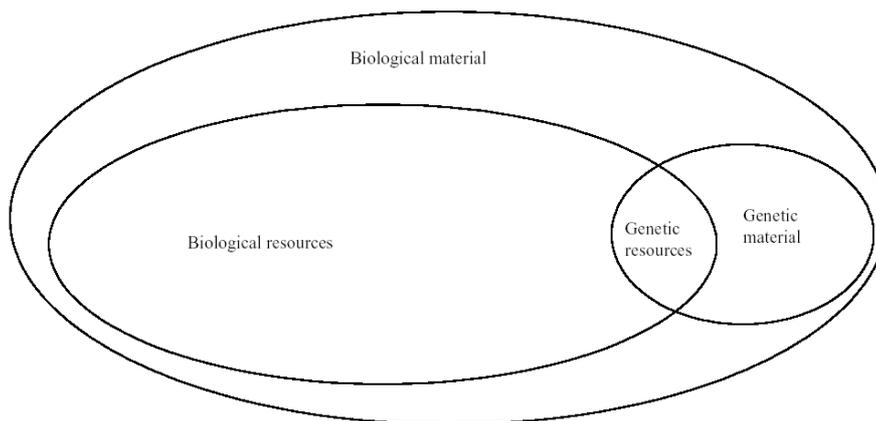


Figure 1 Classification of genetic resources according to the CBD. Source: OECD 2003.

### 5.3.2 Access

The CBD does not define the term “access”. The Parties have used various definitions.<sup>156</sup> An example for a definition is the “obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for pur-

<sup>153</sup> Stoll 2004, p. 87. Stoll infers from this fact that the term ‘genetic resources’ cannot be defined in a way that would allow the implementation of a regulative system. The question whether ‘genetic resource’ does include only material or the information contained in the material can effectively be left open under this definition, which refers to the use. *Compare* for this issue: Fowler 2003.

<sup>154</sup> *Ibid.*

<sup>155</sup> See also *infra* at “intermediaries”.

<sup>156</sup> See Chapter 4.

poses of research, biological prospecting, conservation, industrial application and commercial use, among other things.”<sup>157</sup> Many national ABS laws include in the definition access to traditional knowledge.<sup>158</sup> However, it has been pointed out that too wide of provisions involve the danger that even the accidental taking of small parts of biological material will be considered access to genetic resources.<sup>159</sup>

Elements which can be included in the definition of access to genetic resources and which can be found in national legislation and publications include:

- survey activities,
- entering the place/location where genetic resources are found,
- obtaining/acquisition of GR,
- use of GR,
- study or systematic investigation of any biological resource,
- for scientific and/or commercial purposes, for patenting or for conservation.

Depending on the activities that are included in the definition, already entering a specific spot can be “access” and as a consequence might need an authorization. In other cases only the acquisition or use of GR is covered. Accordingly, depending on how broad the term “access” is defined, bioprospecting, commercialization and research are treated rather restrictively or rather freely. The definition should also take into account (national) scientific interests such as taxonomic research. The Philippines legislation e.g. was criticized because it covered the work of inventories to conserve biodiversity as well.

A more general question is whether scientific and commercial activities should be differentiated. While this is desirable to foster scientific research, the differentiation between the two is not always obvious. Often, scientific research later on leads to commercialization.<sup>160</sup> It is therefore proposed here, to explicitly address the role of intermediaries in the international ABS regime. Thereby, a different regulation of scientific and commercial research can be introduced without the possibility that the scientific institutions act as intermediaries with benefit-sharing agreements later on (see *infra*).

The next question is then what can be “accessed”, i.e. what will be covered by the international regime. While obviously genetic resources are at issue, it is already disputed whether derivatives should be included. The same can be said for intangible components, traditional knowledge, innovations, technologies and practices. Finally, it should be pointed out that a commonly agreed on definition of the term “access” to genetic resources might facilitate

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<sup>157</sup> Decision 391 of the Andean Community “Common regime an access to genetic resources”, Title 1, Art.1. Very similar is the definition in Art. 3 of the ASEAN Framework Agreement on Access to Genetic and Biological Resources.

<sup>158</sup> E.g. Costa Rica, Biodiversity Law, Law No. 7788, Chapter 1, Article 1; draft law in Brazil, Bill of Law No. 306/95.

<sup>159</sup> Godt 2004; Stoll, in: Wolff/Köck 2004, p. 87.

<sup>160</sup> Godt 2004, p. 211.

access and especially prevent misuse.<sup>161</sup> While it can be argued that a definition could prove superfluous and limit the Parties' possibility of finding individual solutions in their countries, the wording concerning access can be such as to allow Parties to include broader definitions.

### 5.3.3 Facilitate access to genetic resources

Facilitate access to genetic resources is one of the purposes of the CBD. According to Art. 15 para. 2 of the CBD "each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention". The national laws on access and benefit sharing do not contain detailed provisions to achieve this aim but remain rather vague.<sup>162</sup> However, even if the focus of the international ABS regime is not this question, it has to be pointed out that both provider and user (countries) can benefit from facilitated access to genetic resources, because restrictive provisions will lead to no access and benefit-sharing taking place. Since provider countries mostly are interested in ABS, it would be appropriate to create conditions that make it easier for industry to access genetic resources.

Possible measures to facilitate access to genetic resources could be:

- Making clear provisions to achieve legal certainty for the user of genetic resources;
- Establishing national focal points in the provider country which are responsible for all matters concerning access to genetic resources, as foreseen under the Bonn Guidelines;<sup>163</sup>
- Excluding arbitrary decisions of the provider country on the application for the access to genetic resources are not possible;
- Preventing obstacles for the access to genetic resources created by the provider country;
- Minimizing costs for access to genetic resources;
- Supporting a fast procedure to gain the permit for the access to genetic resources for specific activities (such as taxonomic research).

Generally, it can be expected that the international regime will also contain aspects relating to facilitating the access to genetic resources. While no detailed provisions can be counted

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<sup>161</sup> Compare the Zimbabwean *Swatzia Madagascariensis* case, where no benefit-sharing in regard to the use of the genetic resource and the traditional knowledge involved took place. Chishakwe/Young 2003, p. 11.

<sup>162</sup> Queensland (Australia) establishes the facilitation of access by biodiscovery entities as one of the purposes of the Act (Art. 3 of the Biodiscovery Bill), but no detailed provisions can be found in the Biodiscovery Bill. India established Biodiversity Management Committees to promote the conservation, sustainable use and documentation of biological diversity (Art. 41 of the Biological Diversity Bill). Costa Rica seeks to promote investment for the conservation and sustainable use of biodiversity by public organizations in cooperation with the private sector (Art. 98 of the Biodiversity Law).

<sup>163</sup> For the number of existing national focal points, see *infra* at 5.3.18.

on, a general provision could include a provision that requires decisions on access to genetic resources to be made in a timely manner, not be prohibitively expensive and be non-discriminatory and require that provider states prevent introducing new obstacles for access to genetic resources.

#### 5.3.4 Prior informed consent

It is recognized that prior informed consent is the core requirement of effective access and benefit-sharing measures.<sup>164</sup> Glowka defined prior informed consent as “(1) consent of the contracting party which is the genetic resource provider, (2) based on full and complete information provided by the potential genetic resource user (3) prior to consent for access being granted [...]”<sup>165</sup> Prior informed procedures consent shall not be so onerous as “to impose restrictions that run counter to the objectives of this Convention” (Art. 15, para. 2 CBD). The prior informed consent allows the provider to get the necessary information to become an equal partner in the negotiations of the access agreement. The chances of a fair and equitable benefit-sharing increase with the level of shared information.<sup>166</sup> Prior informed consent is also important for monitoring and controlling the collection of the material.<sup>167</sup> The prior informed consent is based on accurate information regarding the intended use, e.g. taxonomy, collection, research or commercialization (No. 36 BG). As a consequence, the Bonn Guidelines stipulate that if the genetic resources are used in a different way than indicated, a new consent must be obtained (Art. 16 b v) and No. 34 BG). The legal authority to give prior informed consent for genetic resources is defined in the CBD at the level of the nation state.<sup>168</sup> However, the CBD encourages that prior informed consent should be obtained from indigenous and local communities for use of traditional knowledge associated with genetic resources (see COP decision V/16).<sup>169</sup>

However, the CBD does not require the parties to enact laws to ensure that prior informed consent has been obtained when its government agencies, research institutions or private firms have obtained genetic resources from another country. Such a user obligation would be a prerequisite for a successful implementation of the new regime.<sup>170</sup>

When regulating prior informed consent, the following questions concerning its possible scope arise:<sup>171</sup>

- Which information shall be required (i.e. time, place, method of collection, method of research, expected results, benefits for the user and provider)?

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<sup>164</sup> Report of the Panel of Experts CBD, UNEP/CBD/COP/5/8, 2000, p. 27.

<sup>165</sup> Glowka et al 1994.

<sup>166</sup> Henne et. al. 2003, p. 46.

<sup>167</sup> Mugabe 1997, p. 9.

<sup>168</sup> Rosenthal 2003, p. 5.

<sup>169</sup> Ibid; Seiler/Dutfield 2001, p. 21.

<sup>170</sup> Mugabe 1997, p. 10.

<sup>171</sup> Seiler/Dutfield 2001, p. 22.

- Shall the prior informed consent be necessary for all genetic resources or only for genetic resources of some categories (e.g. in situ), or those found in certain locations (i.e. protected areas)?
- Shall the PIC procedure depend on the purpose of the collection (i.e. commercial, scientific)?
- Shall different types of genetic resources (e.g. for health, for agriculture) require different PIC procedures?

The question from whom the prior informed consent is required, is one of the most important concerning PIC. While prior informed consent is to be sought from national governments, it is not mandatory under the CBD to gain the approval of local communities/indigenous peoples.

The national ABS legislations respond to this problem in different ways. Many national laws, such as the Philippines', require the prior informed consent of the indigenous peoples and local communities. The OAU Model Law states in Art. 5 that any access to biological resources, knowledge and or technologies of local communities shall be subject to the written prior informed consent of the National Competent Authority; as well as that of the concerned local communities, ensuring that women are also involved in decision making. In contrast, under the ASEAN Framework only the consent of the state is necessary, but "active involvement of indigenous peoples and local communities embodying traditional lifestyles" must be ensured (Art. 10). Possible other responsible parties include research institutions, farmers, protected area management authorities and landowners.<sup>172</sup>

From a development, human rights and poverty alleviation perspective, it is desirable to include in the international ABS regime not only the PIC of the state but also that of indigenous peoples and local communities.<sup>173</sup> The advantage for developing countries would be to anticipate internal conflicts and to be able to provide for a comprehensive regulation of both access to genetic resources and traditional knowledge. In their interest, it should also be ascertained that the prior informed consent covers only the agreed on use of the genetic resource and that a different use should again require the prior informed consent of the provider state.

However, the challenge for the user is then to identify exactly whose consent is required, as Ten Kate and Laird pointed out.<sup>174</sup> This can be rather difficult. From a user country's perspective, the necessity to obtain consent of communities should therefore be linked to an obligation of the provider state to facilitate the users' task to get that approval. This could be done by requiring that provider countries give users information on whose consent is required in the concrete case and by issuing guidelines on how and when the prior informed consent is deemed sufficient under the national ABS legislation.

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<sup>172</sup> Henne et. al. 2003, p. 46.

<sup>173</sup> Ibid.

<sup>174</sup> Ten Kate/Laird, p. 28. They also point out the associated questions, such as: How many distinct communities have to be involved? Does the community has legal standing to enter into the agreement? Who is authorized to negotiate on behalf of the community? What happens if only a part of the community consents to the contract?

Finally, a certificate of legal provenance as further detailed infra can help to assure prior informed consent on the one hand and on the other to facilitate the users legal certainty that he has obtained the prior informed consent as required by the provider state.

### 5.3.5 Mutually agreed terms

The phrase “mutually agreed terms” is used in the CBD (Art. 15, 16, 19), but is not defined or explained.<sup>175</sup> Generally, mutually agreed terms (MAT) are understood as the content of an ABS agreement and the result of successful negotiations after obtaining prior informed consent, where both sides find their interests sufficiently accounted for.<sup>176</sup> In the international regime, it must be ensured that mutually agreed terms comply with the CBD, its objectives and the larger policy regime of the CBD.

It is claimed that only basic requirements for mutually agreed terms should be contained in the regime, because they must be flexible to cover each individual case.<sup>177</sup> However, the overview of existing agreements also shows that they can lead to major inequities if not drafted carefully. Thus, there might be a need to specify more detailed provisions of such agreements.

The Bonn Guidelines enumerate in section D a detailed description of the type of provisions that could form part of an ABS agreement. Particularly important is No. 44 which lists points of relevance for ABS agreements. They range from the type and quantity of the genetic resources, include the limitation of its use and the possibility of a renegotiation of the agreement, to the transfer of material to third parties and the sharing of benefits. A need for renegotiations occurs in the case of changing the use (see supra). In this regard, the most important aspect is the transition from non-commercial to commercial use, which leads to benefits for the new user. If no obligation to renegotiate is foreseen, the invalidity of the agreement can be provided for in such cases. As the Bonn Guidelines suggest, the international ABS regime could contain an annex with recommended provisions of and conditions for ABS agreements. Since it was even proposed to introduce standard MTAs, it is unlikely that the leeway of the parties to the agreement would be limited.

### 5.3.6 Benefit-Sharing

The sharing of benefits “is the most strategic [objective of the Convention] in that it provides a direct incentive for conservation and sustainable use and provides development benefits as well.”<sup>178</sup> Without further analyzing the question, whether ABS agreements generally and in all cases contribute to the conservation of biodiversity,<sup>179</sup> it is certain that one

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<sup>175</sup> Henne 1997, p. 71.

<sup>176</sup> Henne et. al. 2003, p. 46.

<sup>177</sup> Henne 1997, p. 78.

<sup>178</sup> Mugabe 1997, p. 7.

<sup>179</sup> *Compare* Heineke/Wolff 2004, p. 33.

of the main goals of the CBD is the fair and equitable sharing of the benefits of access to genetic resources.

Although the CBD establishes in Art. 15 the principle of fair and equitable sharing of benefits arising from the use of genetic resources, it does not establish the specific mechanism for realizing this objective.<sup>180</sup> The adjectives “fair” and “equitable” remain unclear.<sup>181</sup> This is probably due to the fact that the adequacy of the benefits depends on the circumstances of the individual case.<sup>182</sup> Generally, conditions shall be fair and practical for both the provider and the user. Benefits may derive from genetic resources, their associated knowledge, innovations and practices covered by the CBD. The problem is how to deal with products that are adapted or modified from an original genetic resource and contain essential elements of the parental substance. This question will be further discussed under the section “derivatives”.

The structure of benefit-sharing arrangements is ideally led by general principles developed on a national level, but tends to be unique in each case.<sup>183</sup> The examples provided in Annex 3 show that benefits also tend to be more limited than one would expect.

Henne et. al.<sup>184</sup> proposed that a provision on benefit-sharing in the international regime should contain the wording:

*“Benefits should be shared, as the case may be, among those who contribute to resource management, scientific and/or commercial process, holders of associated traditional knowledge and poor people living in the geographical area of origin of the resource.*

*3. Benefits should contribute to the conservation and sustainable use of biological resources as well as to poverty alleviation. It should involve technology transfer and joint research. Priority in benefit-sharing should be given to measures contributing to alleviating poverty, such as the creation of income opportunities for local people and markets for products. Biological material should be cultivated in the areas of origin of the genetic resource. Benefits should include the empowerment of local people and the strengthening of self-governance, cultural identity and self-confidence.*

*4. Benefits should include advance and milestone payments sufficient to contribute to poverty alleviation in the short term and to create an incentive for the conservation and sustainable use of biodiversity. Appropriate institutions should be set up to ensure that payments are used efficiently (e.g. trust funds).”*

With regard to this proposal, a number of comments can be made without calling into question the general legitimacy of such a provision. First, it can be expected that provider coun-

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<sup>180</sup> Reid, in: Mugabe 1997, p. 58.

<sup>181</sup> Brand/ Görg2001, p. 27.

<sup>182</sup> See No. 45 of the Bonn Guidelines - which contain a comprehensive list of possible benefits.

<sup>183</sup> Laird/Wynberg, in: Mugabe 1997, p. 167.

<sup>184</sup> Henne et. al. 2003, p. 48.

tries, especially developing countries, will not consent to a provision that specifies who shall obtain benefits or what they will be used for. This seems largely understandable, even if a detailed regulation might be desirable from the point of view of the user countries. Also, it might be difficult to require generally that advance and interim payments shall be made. In fact, some bioprospecting activities do not generate profits but only costs and this is often times difficult to determine in advance. Both provider and user countries also might not accept the fact that payments should be sufficient to attain a certain goal, not only because of the prescribed goal but also because the amount of payments is not based upon the profits generated.

This said, it is undisputed that it would be highly desirable if benefit-sharing were to contribute to the conservation and sustainable use of biodiversity as well.<sup>185</sup> One way of ensuring that could be to introduce biodiversity funds.<sup>186</sup>

Based on the experience with ABS contracts in the past it can be inferred that benefits have mainly consisted of sample fees, training and better income opportunities for local communities, scientists training, research support and technology transfer to and in the provider country, infrastructure and capacity building. Compared to these benefits, the monetary benefits were either slow in coming or non-existent all together. While it is possibly due to different bargaining powers that monetary benefits are scarce, it is also important to point out the importance of non-monetary benefits for indigenous peoples, local communities and the research institutes of the provider states.

Generally, the international ABS regime cannot make provisions on monetary benefits when the generation of these benefits cannot be predicted. It is thus even more important to ascertain that the provider states will profit from the access activities in the long term, i.e. through collaborative scientific research. At the same time, a broader meaning of benefits arising from the use of genetic resources, such as biodiversity conservation in general, should be fostered.<sup>187</sup>

In sum, it would be desirable that benefit-sharing in the international regime is not only referred to with regard to fairness and equity between the users and the provider state but also in regard to the benefits for biodiversity itself and its stewards, i.e. local communities and indigenous peoples.<sup>188</sup>

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<sup>185</sup> It is also desirable that benefit-sharing contributes to poverty alleviation. However, this is not a goal of the CBD, except under a very broad understanding of the Convention, which assumes that poverty alleviation in all cases also contributes to the conservation and sustainable use of biodiversity. Benefits shared so far were very limited. It is thus not sure whether including additional goals of benefit-sharing into the international ABS regime will actually achieve comprehensive results or whether the regime will be overburdened with too high expectations.

<sup>186</sup> See also *infra*.

<sup>187</sup> Heineke/Wolff 2004, p. 33.

<sup>188</sup> *Ibid.* The fundamental question whether ABS contributes to the conservation of biodiversity will not be discussed further here, although it is often called into question, compare Stoll 2004, p. 88; Görg 2003, p. 2; Brandt/Görg 2001, p. 19 et. seq.; and many more.

### 5.3.7 Traditional knowledge

The Convention on Biological Diversity is the only international legally binding instrument that explicitly refers to the protection of traditional knowledge.<sup>189</sup> Article 8(j) states that [Each Contracting Party shall, as far as possible and as appropriate] “subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.”

The term of traditional knowledge is not defined in the Convention.

The WIPO proposed to define Traditional Knowledge as follows: “The content or substance of traditional know-how, skills, practices and learning, while recognizing that this content or substance may be considered integral with traditional ways of expressing the knowledge and the traditional context in which the knowledge is developed, preserved and transmitted. This reflects the view that TK must refer to 'knowledge' in a general sense, but knowledge with a specifically traditional character. Protection would apply to the knowledge as such, and restrain the unauthorized use of the knowledge; this could include unauthorized disclosure of secret or sacred TK.”<sup>190</sup> Cavalho has proposed a working definition of traditional knowledge to be ideas and practices developed by traditional communities and indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural environments and that serve as means of cultural identification.<sup>191</sup> The provisions on traditional knowledge are closely related to those on access and benefit-sharing.<sup>192</sup>

Under the CBD, where traditional knowledge is not in the public domain, communities have to approve the use of their knowledge and resources.<sup>193</sup> An international ABS regime should make clear that holders of traditional knowledge must consent to the use of their traditional knowledge, something which so far is not so clear under the Convention, because it makes reference to national legislation, i.e. does not protect traditional knowledge itself. A different question is whether an international ABS regime should also introduce rights to traditional knowledge. While it is true that it needs to have legal protection, if the application of such knowledge occurs only with the approval of its holders,<sup>194</sup> it might seem questionable that the ABS regime would be the right forum to provide for such rights or to oblige Parties

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<sup>189</sup> UNCTAD 2000, p. 6; Stoll 2004, p. 82.

<sup>190</sup> Document WIPO/GRTKF/IC/5/12, paragraph 44.

<sup>191</sup> Carvalho 2003, p. 6. For a detailed analysis of the elements that constitute traditional knowledge, see *ibid* p. 7-10.

<sup>192</sup> Stoll 2004, p. 81.

<sup>193</sup> Mugabe 1997, p. 10-11; Stoll 2004, p. 82. *See* for the question of traditional knowledge entering the public domain: Roussel 2003.

<sup>194</sup> Henne et. al. 2003, p. 44.

to introduce such rights. As it has been pointed out, designing such rights is not an easy undertaking.<sup>195</sup>

The issue of a *sui generis* system for the protection of traditional knowledge is being discussed in different fora.<sup>196</sup> The WIPO has analyzed both active and defensive forms of protection of traditional knowledge.<sup>197</sup> The “interim” protection of traditional knowledge<sup>198</sup> with the regime would be rather unfavorable, because it might overburden the negotiations of the regime, lead to a permanent “interim” solution, or even prove to be too contentious to be agreed on. Therefore, the international ABS regime should limit itself to making clear that the use of traditional knowledge without the consent of the holders of the knowledge is considered not to be in accordance with the regime.<sup>199</sup>

### 5.3.8 Derivatives

The CBD makes no mention of derivatives, such as semi-synthesized or totally synthesized compounds based on the structures discovered by studying genetic resources or hybrid plants that result from access to two patents.<sup>200</sup> The Bonn Guidelines refer to derivatives in No. 36 l (procedure for prior informed consent), in No. 44 i (typical elements of mutually agreed terms) as well as in Appendix I B 2, as an element of mutually agreed terms. What is mainly covered are biological resources including “genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity” (Art. 2 CBD). In contrast, some national legislations apply to derivatives as well (i.e. Art 1 of the OAU Model Law). The question is whether access to derivatives shall be ruled *per se* or whether it is sufficient to establish provisions for the access to genetic resources from which the derivatives are extracted. The more practical way seems to be the second one.<sup>201</sup> The Bonn Guidelines provide in No. 36 l and No. 44 that PIC as well as MAT should be based on the “kinds or types of benefits that could come from obtaining access to the resource, including benefits from *derivatives* and products“. Thus they are based on a similar understanding. Derivatives play an important role. In an assessment of the Swiss industry it was found that for example in the pharmaceutical industry, only in rare cases, will a natural material be distributed directly as a product. Therefore, it is only in a small amount of cases that the natural material in the country of origin must be relied upon in large quantities.<sup>202</sup>

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<sup>195</sup> Ibid, p. 45.

<sup>196</sup> See <http://www.wipo.int/tk/en/> for an overview of the WIPO activities on the protection of traditional knowledge.

<sup>197</sup> WIPO 2002, WIPO 2003a, b, c, WIPO 2004.

<sup>198</sup> As proposed by Henne et. al. 2003, p. 44-46.

<sup>199</sup> A growing body of literature is concerned with the role of traditional knowledge and access to traditional knowledge, including RAFI/UNDP 1995; Tobin 1997; NIJAR 1997; Cottier 1998; WTO 2000; Dutfield 2000a, 2000b; Pacon, in: Wolfrum/Stoll 2000; Tobin 2001; WIPO 2001; Yongfeng 2002; Ekpere 2002, pp. 4 seq; UNCTAD 2002; Heineke 2003, Stoll/von Hahn, in: Schricker 2003. For the importance of gender issues in this respect see Jaireth in: Stoianoff 2004, P. 208-211.

<sup>200</sup> Ten Kate/Laird 1999, p. 17.

<sup>201</sup> Glowka in: Mugabe 1997, pp. 36 seq.

<sup>202</sup> Bättig 1998, p. 5.

It has been held that the access and benefit-sharing provisions of the CBD only cover the genetic material containing genetic information but not the information itself.<sup>203</sup> Therefore, the derivatives would not be covered by the ABS provisions and the acquisition of patents based on that genetic information, without the ownership of the original material being relevant.<sup>204</sup> This position is at least questionable. But it has also been pointed out, that it is almost impossible to monitor all the transactions within the increasingly competitive market for genetic material - including its extracts.<sup>205</sup> Due to the fact that derivatives are most probably proprietary and subject to intellectual property rights, a state's control is virtually impossible. It has to be pointed out that, in case of regulating only access to genetic resources, it shall be ensured that benefit-sharing arrangements consider the potential use of its derivatives.<sup>206</sup>

### 5.3.9 Intermediaries

An important role in access to genetic resources and their commercialization is played by public *ex-situ* collections and academic research institutions such as universities which do basic research, such as taxonomic research. The Swiss plant protection industry for example receives their genetic material needed for research directly from universities or research institutes.<sup>207</sup> At the same time, professional brokers, who sell genetic resources to companies are main players in the commercialization of genetic resources as well. Especially in the pharmaceutical and plant protection industries, genetic resources needed for research are acquired through private screening companies which are located, for the most part, in the USA.<sup>208</sup> Many industries, with the exception for example of the foodstuffs industry, have no direct contacts to developing countries.<sup>209</sup> At the same time, universities and the national herbariums in developing countries often look for partners in industrialized countries for joint projects and offer genetic resources (mostly plants), usually free of cost. This is due to the fact that in many instances joint projects can only be realized with the financial support of a third party, in most cases, industry.<sup>210</sup> Overall, intermediaries thus play a pertinent part as a link between the providers side and the user side of genetic resources.<sup>211</sup> *Ex-situ* collections will be discussed separately.

It is often pointed out that overly restricting access to genetic resources would impede academic research: Too much paperwork could not be handled by academic institutions. Industry representatives have said that an overly restrictive policy of granting access could sig-

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<sup>203</sup> Stoll 2004, p. 87.

<sup>204</sup> Ibid.

<sup>205</sup> Reid in: Mugabe 1997, pp. 58, 61.

<sup>206</sup> Ten Kate/Laird 1999, p. 20.

<sup>207</sup> Ibid, p.7.

<sup>208</sup> Bättig 1998, p. 4.

<sup>209</sup> Ibid.

<sup>210</sup> Ibid.

<sup>211</sup> Ten Kate/Laird 1999.

nificantly reduce the transfer of technology and even diminish the attractiveness and significance of natural substances, particularly in the chemical-pharmaceutical research.<sup>212</sup>

Clarifying the role of intermediaries in the international ABS regime might thus be helpful in two regards. First, it could provide scientific intermediaries with greater flexibility in case they are doing academic research, such as taxonomic studies, the mapping of biodiversity etc. Second, provider countries could be ascertained whose provision of uncomplicated access to academic researchers will not result in an unauthorized use of the resources later on. This use can also be made by the researchers themselves, as the *Swartzia Madagascariensis* case shows, where the University of Lausanne obtained a patent on antimicrobial diterpenes based on a traditional use in Zimbabwe. The agreement for the bioprospecting was based on forestry law, which does not adequately address the issues relevant for genetic resources.<sup>213</sup>

An international regime on access and benefit-sharing should therefore contain a provision addressing the role of intermediaries and stress their obligation to transfer genetic resources to third parties only with the consent of the provider country.

#### 5.3.10 Collaborative scientific research

Collaborative scientific research is mentioned in the CBD in Art. 15 par. 6: The provider country shall fully participate in the scientific research based on genetic resources. Also most of the national ABS laws consider collaborative scientific research (i.e. OAU in Art. 8 para. 2, ASEAN in Art. 11). Participation in the research means obviously more than the provision of information about it or the unilateral transfer of technology, because national scientists should be directly involved in the development. Collaborative scientific research is a type of a non-monetary benefit which is often a part of ABS agreements. Because of the fundamental character of scientific research for the future commercial use of biodiversity, the research can be very beneficial for the provider country.<sup>214</sup> With regard to an international regime, the importance of a provision on collaborative regime is often mentioned. As with regard to other benefits, it is unclear, how precise a provision on collaborative scientific research can be, since not all access activities generally include the possibility for collaborative scientific research. However, an international ABS regime can stipulate that collaborative scientific research should be part of mutually agreed terms, wherever possible.

#### 5.3.11 Technology Transfer

The CBD contains in Art. 16 rather detailed provisions on technology transfer. While Art. 15 obliges Parties to facilitate access to genetic resources, Art. 16 contains a similar obligation to provide and facilitate access for and transfer of technologies both for the conserva-

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<sup>212</sup> Bättig 1998, p. 11.

<sup>213</sup> Chishakwe/Young 2003, p. 11.

<sup>214</sup> Seiler/ Dutfield 2001, S. 111.

tion of biodiversity and the use of genetic resources. The Parties have to ensure “that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries“ (Art. 16 para. 4 CBD). Regarding an international regime, the integration of the results of the COP 7 debate on Technology Transfer should be considered.<sup>215</sup>

### 5.3.12 Biodiversity funds

From a user country perspective an important endeavor of an ABS agreement and even more of an international ABS regime is its contribution to the conservation of biological diversity.<sup>216</sup> One of the underlying assumptions of the current access and benefit-sharing debate is that an economic evaluation of biodiversity contributes to its conservation because shared benefits compensate local and indigenous communities as well as governments for not extensively exploiting natural resources.<sup>217</sup> So far, however, it can not be argued that either individual access and benefits-sharing agreements<sup>218</sup> or the efforts of developing legal instruments for ABS<sup>219</sup> have contributed much to the conservation and sustainable use of biodiversity. One possibility to link benefits to conservation could be via a Trust Fund.<sup>220</sup> Such a Trust Fund is envisaged by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPRGFA). Among other contributions, users of plant genetic resources for food and agriculture shall provide a certain percentage of the commercial benefits of the use of material contained in Annex I towards the future Fund (Art. 19.3 f ITPGR).

National legislation and policies frequently provide no obligatory earmarking of the revenues.<sup>221</sup> However, a number of regional and national ABS provisions set up biodiversity funds.

In the complementary provisions of Decision 391 of the Andean Community, the member countries are requested to set up funds financed by the profits obtained with access agreements to promote compliance with the aims of the Decision, which are described in Art. 2 (e. g. promote the conservation of the biological diversity and the sustainable use of the biological resources).

The Framework Agreement on ABS of the ASEAN countries creates in Art. 12 a Common Fund for biodiversity conservation. It shall be endowed by a share of the revenues derived from any commercialization of the use of the resources, from a portion of the charges and

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<sup>215</sup> Compare also: Stoianoff 2004, p. 46-48.

<sup>216</sup> BMU 2001.

<sup>217</sup> Cf. critically: Heineke/Wolff 2004. p. 32.

<sup>218</sup> See Annex 3.

<sup>219</sup> Heineke/Wolff 2004. p. 32.

<sup>220</sup> Ibid, p. 33.

<sup>221</sup> Ibid.

fees on access application imposed by the member states and a portion of negotiated financial benefits.

In India, the National Biodiversity Fund may also profit from benefit sharing, through an order from the National Biodiversity Authority. The Fund shall be applied for channeling benefits to the “benefit claimers”, the conservation of biological resources, the development of biodiversity-rich areas and the socio-economic development of these areas (section 27 of the act).

The Philippines’ Wildlife Law also establishes a wildlife fund in sec. 29 of the act.

So far, only limited experience with regards to these funds has been gained. Since monetary benefits of ABS agreements seem to be scarce, it cannot be expected that biodiversity funds will be able to contribute to the conservation of biodiversity based solely on contributions from ABS contracts.<sup>222</sup> However, they could be based at least partly on these contributions. From a user country perspective it seems highly desirable that biodiversity funds be set up to ensure that benefit-sharing contributes to the conservation of biological diversity.

### 5.3.13 *Ex-situ* collections

Art. 15 para 3 of the CBD excludes genetic resources that were acquired prior to the entry into force of the Convention. This said, it is possible that Parties include access to their *ex-situ* collections into ABS provisions. This would not represent an obligation of a retroactive nature as has been claimed,<sup>223</sup> because it would not be an application of the CBD, but a regulation of genetic resources, which the state is free to do. From a national perspective, it does not make a legal difference whether a country introduces access legislation with regard to *in-situ* or *ex-situ* collections or traditional knowledge. In all cases, it could be argued that this represents a retroactive obligation, because all types of resources have been there before the entry into force of the legislation. The relevant point, however, is the access activity which would both in the case of *in-situ* and *ex-situ* resources take place after the entry into force of the Convention.

At the national level, most ABS laws do not apply to *ex-situ* collections. Ten Kate/Laird point out that the effect of ABS laws on pre-CBD collections are often unclear or legally questionable, such as the Andean Community’s Transitory Provision, which is both retrospective and extra-territorial, because it applies to genetic resources that are already someone’s “illegal” possession and obliges them to negotiate ABS agreements.<sup>224</sup> The difference between this provision, which does not only apply to material acquired before the entry into force of the CBD but also to material held outside the jurisdiction of the five Andean member states, and ABS legislation that introduces access requirements for *ex-situ* collections is

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<sup>222</sup> This assumption can be substantiated by the example the INBio-Merck agreement in Costa Rica, where the “\$100,000 provid[ing], direct support to [Costa Rica’s] conservation efforts ... [may be a ‘drop in the bucket’], ... given the \$1 billion price tag for ten years worth of maintenance of Costa Rica’s national park system”. Columbia University 1999, p. 81.

<sup>223</sup> Ten Kate/Laird 1999, p. 20.

<sup>224</sup> Ibid.

that the latter relates neither to material held extra-territorially nor to material that was already acquired by the person, who is now required to enter into an ABS agreement. There is no legal difference with regard to the time of acquisition (after the entry into force of both the CBD and the national ABS legislation) between a contract on *in-situ* or *ex-situ* genetic resources. This, however, does of course only apply to genetic resources that are under the jurisdiction of the regulating Party. If national ABS legislation applies to genetic resources held in *ex-situ* collections outside the *country*, this will represent not a retroactive but an extra-territorial regulation, which would not be admissible.<sup>225</sup> A special situation applies to botanical garden, which to a large extent have independent systems in place, such as the IPEN system, thus they will be discussed separately.

Regarding a system of certificates of legal provenance it would be highly desirable to include *ex-situ* collections into such a system on the one hand. That would mean for *ex-situ* collections that they should issue certificates of legal provenance when transferring genetic resources. On the other hand, they should participate in a simplified system (compare chapter 6.7).

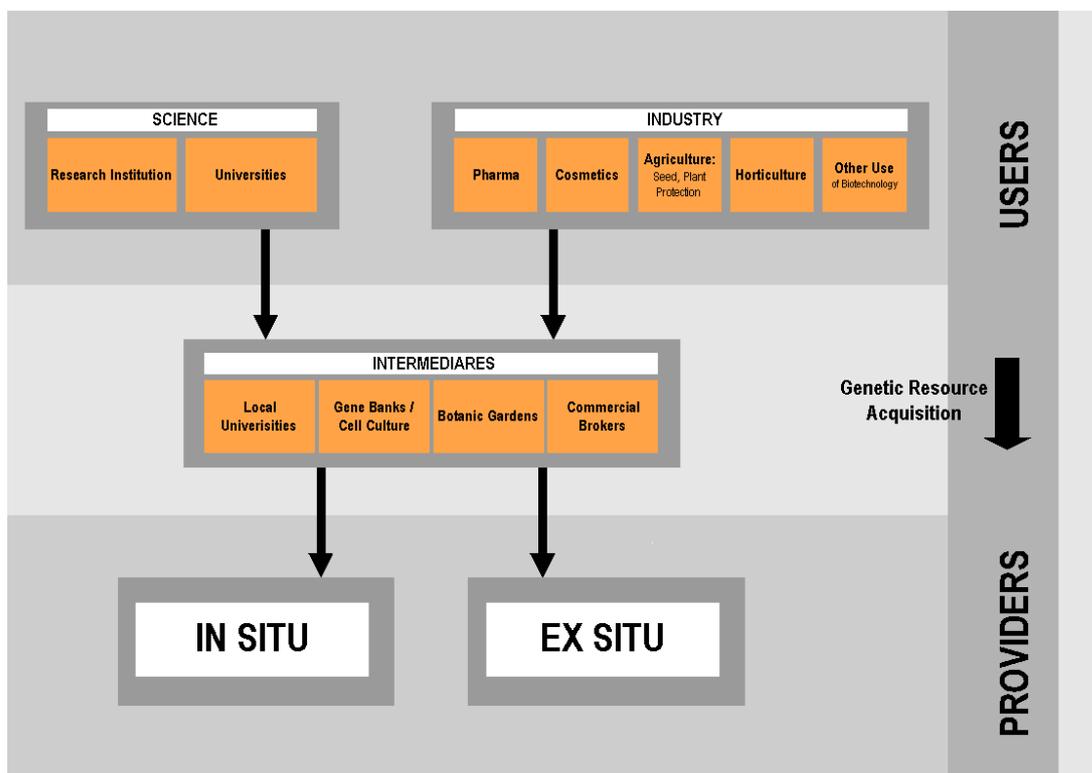


Figure 2: Acquisition of genetic resources from in-situ and ex-situ sources.  
Source: Öko-Institut.

<sup>225</sup> Generally, extra-territorial regulations can be allowed under certain conditions. Under European law, competition law provisions are applied extra-territorially if the effect of the incriminated act is on European territory. Something else could only be considered right, if genetic resources that were acquired after the entry into force are concerned.

### 5.3.14 Monitoring

The prerequisite for efficient enforcement measures is monitoring. Access to resources needs to be monitored during collection. There is a concern that some regulations currently proposed for monitoring, e.g. in Australia will unnecessarily hinder genuine scientific access to material.<sup>226</sup> Furthermore monitoring the use of genetic resources in other countries is difficult.<sup>227</sup> Due to the lack of capacity and means, the monitoring situation is even worse in developing countries which are often provider countries. Communication between the parties and mutual participation can facilitate the monitoring and reduce the chance of defec- tion.<sup>228</sup>

It has been said that it remains virtually impossible to prevent genetic resources from leav- ing a country.<sup>229</sup> However, a system for track the flow of genetic resources (see *infra*) could provide such a means. It would thus allow efficient monitoring of the resources.

### 5.3.15 Compliance and enforcement

One has to distinguish clearly between the enforcement of the CBD provisions on access and benefit-sharing respectively on the rules of an international regime and the enforcement of national ABS legislation.

With regard to national law, even companies point to the lack of enforcement of ABS provisions.<sup>230</sup> Without enforcement national ABS provisions remain a toothless tiger. Almost all of the examined national ABS legislations (except for the ASEAN Framework) provide for enforcement provisions, even if monitoring is only mentioned in the Biodiscovery Bill of Queensland. This last bill is very detailed concerning ensuring the compliance with its provisions. In Art. 50-60 the offences and in Art. 61-94 it covers monitoring and enforce- ment. Also, many national legislations regulate dispute settlement, some in a formal way (“appeals” in Art. 103 seq. of the Biodiscovery Bill of Queensland), some in a more infor- mal way (dialogue and arbitration process in Art. 9 of the ASEAN Framework).

Like the provider countries, the user countries are interested that their counterpart comply with the provisions.<sup>231</sup> The user of genetic material wants to ensure that access to genetic material is not unlawfully denied. The provider country intends the conservation of the bio- diversity and the equitable sharing of benefits. There are various possible consequences of an infraction of national ABS legislation and access contracts. They can range from civil remedies and the obligation to pay compensation for lost benefits in case of breach of the contract to administrative measures such as confiscation, ban on activities and reporting of the transgression to the international CBD secretaries to fines. The penalties can be included

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<sup>226</sup> Bremner 2004, p. 14.

<sup>227</sup> Henne et. al. 2003, p. 49.

<sup>228</sup> Columbia University, 1999, p.78.

<sup>229</sup> Reid: in Mugabe 1997, p. 58.

<sup>230</sup> Ten Kate/Laird 1999, p. 297.

<sup>231</sup> Mugabe 1997, p. 28.

in the access agreement, so the contracting parties are aware of the consequences of their misconduct. In addition, a user of genetic resources who receives these from a third party runs a number of legal risks, if the resources were not acquired legally according to the ABS laws of the source country.<sup>232</sup> An international ABS regime could require Parties to ascertain effective enforcement of national ABS provisions, especially in user countries, where penalties for user measures should present a strong incentive not to breach provisions. It has been proposed that this could be achieved, for instance, by establishing an international obligation to implement national enforcement mechanisms (judicial and criminal) against the illegal access and use of genetic resources and traditional knowledge.<sup>233</sup>

Regarding an international ABS regime, it has to be pointed out that the CBD itself, as the majority of multilateral environmental agreements, does not contain strong rules. Only Art. 7 refers to monitoring, enforcement provisions do not exist. Of course, the Bonn Guidelines do not contain enforcement regulations due to their voluntary nature. Regarding monitoring a system of certificates of legal provenance could play an important role in the monitoring of the ABS regime.<sup>234</sup>

To further compliance, a so-called ABS Compliance Body has been proposed.<sup>235</sup> Rather unconventionally, the Compliance Body is foreseen not to settle disputes between the Parties to the regime but disputes concerning the implementation of an ABS agreement. It shall be approached by the Parties and if referred to in the ABS agreement, by any party to the agreement. Such a compliance body would be somewhat of a *novum* in international law, since it would be an institution under international law, which would be responsible for the settlements of both disputes between the state Parties to the regime as well as between private entities. In such a function, however, it should be referred to as a dispute settlement body, since a compliance body generally oversees the implementation of a regime by the state Parties, but does not settle disputes. Whether instituting such a body would be useful remains questionable. First, state Parties to an international treaty generally refrain from

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<sup>232</sup> Ten Kate/Laird 1999, p. 22-23.

<sup>233</sup> Baumüller/Vivas-Eugui 2004, p. 22.

<sup>234</sup> In addition, Henne et al. propose to introduce an ABS advisory body to facilitate legislation and negotiation (Henne et. al. 2003, p. 54). The reasoning behind that is that implementation often fails due to a lack of capacity and knowledge and to impracticability. It is envisioned as an independent body, consisting of a limited number of experts and practitioners from relevant disciplines (biology, biotechnology, law, sociology, rural development, economics, etc.) and include two representatives of traditional knowledge holders. Members are to be linked to a wide network of scientists etc (ibid). While this idea seems generally appealing, an advisory body would represent a new structure, which would probably meet the resistance of the Parties financing it. At the same time it is questionable whether such an institution would represent a necessary structure. First, there exists an Ad Hoc Open-Ended Working Group on ABS at CBD level. At the same time the scientific community working on ABS is closely connected one, which represent a very good network. Second, the democratic legitimacy of such a group would be somewhat questionable, even if the experts are independent, because a small group of only twelve members could hardly be a representative group of the different interests involved. Finally, the proposed function of the Body seems difficult to fulfil, since its emphasis shall be on “the equity and fairness of the benefit-sharing mechanism” (ibid). This can in many instances be a question that would be answered differently by providers and users. Thus, it can be feared that such a Body would be subject to highly politicised influences from the different sides, which would not be desirable. In sum, the “value-added” of such a body is thus not perceivable.

<sup>235</sup> Ibid, p. 44-45.

invoking dispute settlement bodies as far as possible.<sup>236</sup> Second, parties to a material transfer agreement would have to submit themselves under the jurisdiction of the body. In sum, the body might not be used much.<sup>237</sup>

#### 5.3.16 Advisory Body

In addition, Henne et al. propose to introduce an ABS advisory body to facilitate legislation and negotiation.<sup>238</sup> The reasoning behind that is that implementation often fails due to a lack of capacity and knowledge and to impracticability. It is envisioned as an independent body, consisting of a limited number of experts and practitioners from relevant disciplines (biology, biotechnology, law, sociology, rural development, economics, etc.) and include two representatives of traditional knowledge holders. Members are to be linked to a wide network of scientists. While this idea seems generally appealing, an advisory body would represent a new structure, which would probably meet the resistance of the Parties financing it. It could be questioned whether such an institution would represent a necessary structure. First, there exists an Ad Hoc Open-Ended Working Group on ABS at CBD level. At the same time the scientific community working on ABS is a closely connected one, which represents a very good network. Second, the democratic legitimacy of such a group would be somewhat questionable, even if the experts are independent, because a small group of only twelve members could hardly be a representative group of the different interests involved. Finally, the proposed function of the Body seems difficult to fulfill, since its emphasis shall be on “the equity and fairness of the benefit-sharing mechanism”.<sup>239</sup> This can in many instances be a question that would be answered differently by providers and users. Thus, it can be feared that such a Body would be subject to highly politicised influences from the different sides, which would not be desirable. On the other hand, an ABS advisory body could be a useful tool to help countries to implement ABS legislation.

#### 5.3.17 Settlement of disputes

Art. 27 of the CBD contains rather detailed provisions concerning the settlement of disputes. The question whether an international regime on access and benefit-sharing shall include a dispute settlement mechanism cannot be answered easily. On the one hand the establishment of a formal dispute settlement system is connected with a rather huge effort, because responsible entities have to be created, respectively enlarged. On the other hand, an international regime with an efficient dispute settlement system might be considered more transparent and legitimate by the involved parties and would probably work more smoothly than one without such mechanism.<sup>240</sup>

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<sup>236</sup> An exception to this rule is the WTO dispute settlement body, which represents a special case, because it possesses effective means to enforce its judgments.

<sup>237</sup> It should also be pointed out that non-binding measures complementary to formal dispute resolution such as mediation, codes of conduct, guidelines, and model contracts can play an important role.

<sup>238</sup> Henne et. al. 2003, p. 54.

<sup>239</sup> Ibid.

<sup>240</sup> Glowka 2004, p. 38.

### 5.3.18 National focal points

National focal points exist in the majority of the Parties of the CBD and among other things provide general information on biodiversity issues (see figure 3). They are also foreseen under the Bonn Guidelines and provide a helpful institution not only in matters regarding access and benefit-sharing. So far, national focal points provide very little information on national ABS laws, even in countries where these play a strong role. While many countries have very detailed descriptions of their national legal frameworks with regard to biodiversity, access and benefit-sharing is not mentioned. The online information provided by national focal points also does not provide practical help for users wishing to enter into access negotiations. As the Bonn Guidelines do, the international regime should therefore stress the important role that national focal points can play in the overall ABS system.

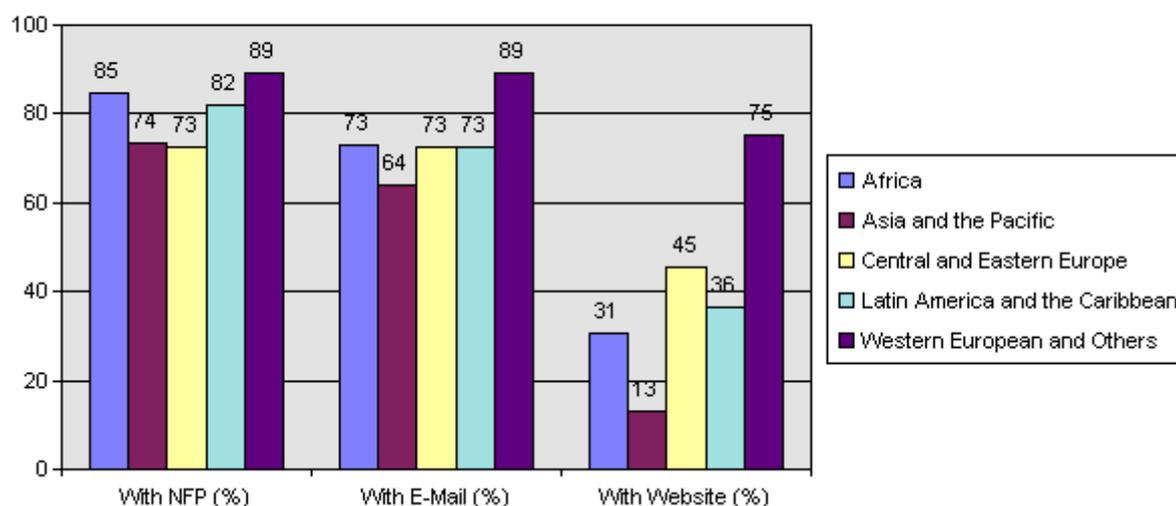


Figure 3 National Focal Points. Source: CBD Clearing House Mechanism, <http://www.biodiv.org/chm/stats.asp>.



## 6 Certificate of origin/source/legal provenance

One of the more contentious issues in the possible negotiations of an international regime on access and benefit-sharing is the form and role a so-called certificate of (geographical) origin, source or legal provenance could play in an international ABS regime. Certificates of origin, source or legal provenance pertain to user measures which enter into the discussion more and more, because it is becoming clear that the legislative activities of provider states alone will not be able to implement the ABS provisions of the Convention.<sup>241</sup>

The term ‘certificate of origin’ in the framework of the Convention was first coined to define a standardized form to be issued as evidence of Prior Informed Consent (PIC) for the purposes of disclosure of origin in patent applications.<sup>242</sup> Now it is also used to signify a standardized system of documentation for tracing the flow of genetic resources.<sup>243</sup> Besides different functions a certificate of origin may take, there are also alternative concepts of a certificate being discussed.

### 6.1 Definitions

A certificate of origin generally speaking is a standardized official document, which states the origin of a good. Certificates of origin are used in international trade in order to declare the country of origin when exporting or importing goods. They are used for example in the countries of the North American Free Trade Agreement (NAFTA) in order to qualify for the cuts in tariffs conveyed under that agreement. In certain cases they may include such information as the local material and labor contents of the product, in order to be able to identify the country of origin, which is defined according to the origin of the material and/or the value added through labor. In the framework of the discussion on an international ABS regime as well as in the framework of other international regimes such as the TRIPS Council and the WIPO, a number of terms is used, with differing implications and meanings.<sup>244</sup>

#### 6.1.1 Certificate of origin

The CBD defines a “country of origin of genetic resources” as “the country which possesses those genetic resources in *in-situ* conditions”. The “country providing genetic resources” means the country supplying genetic resources collected from *in-situ* resources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country (Art. 2 CBD).

A certificate of origin under the CBD, as a consequence, should indicate the actual origin of the genetic resource. A country providing the resource is not necessarily the country of ori-

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<sup>241</sup> Stoll 2004, p. 85.

<sup>242</sup> Barber/Johnston/Tobin 2003, p. 38.

<sup>243</sup> Ibid.

<sup>244</sup> For further examples see Correa 2003, p. 6.

gin and a certificate naming the country providing the resource would not necessarily be a certificate of origin.<sup>245</sup>

However, provisions on prior informed consent and benefit-sharing in the CBD relate to the country providing the resource.<sup>246</sup> Consequently, a certificate on the origin of the resource would relate to the country which possessed the resource *in-situ*, but according to the definitions of the CBD not necessarily to the country which gives its consent to the access to the genetic resource. This perceived contradiction is easily explained by Art. 15.3 CBD, which states that “[...] the genetic resources being provided by a Contracting Party [...] are only those that are provided by Contracting parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.” The term of the “country providing the resources” thus serves only to include those countries that while not being a country of origin provide genetic resources that they have acquired in accordance with the CBD.

However, the term ‘certificate of origin’ is used quite often to imply that ABS requirements such as prior informed consent have been fulfilled.<sup>247</sup> If the term is to imply in the framework of an international regime, that PIC and MAT have been obtained, the international regime also would have to contain clear definitions of these requirements. Otherwise, differing standards would make it highly difficult to ensure that all certificates of origin are based on the same understanding of PIC and MAT. One form of such a certificate could be a standardized Material Transfer Agreement (MTA), which makes clear that PIC and MAT have been obtained.

In many cases it will be difficult to declare the actual country of origin, e.g. when the genetic resource was obtained through a third party. Also, certain materials may be found in many – especially neighboring - countries.<sup>248</sup> Furthermore, the distinctive characteristics of cultivated species may be acquired in different countries, such as in the case of plant varieties that incorporate traits from different places.<sup>249</sup>

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<sup>245</sup> Correa 2003, p. 5.

<sup>246</sup> Art. 15.5: „Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.“ And Art. 15.7 CBD: „ Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanisms established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.“

<sup>247</sup> See for example COM (2003) 821, p. 20.

<sup>248</sup> Correa 2003, p. 5.

<sup>249</sup> Ibid. It has to be pointed out, however, that the latter resources will generally be covered by the Multilateral System under the International Treaty on Plant Genetic Resources.

### **The certificate of origin in Costa Rica's legislation**

“In order to certify the legality of access, the Technical Office will issue to the applicant a certificate of origin, also denominated “legal origin certificate” which includes: place and date of access, owner of the elements or resources of biodiversity, the obtained material, quantity, and the person, community or communities that have contributed or will contribute with their related knowledge, innovations and traditional practices. Furthermore, it will indicate whether the interested party fulfilled the regulations established for the prior informed consent and the mutually agreed conditions for the basic research, bioprospection or economic exploitation, as well as the date and number of the corresponding resolution.”<sup>250</sup>

#### **6.1.2 Certificate of geographical origin**

A ‘certificate of geographical origin’ provides information on the country or region of origin of the genetic resource in the sense mentioned above and makes clear that it does not imply additional requirements such as PIC and MAT. When one is speaking about ‘geographical origin’, this does not necessarily imply that the genetic resource was legally obtained. Different national laws refer to the geographical origin of genetic resources. The EC Biotechnology Directive<sup>251</sup> refers to the geographical origin.<sup>252</sup>

The term “geographical origin” would thus stand behind what many countries from the Global South demanded, i.e. to ensure through certificates that the requirements of the CBD with regard to prior informed consent and mutually agreed terms are fulfilled by users.

#### **6.1.3 Certificate of Source**

The origin does not have to coincide with the source from which the user obtained the genetic resource. As mentioned, it might be difficult to know the origin, in the sense of ‘where the resource was first found’. In order to avoid the difficulties associated with identifying the actual origin of the genetic resources, it was proposed to instead introduce certificates of source.<sup>253</sup> As opposed to a certificate of origin, a certificate of source does not necessarily declare where the resource originally came from but only where the user obtained it. The certificate of source could thus be understood in the sense of a certificate of the “country providing the resource”.

Indian patent law obliges the patent applicant to disclose both the source and geographical origin of the biological material, which is used in the invention. From the submissions of

<sup>250</sup> Article 19, Costa Rica Decree No 31514-MINAE.

<sup>251</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213/13, 30.7.1998.

<sup>252</sup> Recital 26 of the Directive states: „Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”

<sup>253</sup> Barber/Johnston/Tobin 2003, p. 38.

different countries, it has been inferred that countries mostly would favor an obligation to disclose the source of the resources.<sup>254</sup>

However, to introduce a “certificate of source” has been deemed problematic, because it could be interpreted to support the position that the right to a genetic resource stems from the source and not the country of origin.<sup>255</sup>

#### 6.1.4 Certificate of Legal Provenance

In the last years, a third concept has been introduced: the ‘certificate of legal provenance’. Such a certificate has been introduced in Costa Rica and Mexico to designate documentation providing evidence that the laws of the country of origin have been complied with. It has also been proposed by the Group of Megadiverse Countries, which see it as a possibility to ensure that all requirements established in Article 15 of the CBD have been complied with. The Group of Megadiverse Countries also demands developing a proposal for the use of this certificate in procedures for granting intellectual property rights.<sup>256</sup>

A certificate of legal provenance would be made available by the provider country when all requirements under national ABS legislation have been fulfilled. The advantage of this concept would be fourfold: First, it would ascertain that prior informed consent and mutually agreed terms as well as all other requirements, which might exist under national ABS legislation, have been observed. Second, (fraud left aside), it would exculpate everybody who would be in charge of ensuring that the resource was acquired correctly – be it a national patent office or a customs officer – from verifying the content of the document. Third, the concept of a certificate of legal provenance would allow provider countries to issue a certificate if they are merely the country of source but are willing to certify that there is no country of origin that the user can name with sufficient certitude. Fourth, users could be sure that they have fulfilled the requirements, which would contribute to legal certainty on the user side.

A certificate of legal provenance can be characterized as follows:

- A legal guarantee issued by a governmental institution,<sup>257</sup>
- That is internationally recognized,
- Certifying that the exporter has complied with the legal provisions if existing concerning ABS in that country,
- Requiring a clear concept of the term ‘origin’, of who is the provider of the resource and provenance (especially in the case of *ex-situ* collections).

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<sup>254</sup> Correa 2003, p. 6.

<sup>255</sup> Barber/Johnston/Tobin 2003, p. 38.

<sup>256</sup> Group of Megadiverse Countries, Conclusions and Recommendations, November 2002.

<sup>257</sup> As opposed to Tobin/ Cunningham/ Watanabe 2004, it is not thought practical that a CLP would be issued by provider of the relevant genetic resources such as a genebank, herbaria etc.

### 6.1.5 Negative Certificate

What can also be found in a number of ABS laws is something that could be deemed a “negative certificate of origin”. Under the complementary provisions of Decision 391 of the Andean Community sanitary certificates issued for the export of biological resources under a different Decision of the Andean Community have to contain the statement that the “use of this product as a genetic resource is not authorized”. This certificate relates to import and export regulations, which will be discussed further under 6.3.2.

### 6.1.6 Summary

In sum, the different definitions used in the ABS debate reflect to a large extent their proponents’ position on the question of disclosure, especially in the context of disclosure requirements in patent law. The possible difficulties of obtaining information on the actual country of origin, where this information is not available to the user speaks for a “certificate of geographical origin” or “certificate of source”. On the other hand, a certificate, which is reduced to this function would only partially fulfill the purpose of strengthening the position of the provider states, as endeavored by many countries in the negotiations of an international regime.

The difficulties that could be associated with the introduction of a “certificate of origin” according to industrialized countries, namely the difficulties to designate the actual country of origin could be circumvented, if a “certificate of legal provenance” would be the basis of the discussion. On the one hand, countries that have introduced access requirements would be able to better enforce these requirements. On the other, countries that allow access to genetic resources without requiring prior informed consent and/or benefit-sharing would also be able to certify that the genetic resources were acquired legally.

It also has to be pointed out that while it might be difficult to specify the country where the genetic resources originated, it should not be difficult for a user to name the source of the resource. Under the CBD, this can be:

- A country of origin of the genetic resource. In case the user legally acquired the genetic resource, he should be able to specify that he adhered to the legal obligations under the country of origin’s ABS legislation. If the country of origin does not have any requirements for access to genetic resources, this would have to be certified as well.
- An *ex-situ* collection. If the genetic resource was acquired prior to the entry into force of the CBD, the genetic resources concerned are not covered by the CBD. As a consequence, the country home to the *ex-situ* collection could certify that the genetic resources were acquired legally. If the genetic resource was acquired after the entry into force of the CBD, they would be covered by the Convention’s obligations. The country of the *ex-situ* collection would have to certify that the genetic resource was acquired legally, i.e. according to the rules of the Convention. If the resource was not acquired according to the CBD, it would be justified to deny the po-

tential user a certificate of legal provenance, since the user countries have an obligation to ensure that users under their jurisdiction respect the obligations of the CBD in regard to access and benefit-sharing.

- A third country. If the genetic resource is provided by a third country, the same conditions as supra apply. If the provider is a private third party but not an *ex-situ* collection, the third country has the same obligations as with regard to an *ex-situ* collection. If the provider can prove that he has acquired the genetic resource prior to the entry into force of the Convention, the third country can certify the legal provenance of the resource. If he acquired the resource after the entry into force of the CBD, the third country should only certify the legal provenance of the resource if the private provider can prove that he acquired the resource according to the provisions of the CBD.
- An intermediary. If the user is acquiring the genetic resource from an intermediary, the latter should be able to provide him with a certificate of legal provenance. If the intermediary is not able to do so, this can indicate that the genetic resource was not acquired legally. The user then bears the risk of dealing with an “illegal” resource.<sup>258</sup>

Thus, it is not conceivable that the requirements of a certificate of legal provenance would pose problems to users of genetic resources or user countries that are insurmountable.<sup>259</sup> A user, under this system, should be able to prove the legal provenance of the genetic resource or else the resource was not acquired legally – in which case the user does not deserve to profit from the genetic resource. Accordingly, the user country should not support scientific or commercial use that is made with genetic resources that were not acquired legally. This conclusion is based on the assumption that user states have an obligation to support the goals of the Convention, including access and benefit-sharing with prior informed consent and under mutually agreed terms.<sup>260</sup>

In sum, the introduction of a certificate of legal provenance would be preferable to other options, because it would be an effective means as compared to other forms such as a certificate of source. Hereinafter, certificates are thus referred to as ‘certificates of legal provenance’ or CLPs.

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<sup>258</sup> For a legal analysis of the possible consequences for users if they acquire resources illegally or from an intermediary, who has acquired the resources illegally, compare ten Kate/Laird 1999, p. 22- 26.

<sup>259</sup> An alternative model foresees to grant both certificates of origin and certificates of legal provenance, depending on their source. Tobin/Cunningham/Watanabe 2004, p. 3.

<sup>260</sup> COP-Decision V/26 urged „recipient countries to adopt, appropriate to national circumstances, legislative, administrative or policy measures consistent with the objectives of the Convention that are supportive of efforts made by provider countries to ensure that access to their genetic resources for scientific, commercial and other uses, and associated knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity, as appropriate, is subject to Articles 15, 16 and 19 of the Convention, unless otherwise determined by that provider country.”

## 6.2 Implications if certificates are to cover traditional knowledge

Art. 8 (j) of the Convention requires states “as far as possible and as appropriate” to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.” This requirement, however, is “subject to [the country’s] national legislation”. There exists thus no strict requirement in the Convention to obtain prior informed consent for the use of traditional knowledge. However, the application of “knowledge, innovations and practices of indigenous and local communities” shall be promoted with the “approval and involvement of the holders of such knowledge”. This obligation is first of all addressed to the provider states, i.e. the states in which indigenous and local communities live.

Prior informed consent under the Convention is to be awarded by the Contracting Parties, Art. 15.5 CBD. Neither access to genetic resources nor access to the associated traditional knowledge requires the prior informed consent of the indigenous and local communities. The obligations of the Convention are limited to requiring provider states to involve the latter and seek their approval “subject to its national legislation”. Furthermore, the benefits accruing from the use of traditional knowledge shall be shared with the indigenous and local communities.

However, prior informed consent has become a term that is often used to indicate that indigenous and local communities have agreed to the access to the genetic resources and/or the associated traditional knowledge.<sup>261</sup> It has to be pointed out, that “prior informed consent” might refer to both the consent of the provider state (as foreseen in the Convention) and/or to the consent of indigenous communities.

The Terms of Reference for the Ad hoc Open-ended Working Group on Access and Benefit-sharing included to consider as a possible element for the international regime:

“d) (xiii) Internationally recognized certificate of origin/source/legal provenance of genetic resources *and associated traditional knowledge*.”<sup>262</sup> Hereinafter is discussed, if and how traditional knowledge can be included into a certificate of origin.

*Tobin* pointed out the role that certificates of origin could play in securing the protection traditional knowledge and its holders.<sup>263</sup> He holds that a certificate should not only cover genetic resources but also traditional knowledge to support the effective implementation of requirements of prior informed consent, in order to provide a greater measure of security to provider countries and indigenous peoples.<sup>264</sup>

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<sup>261</sup> See supra at 5.3.4.

<sup>262</sup> CBD 2004, COP-Decision VII/19. Emphasis added.

<sup>263</sup> Tobin 1997, p. 329 – 340.

<sup>264</sup> Tobin 2001, p. 57.

Compared to the role a certificate could play with regard to genetic resources, the nature of traditional knowledge makes it more difficult to document it and the associated prior informed consent and track the flow of TK through a certificate. This is due to a number of reasons:

- There is no generally agreed on definition of traditional knowledge,<sup>265</sup>
- Harmonizing standards with regard to traditional knowledge may conflict with the diversity of existing traditional knowledge and of relevant customary law and practice,<sup>266</sup>
- Traditional knowledge is intangible in nature, which makes it even more difficult to be tracked than genetic resources,<sup>267</sup>
- Currently, the possibilities of protect traditional knowledge are insufficient,<sup>268</sup>
- With regard to traditional knowledge it is not always clear who “possesses” the traditional knowledge and to what extent neighboring communities, which might even be located in other countries, hold rights to the knowledge as well,<sup>269</sup>
- As a consequence, conflicts of interest might arise with regard to the certification of prior informed consent on the use of traditional knowledge between different indigenous communities and peoples and/or governments,
- The status of traditional knowledge which is in the public domain is often unclear,<sup>270</sup>
- Finally, in different countries there are different understandings with regard to the legal standing of indigenous peoples, their cultures of protecting their traditional knowledge and other issues.<sup>271</sup>

A wide variety of proposals relate to the development of a *sui generis* IPR system for the protection of traditional knowledge.<sup>272</sup> The magnitude of proposals show that there is currently no consensus as to how traditional knowledge can be protected effectively on a national or international level.<sup>273</sup>

So far, only very few countries have instituted special legislation with which to protect traditional knowledge, such as the Philippines’ Indigenous Peoples Rights Act or Peru’s Law introducing a protection regime for the collective knowledge of indigenous peoples derived

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<sup>265</sup> WIPO 2004, p. 4. Carvalho suggests that it is not meaningful to look for a final and complete definition of traditional knowledge due to the vast scope of the term, Carvalho 2003, p. 5.

<sup>266</sup> Alexander et al 2003, p. 7.

<sup>267</sup> Ibid, p. 38.

<sup>268</sup> Tobin 2001, p. 47.

<sup>269</sup> Rosenthal 2003, p. 5.

<sup>270</sup> Dutfield 2000a, p. 62.

<sup>271</sup> Tobin 2001, p. 60.

<sup>272</sup> Nijar 1997; Halewood 1999; Gupta, 1999; Biber-Klemm 2000.

<sup>273</sup> These proposals will not discussed any further here, since this would be beyond the scope of this study.

from biological resources.<sup>274</sup> In other countries, traditional knowledge is sometimes covered by general ABS legislation e.g. by means of provisions, which require PIC if access to traditional knowledge associated with genetic resources shall be provided. In many ABS acts, however, traditional knowledge does not play a role. Also, not all ABS legislation requires the prior informed consent of indigenous peoples/local communities.

In sum, few national laws contain and specify the obligation to obtain prior informed consent of indigenous peoples. A certificate of legal provenance, however, would only certify that the traditional knowledge has been obtained according to the legal provisions of the provider country. As pointed out above different interests can prevail between indigenous communities and governments or even between different communities or parts of communities. Even without any conflicts between communities, it has been held that prior informed consent should mean the consent of all communities and that it is impossible to ensure that PIC has been sought and received under existing regimes.<sup>275</sup> Without a national framework it might be difficult for users of genetic resources to ensure that prior informed consent was obtained.

If a certificate was designed as a certificate of origin it would have to include information on the origin of the traditional knowledge. Under the broader concept of a certificate of origin, it should also confirm that prior informed consent with regard to access to the traditional knowledge was obtained. In this regard, the issues discussed above are relevant: namely, whether prior informed consent can be given by the provider state also with regard to the traditional knowledge or whether indigenous communities have to consent as well.

If it is accepted that traditional knowledge has to be obtained with the consent of indigenous peoples, the certificate would also have to include proof of prior informed consent. This could in practice be a Material Transfer Agreement, a benefit-sharing agreement or another agreement certifying that the consent was given. For those institutes in charge of checking the certificate the question arises, how to verify that these documents are valid, obtained from the communities entitled to give the consent or even whether the agreement is fair and equitable. It would be especially difficult to answer the question of who is entitled to give the consent,<sup>276</sup> and therefore whether the right group/collective gave the consent.

Thus, from a practical point of view, a number of questions have to be addressed if a certificate is to attest that prior informed consent has been obtained with regard to the traditional knowledge concerned.

First, if the assessment made above that a certificate of legal provenance would be the preferred option for a certificate is accepted, the certificate would only state that with regard to traditional knowledge all legal requirements of the provider state concerning PIC and tradi-

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<sup>274</sup> Compare UNTAD, TD/B/.Commission.1/EM.13/2, 2000, p. 14 – 15., Andean Community, Brazil, Costa Rica, Panama, Philippines, Peru, Bangladesh, Draft Biodiversity and Community Knowledge Act; OAU Model Law on Rights of Local Communities, Farmers, Breeders and Access; Pacific Forum, Draft Protection of Traditional Knowledge and Expressions of Culture Act; Pakistan, Draft Law of Access and Community Rights; Philippines, Indigenous Peoples Rights Act; Third World Network, Community Intellectual Rights Act, 1996. See for an assessment Dutfield 2000b.

<sup>275</sup> Vandana Shiva, cited according to Tobin 1997, p. 333.

<sup>276</sup> Tobin 1997, p. 333.

tional knowledge have been observed. The certificate would not contain detailed information regarding the kind of agreement between the indigenous communities/peoples, the kind of traditional knowledge concerned etc. The advantage of such a certificate would be again that those in charge of inspecting the certificates, e.g. patent offices, border controls etc. would be relieved of the burden of verifying whether the certificate conforms to national or international standards. At the same time, it would be the national governments in the provider states which would define in which cases the traditional knowledge was obtained legally. In sum, in the case of a certificate one would always run the risk that it will certify PIC with regard to traditional knowledge that might not be considered a consent by all stakeholders, either because the state decided what constitutes consent or because relevant indigenous communities/peoples were not involved in the decision.

Second, the certificate would have to specify the traditional knowledge in a form that enables third parties to identify what is covered by the certificate, for example in order to determine prior art in a patent application. This could be supported by the use of national registers. If traditional knowledge was included in a national register, it would be sufficient to indicate a registration number for the traditional knowledge, especially in cases in which the knowledge is intended to be kept confidential.

Currently, a number of such registers and databases exist with different objectives and functions.<sup>277</sup> *Alexander et. al.* give an overview of existing database and register systems for traditional knowledge, which have different objectives. Generally, TK registers can have three main functions: first, to protect traditional knowledge against loss, second, to identify the existence of traditional knowledge, in order to identify whose rights have to be protected and third, to serve as evidence of prior art in patent applications.<sup>278</sup> Also, objectives can be to claim rights or prevent appropriation of traditional knowledge, to enable the transmission of traditional knowledge, to identify TK holders entitled for benefit-sharing, as well as to serve for specific cultural and other purposes.<sup>279</sup> In the beginning, databases and registers were mainly started to preserve traditional knowledge and to allow the use by indigenous communities<sup>280</sup> as well as the scientific world.<sup>281</sup> The objectives which relate to the – active and passive<sup>282</sup> – protection of indigenous TK by parties not entitled to the knowledge is a later development.<sup>283</sup> In all of these databases/registers, the issue of public access and the assignment of rights over the traditional knowledge plays an important role.

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<sup>277</sup> Alexander et. al. 2003. Downes, Laird et al. 1999, p. 5 define a register to be “not merely a list or database designed to provide information to users. It is a list or database into which people put information in order to gain legal rights relating to that information. “Registering” something in a registry “puts it on the record” and puts the public “on notice” that the registrant asserts a claim.”

<sup>278</sup> Tobin 2001, p. 57.

<sup>279</sup> Alexander et. al. 2003, p. 26.

<sup>280</sup> E.g. the Traditional Knowledge Database of Inuit of Nunavik, Canada.

<sup>281</sup> E.g. the Natural Products Alert (NAPRALERT) at the University of Illinois and the CABI Medicinal Plant Database in Wallingford, UK.

<sup>282</sup> Van Overwalle refers to positive and defensive protection routes, see Overwalle 2004, p. 5 – 12.

<sup>283</sup> E.g. the Traditional Knowledge Digital Library (TKDL) in India, which was set up as a response to the difficulties in turning over two patents granted on products based upon Indian TK: the patent on turmeric and the patent on Neem.

From a general point of view, the inclusion of traditional knowledge into a certificate will have to face questions that relate to the overall design of a system to protect traditional knowledge. It should not be perceived to contribute to the erosion of knowledge. This is a critical question which cannot be answered here but deserves attention. It has been pointed out that there is a danger of introducing counterproductive regimes that promote division amongst indigenous peoples, legitimize the appropriation of traditional knowledge and add to legal uncertainty.<sup>284</sup> A system of certificates could be perceived to contribute to these dangers, because it will add pressure to the call for national laws for the protection of traditional knowledge, which should not be adopted in a hasty manner.<sup>285</sup> Also, it will add to the perception that only an international rights regime can effectively address the protection of property rights on traditional knowledge.

### 6.3 Possible frameworks of a certificate

The certificate of origin is often discussed in conjunction with disclosure requirements under intellectual property law. Therefore, the distinction between a certificate of origin and a disclosure requirement under patent law is not always made carefully. But introducing a certificate of origin could not only be relevant in the field of intellectual property but in relation to the whole chain of the ABS process as proposed by among others *Ruiz and Tobin*.<sup>286</sup> The certificate could accompany the genetic resource from the collection phase through export and research application until the marketing of the end-product.<sup>287</sup> If measures of genetic tracking are used, these could pertain to international transport of genetic materials, IPRs and controls on marketing and commercialization.<sup>288</sup> In the following it will be laid out how a certificate of origin can be used to track the flow of genetic resources and their use. The different options are partially interdependent, however, in order to clearly differentiate between them, they will be discussed separately.<sup>289</sup>

The following section deals with the question of practicality of a certificate. Then legal issues will be discussed. Section 6.6 estimates the – positive and negative – impacts a system of certificates of origin might have on the German commercial and non-commercial actors. Finally, section 6.7 will try to describe a possible model for a system of certificates of origin.

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<sup>284</sup> Tobin 2001, p. 63-64.

<sup>285</sup> Tobin 2001.

<sup>286</sup> COM (2003) 821, p. 20; Ruiz et. al. 2003, p. 2; Barber/Johnston/Tobin 2003.

<sup>287</sup> Barber/Johnston/Tobin 2003, p. 38.

<sup>288</sup> IUCN, 2004b, p. 16.

<sup>289</sup> A further proposed use for the certificate, which is not discussed here is for scientific publications, Tobin/ Cunningham/ Watanabe 2004, p.1.

### 6.3.1 Documenting the flow of genetic resources

The introduction of an international system for documenting the flow of genetic resources by means of certificates has been recommended. The overall goal of a standardized system is envisioned to “in short, harmonize procedures for identifying the existence of PIC; protect the confidentiality of contracts; reduce transaction costs; facilitate tracking of gene flows; promote increased trade in genetic resources; and provide an incentive for countries of origin to develop more flexible ABS rules and procedures.”<sup>290</sup> Thus, a system for documenting the flow of genetic resources is not a goal in itself but can be seen as a measure to facilitate other user measures, such as import and transport regulations and the disclosure of origin in patent law. It has been proposed to include into such a certificate information on provider, user and countries of origin, details of genetic resources, traditional knowledge and approved uses as well as restrictions on the use, the period of the agreement, conditions on transfer of rights to third parties and the issuing authority.<sup>291</sup> Besides tracking the gene flow itself, it was also proposed that the system should track the flow of traditional knowledge attached to the genetic resources.<sup>292</sup> As pointed out above, the tracking of traditional knowledge is more difficult due to its intangible nature. However, in combination with registers for traditional knowledge, it could be possible to describe – without the knowledge entering the public domain – the TK in order to be able to track it.

One advantage of such a system could be to provide transparency regarding the use of resources. Many critics of the current system of ABS point to the fact that genetic resources are being taken out of provider countries without the latter being able to follow what is being done later with them. Often, this becomes apparent only later, when users apply for patents, making use of genetic resources, which is often referred to as “bio-piracy”. Genetic resources can be easily acquired illegally and tracing their use outside the country of origin has been called “nearly impossible”.<sup>293</sup> It might, however, be possible under a uniform international system.

A system of tracking the flow of genetic resources, the possible practical implementation details of which will be elaborated further under point 6.7, could also, with increased transparency, serve to build confidence among the different actors involved. As mentioned in the introduction, besides aspects of equity, building trust should be one of the main endeavors of an international ABS regime.

### 6.3.2 Import and export regulations

Closely connected to this first proposal is the idea of introducing a legal obligation to prove legal acquisition according to the laws of the country of origin when importing and exporting genetic resources.<sup>294</sup> Worldwide, there is a complex and sophisticated system of import-

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<sup>290</sup> Barber/Johnston/Tobin 2003, p. 38.

<sup>291</sup> Ibid, p. 38.

<sup>292</sup> Ibid, p. 38.

<sup>293</sup> Henne et. al. 2003, p. 37.

<sup>294</sup> BMZ 2001, p. 15.

ing, exporting and transporting goods. Customs and international transport might be some of the most strictly regulated fields of international relationships. Also, especially with regard to the import of biological material, national laws and controls are very elaborate. This is due to concerns of environmental harm, the protection of animal, plants and human health, as well as economic reasons.

One example of an international import and export regime that works rather well is CITES, which regulates the international trade in endangered species.

Most, if not all user countries of genetic resources have extensive regulation and procedures in place to monitor the import of animals, plants and micro-organisms.<sup>295</sup> The use of certificates to control ABS requirements at the point of import of genetic resources, however, is more demanding compared to controlling animals or even plants or parts of plants. In many instances only minor quantities of material might be needed for initial research or commercial purposes. This makes controlling the import of genetic resources rather difficult. Some even regard it as completely impractical.<sup>296</sup> This might especially be the case for the control of minimal quantities of resources and the ‘import’ of traditional knowledge associated with genetic material.<sup>297</sup>

Furthermore, including the control of the import and export of genetic resources in existing procedures would entail additional administrative burdens and costs.<sup>298</sup> This pertains not only to the administration but also to users. Importing institutions would have to cope with additional difficulties and costs, making scientific and commercial research more cumbersome.<sup>299</sup> In this context one has to keep in mind that the goal of an international ABS regime cannot be to deter users from scientific and commercial research. Apart from a number of critics, who generally consider the commercialization of genetic resources as detrimental for biological diversity and indigenous peoples and communities,<sup>300</sup> the majority of the negotiating parties will favor solutions that enable an ongoing exchange of genetic resources between providers/provider countries and users/user countries.

On the other hand, existing import and export regulations already cover biological material of all kinds. CITES also subjects the export and import of small parts of protected species such as pieces of skin, tissue or cell cultures to the permitting system. Thus, there has already been sufficient experience with regard to the export and import of controlled substances and specimens. As will be explained further *infra*, an export/import system that is to function effectively will depend on a central monitoring system.

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<sup>295</sup> Barber/Johnston/Tobin 2003, p. 26.

<sup>296</sup> Nordic Council of Ministers 2003, p. 154.

<sup>297</sup> Barber/Johnston/Tobin 2003, p. 27.

<sup>298</sup> *Ibid.*

<sup>299</sup> *Ibid.*

<sup>300</sup> See e.g. Friends of the Earth International 2004.; Shiva 2000; Mooney 2000. For a discussion of this standpoint compare Godt 2004, p. 206- 208.

### 6.3.3 Transport regulations

Transport regulations cover mainly the safe transport of goods.<sup>301</sup> Special rules apply to transport by sea, air, and postal services. International organizations such as the International Maritime Organization (IMO), the International Civil Aviation Organization (IACO), the Universal International Postal Union, The World Health Organization (WHO) and the OECD have developed rules or schemes that address issues of safe transport.<sup>302</sup>

International rules also already specifically cover the transport of biological and genetic material. The EC and other bodies as well as national governments have regulations for the transport of biological material, such as micro organisms, including genetically modified organisms and infectious materials in place. If a system was to cover transport regulations as well, it could thus be based to a large extent on existing rules.

### 6.3.4 Registration of the use of genetic resources

Another possible function of certificates of origin would be to control the use or further transfer of genetic resources in user countries with the help of certificates of origin.<sup>303</sup> Companies could be generally required to present certificates of origin when making commercial use of genetic resources.<sup>304</sup> Such a possibility has been called practically infeasible due to the large volume of genetic material being used.<sup>305</sup> While this is questionable – there is a broad range of activities that underlie national registration requirements – the idea is likely to meet with strong resistance from industrialized countries. However, it has to be pointed out that this would possibly be the most effective way to ensure that a general control of the use of genetic resources takes place.

An alternative to a registration requirement would be to oblige the users of genetic resources to inform the administration in user countries of the uses made of the resources and the obligation to present a CLP when doing so.

### 6.3.5 Development and research policies

The EC Commission has indicated a further field in which certificates of origin might prove useful. It has declared its intent to examine means to incorporate into its standard contracts for economic or development cooperation the principles of the Bonn Guidelines when such contracts involve the use of genetic resources and/or traditional knowledge.<sup>306</sup> To make the control of the ABS requirements operational, it could be helpful to integrate the concept of

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<sup>301</sup> Barber/Johnston/Tobin 2003, p. 27.

<sup>302</sup> Ibid.

<sup>303</sup> IUCN 2004b, 16.

<sup>304</sup> Nordic Council of Ministers, 2003, p. 154.

<sup>305</sup> Ibid.

<sup>306</sup> COM(2003) 821, p. 23.

certificates of legal provenance, which help to ensure that national requirements have been complied with, without the need to examine the individual MAT.

A similar concept could be applied to EC or nationally financed R&D projects, which involve genetic resources. It would be an effective means of enforcement to make the granting of support for research activities, which involve the use of genetic resources, dependant on the presentation of a certificate.

### 6.3.6 Disclosure of origin in food and drug administration applications

Another proposal relates to the disclosure of the origin of the genetic resources in applications for permits from food and food and drug administration for permits for food and drugs based on genetic, biochemical and biological material and associated knowledge.<sup>307</sup> This would also be an effective way to ensure compliance with an ABS regime. Again, the concern that the competent authority will be overburdened with checking on the origin of the material and the associated knowledge must be taken seriously. Thus a certificate of legal provenance could be useful in this regard.

### 6.3.7 Patent law

In patent law, a certificate of origin could be used as a means to fulfill disclosure requirements. A number of disclosure requirements are known in intellectual property law, such as Rule 27(1)(b) of the European Patent Convention, Art. 81 of the European Patent Convention, as well as under Art. 50 of EC Regulation 2100/94 on Community Plant Variety Rights.<sup>308</sup> As *Correa* has pointed out a disclosure of origin in patent law by means of certificates of origin/source/legal provenance may fulfill three functions relevant to the operation of the patent system.<sup>309</sup> First, it would improve the substantive examination of patent applications involving biological or genetic material and related traditional knowledge. Thereby, it would help to identify possible cases of misappropriation of biological materials and facilitate actions to challenge the validity of wrongly granted patents. Second, it would improve the determination of inventorship by the patent offices or courts. An act of invention is a requirement for a patent and the disclosure could help ensure that an act of invention took place. Third, the disclosure may in some cases facilitate the execution of the invention, e.g. where the biological material is endemic to a specific location. With regard to access and benefit-sharing, intellectual property rights can play a role in ensuring that an access agreement actually creates benefits from genetic resources, shares those benefits equitably and respects the interests and concerns of the resource providers.<sup>310</sup>

A range of voluntary and mandatory measures relating to disclosure of the origin of genetic resources, traditional knowledge and prior informed consent for their use have been adopted

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<sup>307</sup> Henne et al 2003, p. 53.

<sup>308</sup> See COM(2003) 821, p. 17-18.

<sup>309</sup> Correa 2003, p. 2-3.

<sup>310</sup> WIPO/GRTKF/IC/6/5, Annex, p. 2. This, however, is a highly disputed position.

by national governments and regional economic groupings in their procedures for intellectual property protection, with a tendency of developed countries to adopt voluntary and developing countries to adopt mandatory requirements.<sup>311</sup> Various proposals have also been put forward in the international discussion addressing the interaction between ABS and intellectual property rights ranging from encouraging to requiring the disclosure of the origin and traditional knowledge in patent applications.<sup>312</sup> The WIPO provided an in-depth analysis of disclosure requirements related to genetic resources and traditional knowledge.<sup>313</sup>

In this regard, the different options discussed above are relevant. In the case of a certificate of *geographic* origin, the applicant might have to declare only where the genetic resource originated, without further evidence of whether he acquired it pursuant to the requirements of Art. 15 of the CBD or national laws implementing the CBD. Contrary to this a certificate of origin could also include documentary evidence of PIC or even benefit-sharing agreements. As the so-called 'triploid' requirements, the Group of Megadiverse Countries has demanded that proof of origin, PIC and benefit-sharing shall be required as a precondition for patentability.<sup>314</sup> A certificate *of source* on the other hand would only disclose where the genetic material was obtained but make no statement as to whether it was obtained legally. As explained above a *certificate of legal provenance* would state officially that the legal requirements of the country of origin have been satisfied.

There are different possibilities with regard to the inclusion of such a certificate into patent law<sup>315</sup> (and thus to its binding force and enforcement). The disclosure of origin or legal provenance can be a (1) free-standing or a (2) self-standing requirement in patent law or a (3) formal condition of patentability or (4) if lacking allow the withdrawal of the patent or limit its enforceability.<sup>316</sup>

#### 6.3.7.1 Fee-standing requirement

In the case of a free-standing requirement the declaration of the origin (or of additional information such as PIC) is facultative. As such, it does not entail any (negative) consequences, if the applicant does not declare the origin of the genetic resource. The applicant is encouraged to disclose the origin but is not required to disclose it in order to obtain the patent.<sup>317</sup>

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<sup>311</sup> WIPO/IP/GR/00/3 "Information provided by WIPO Member States Concerning Special Provisions to Ensure the Recording of Some Contributions to Interventions"; Barber/Johnston/Tobin 2003, p. 7.

<sup>312</sup> See among others WTO documents IP/C/W/195/, IP/C/W/228, WT/GC/W/233, IP/C/M/32, IP/C/M/33; UNCTAD documents TD/B/COM.1/EM.13/3; WIPO documents SCP/3/10, WIPO/IP/GR/00/2, WIPO/IP/GR/00/4.

<sup>313</sup> Draft Technical Study on Disclosure requirements Related to Genetic Resources and Traditional Knowledge, WO/GA/30/7, 15 August 2003.

<sup>314</sup> WTO, Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, 24 June 2003, IP/C/W/403, p. 1.

<sup>315</sup> Other legal bases for disclosure of the origin of genetic resources/TK include contractual obligations, compliance with morality and *ordre public* obligations, and equitable principles, WIPO 2003, WO/GA/30/7, p. 33 - 49.

<sup>316</sup> WIPO 2003, WO/GA/30/7, p. 49 - 59.

<sup>317</sup> CBD, 2003, UNEP/CBD/WG-ABS/2/3, p. 13.

### *European Union*

This approach has been chosen in the Biotechnology Directive<sup>318</sup> of the European Union in its recital 27, which reads: “Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”<sup>319</sup>

### *Sweden*

The Biotechnology Directive was implemented in Swedish patent legislation as of 1 May 2004. The Patent Regulations contains in Section 5a a requirement stating that if an invention relates to biological material, the applicant shall provide information concerning the geographical origin of that material. However, there are no consequences or sanctions if such information is not given.

### *Denmark*

A similar provision has recently been introduced into Danish law.<sup>320</sup> Under the revised Danish law, an application for a patent that makes use of plant or animal genetic resources has to include information on the geographical origin of the material, where the patentee is in possession of this information. The applicant also has to declare that he does not know the geographical origin of the resource, if this is case. Not having information on the origin of the genetic resource does not affect the processing of the application or the validity of the patent rights, which follow from the patent.

### *Germany*

The German draft law for the implementation of the Biotechnology Directive uses the same approach. The proposed Section 34a states that if an invention concerns biological material or uses biological material, the patent application shall contain information on the geographical origin of the material, if this is known. The examination of the application and the validity of the patent rights remain untouched.

### *Summary*

As a consequence of these provisions, disclosing the origin of the genetic material cannot be enforced in any way by the patent office or the administration in the user states. Although it is an obligation it thus remains rather toothless. A further option for a free-standing re-

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<sup>318</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213/13, 30.7.1998.

<sup>319</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213/13, 30.7.1998. The wording does not preclude Member States of the EU to introduce self-standing requirements.

<sup>320</sup> Law for the revision of the patent law (Lov om ændring af patentloven, varemærkeloven, lov om brugsmønstre m.v., lov om mønstre og lov om plantenyheder).

quirement is to ease conditions for patenting, e.g. by reducing patent fees.<sup>321</sup> This works towards providing an incentive for the disclosure but also remains a weak option.

#### 6.3.7.2 Self-standing requirement

In the second case the requirement to disclose the origin/source/legal provenance of the genetic resource (and/or PIC or MAT) is required by patent law, but the legal consequences lie outside the ambit of patent law ( i.e. in civil law, with liability clauses, in administrative law by means of fines or even in criminal law).

A number of countries have introduced a self-standing (distinct, stand-alone)<sup>322</sup> requirement in patent law.

##### *Norway*

A self-standing requirement in patent law was introduced into the Norwegian patent act, which entered into force on 1 February 2004.<sup>323</sup> The patent act requires that if an invention covers or uses biological material, the patent application has to include information about the country from which the material was received or collected (provider country). If national legislation in the provider country requires prior informed consent for the collection of biological material, the patent application has to include information that such consent has been obtained. If the information required is unknown, the applicant has to specify this. The obligation applies also if the inventor has changed the structure of the received material (i.e. towards derivatives). In cases in which the provider country is not the same as the country of origin of the biological material, the country of origin shall also be identified in the application. ‘Country of origin’ is defined in the act as the country in which the material was collected from in situ sources.

Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to provide information is without prejudice to the processing of patent applications or the validity of the granted patents.

The Norwegian patent clause is considered a success by the patent authorities and patent applicants are estimated to disclose the required information. So far, no cases of non-compliance or court cases have been reported.<sup>324</sup>

##### *Nordic Approach*

Overall, while differences of opinion exist, the “Nordic Approach” maintains that not regulating the issue of genetic resources is not an option.<sup>325</sup> According to the Nordic countries,

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<sup>321</sup> Godt, 2004, p. 210.

<sup>322</sup> CBD, 2003, UNEP/CBD/WG-ABS/2/3, p. 13.

<sup>323</sup> § 8 b of the Norwegian Patent Act (Lov om patenter).

<sup>324</sup> Interview with the responsible official in the Patent Office, Norway.

<sup>325</sup> Nordic Council of Ministers 2003, p. 156.

international pressure, growing distrust between provider and user countries as well as the legitimate interest that access laws should be complied with, necessitate that user states introduce measures to implement the access and benefit-sharing provisions of the CBD.<sup>326</sup>

### *Belgium*

The Belgian draft law on patents for biotechnology inventions of 21 June 2002 foresaw a provision that forbade the exploitation of patents that are developed against the *ordre public*.<sup>327</sup> This was to be the case, when an invention was developed against the provisions of Art. 3, 8, j), 15 and 16 of the CBD.<sup>328</sup>

However, in the draft law of 21 September 2004 this provision is not contained any longer. Art. 5 amending Art 15 of the patent law remained of the draft law of 2002.<sup>329</sup> It provides that the geographical origin of biological resources shall be mentioned in the patent application, if it is known. It is foreseen that the king can decide on applicable conditions and executive measures in regard to this provision.<sup>330</sup>

#### 6.3.7.3 Formal prerequisite of patentability

The third option would be to make the disclosure of origin a formal condition of patentability.<sup>331</sup> In this case a number of possibilities are conceivable for including a certificate of origin in the patent system. The harshest possible consequence of an obligatory disclosure requirement in patent law is to deny the issuing of a patent if the origin of the genetic re-

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<sup>326</sup> Ibid.

<sup>327</sup> Projet de Loi modifiant la loi du 28 mars 1984 sur les brevets d'invention, en ce concern la brevetabilité des inventions biotechnologiques, Chambre des Représentants de Belgique, 21 juin 2002, Art. 4 § 4. The explanations of the draft laws further explain this provisions by stating: "La biopiraterie est une question cruciale qui mérite, par son importance, d'être traitée afin de lutter contre le pillage des ressources biologiques des pays du tiers monde ou en voie de développement. C'est pourquoi, il convient également, dans le cadre de la transposition de la directive, de prendre en considération la Convention de Rio sur la biodiversité biologique, notamment en ce concern le droit souverain des États d'exploiter leurs ressources génétiques (article 3 Convention de Rio), ainsi que le droit des communautés autochtones et locales sur leurs connaissances et à un partage equitable des avantages découlant de l'utilisation de ces connaissances (article 8 j).

<sup>328</sup> Ibid Art. 6.

<sup>329</sup> Art 15 § 1 of the Belgian patent law reads: "La demande de brevet doit contenir :

- 1) une requête en délivrance d'un brevet adressée au Ministre;
- 2) une description de l'invention;
- 3) une ou plusieurs revendications;
- 4) les dessins auxquels se réfèrent la description ou les revendications;
- 5) un abrégé."

<sup>330</sup> The addition to Art. 15 § 1 reads:

- 6) "une mention de l'origine géographique de la matière biologique d'origine végétale ou animale à partir de laquelle l'invention a été développée, lorsque celle-ci est connue. Le Roi peut fixer les conditions et les mesures d'exécution applicables."

<sup>331</sup> The hotly debated question whether doing so would conflict with Art 27.1 or Art. 29 of the TRIPS Agreements was to not to be analysed in this study. Claiming an infringement of TRIPS if an obligatory disclosure of the origin of genetic resources is a prerequisite of patenting: European Communities, IP/C/W/383, 2002, pp. 10 seq.; Carvalho 2000, p. 371; Sampath/Tarasofsky 2002, p. 113. Claiming the compatibility of an obligatory disclosure requirement and TRIPS: Switzerland, IP/C/W/400/Rev.1, Vivas 2003; Godt, 2004, p. 211.

source is not at all or not correctly disclosed. Such provisions can be found in a number of national laws.

### *Brazil*

In Brazil, the granting of industrial property rights obtained through the use of components of the genetic heritage is contingent on the observance of the access and benefit-sharing legislation. The applicant is obliged to specify the origin of the genetic material and the associated traditional knowledge.<sup>332</sup>

### *Costa Rica*

In Costa Rica, the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission, which is responsible for the management of biodiversity, before granting protection of intellectual or industrial property to innovations involving components of biodiversity. A certificate of origin, which is issued by the Technical Office of the Commission, and the prior informed consent must be presented. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation.<sup>333</sup>

### *Andean Community*

The second “complementary provision” of Decision 391 provides that the Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, which were obtained or developed by means of an access activity that does not comply with the provisions of Decision 391, which requires fair and equitable distribution of the profits from the use of genetic resources. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.<sup>334</sup>

In 2000 the Andean Community took another Decision on the common intellectual property regime, which provides that the competent national authority may, either *ex officio* or at the request of a party, and at any time, declare a patent null and void. The condition hereof maintains that one of the following scenarios shall apply: (1) The products or processes in respect of which the patent is being filed have been obtained and developed on the basis of genetic resources or their by-products originating in one of the Member Countries, if the applicant failed to submit a copy of the contract for access to that genetic material. (2) The products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to Indigenous, African-American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the

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<sup>332</sup> Art. 31 Provisional Measure No. 2.186-16, Brazil.

<sup>333</sup> Art. 80 Biodiversity Law No. 7788 1998, Costa Rica.

<sup>334</sup> Second “Complementary Provision” of Decision 391, Andean Community.

document certifying the existence of a license or authorization for use of that knowledge originating in any one of the member Countries.<sup>335</sup>

### *Egypt*

In Egypt, it is provided that an inventor of an invention involving a biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, has to have acquired the sources in a legitimate manner.<sup>336</sup>

### *India*

Under Indian patent legislation an applicant has to disclose the source and geographical origin of biological material when used in an invention. The law allows an opposition to the patent application to be filed within four months if the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the intervention. The grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of the biological resource or knowledge in the patent application, and prior disclosure of knowledge, oral or otherwise.<sup>337</sup>

#### 6.3.7.4 Prerequisite of enforceability/validity

Not making the granting and validity of a patent subject to disclosure but rather the patent's enforceability has been proposed in order to avoid the – contended – conflicts with international patent law.<sup>338</sup> This concept is based on the US doctrine of 'clean hands': Accordingly, a patent owner would be precluded from enforcing his patent before a court, if he has obtained the patent without disclosing the origin of the genetic resource and prior informed consent. The reasoning is that if an applicant who is filing for a patent fails to be candid on matters that concern the patentability such as novelty or inventiveness, then his application should be invalidated. But when matters are concerned that are not essential to the granting of the patent, the courts would declare the patent non-enforceable.

This proposal seems interesting, especially because it would avoid lengthy conflicts on TRIPS conformity that other options might entail. However, the non-enforceability would only become relevant when someone is challenging a patent before a court of law. Also, patents that have already been granted are usually difficult to overturn on formality grounds unless the failure to comply can be shown to have been fraudulent.<sup>339</sup>

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<sup>335</sup> Art. 75 Decision 486, Andean Community.

<sup>336</sup> Art. 13 Law on the protection of intellectual property rights, 2002, Egypt.

<sup>337</sup> Section 10 Patents Act 1970 as amended by the Patents Second Amendment Act of 2002, India.

<sup>338</sup> Carvalho, 2000.

<sup>339</sup> Baumüller/Vivas-Eugui 2004, p. 21.

Finally, patent laws or other acts can also stipulate that the lack of disclosure leads to a revocation<sup>340</sup> or the nullity<sup>341</sup> of patents.<sup>342</sup>

So far it seems that neither of these patent law provisions has been put to practice. This also might be due to the fact, that most commercial users apply for patents in the US, Japan or the EU but not in countries of origin.

### 6.3.8 Summary

The examples above demonstrate different options for disclosure requirements in patent law. Since they have been introduced quite recently, there have been no or only limited practical experiences with their implementation.<sup>343</sup> The current debate on disclosure requirements also reveals that there is no consensus on the question whether and how the disclosure of the origin/legal provenance of genetic resources can contribute to the goals of the CBD.<sup>344</sup> However, even the International Chamber of Commerce see it as “entirely reasonable” to disclose where patentees obtained their genetic resources.<sup>345</sup>

The EC favours a self-standing disclosure requirement.<sup>346</sup> It envisages allowing members to keep track, at global level, of all patent applications with regard to genetic resources for which they have granted access.<sup>347</sup> But according to the EC, sanctions could also include halting the processing of the patent application until the patent applicant has provided the required declaration, and the invalidation or revocation of the patent if the incorrect declaration of the source is due to fraudulent intention.<sup>348</sup> Another option would be to connect the sanctions to the income generated by the use of the patent.

The self-standing requirement in patent law to disclose the origin or preferably the legal provenance of the genetic resource would have a number of advantages. First, it would avoid the very difficult and contentious question of the compatibility of international law and the new regime, which could, due to the number of actors involved (TRIPS Council, WIPO etc.), paralyse negotiations and make the acceptance of a regime dependent on changes in other international treaties, such as the Patent Cooperation Treaty.<sup>349</sup>

Second, linking a system which tracks the flow of genetic resources by using certificates of origin to the patent system offers the advantage of being able to control the flow of re-

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<sup>340</sup> See the Indian patent law, *supra* under 7.3.7.3.

<sup>341</sup> See Andean Community, *supra* under 7.3.7.3..

<sup>342</sup> Because the deny the initial validity of the patent, both options are considered to be in breach of the TRIPS Agreement, Carvalho, p. 387-389.

<sup>343</sup> Morin 2004a, p. 6.

<sup>344</sup> See Morin 2004a,b; Luafi/Morin 2004, Kushan 2002; Wisner 2001,

<sup>345</sup> ICC 2002.

<sup>346</sup> COM(2003) 821, p. 17.

<sup>347</sup> *Ibid.*

<sup>348</sup> COM(2003) 821, p. 19. See also *infra* at 8.3.7.4.

<sup>349</sup> While it is disputed whether the PCT would have to be amended in order to allow the introduction of disclosure requirements in national patent law, those have been proposed by Switzerland: See PCT/R/WG/4/13, Proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. The EU Commission considers this not to be necessary.

sources more effectively. It has been pointed out that transport as well as export/import controls run the risk of being rather ineffective. Conversely, a disclosure, even if self-standing, would provide an effective alternative for monitoring the flow of genetic resources.

At the same time, a self-standing disclosure requirement in patent law would not effectively deter people from using genetic resources without fulfilling the requirements of the country of origin, if the (self-standing) sanctions in patent law are insufficient. Thus, a provision such as the Swedish one, which does not foresee any sanction could prove practically useless in bringing users to conform to ABS standards.

The option of requiring disclosure of origin as a formal requirement of patentability is not only problematic in terms of its compatibility with international law but it also gives rise to practical problems. In the event the law obliges applicants to present an agreement the patent offices would have to examine its validity, an undertaking which might exceed the capacities and knowledge of the patent offices.<sup>350</sup> This, however, could be circumvented by requiring the presentation of certificates of legal origin, which would ease the burden on the patent offices.

The exact wording of a disclosure requirement in patent law relating to the origin or legal provenance of genetic resources and/or traditional knowledge raises a number of highly technical questions, which have been highlighted by a WIPO study.<sup>351</sup> Among other things, the question of when a disclosure has to take place is crucial. Existing national or regional measures include options such as a disclosure obligation when an invention is based on biological material, is obtained and/or developed by means of access activities, or involves or uses elements of biodiversity.<sup>352</sup> Each option has different consequences, which have to be taken into account. In sum, a disclosure requirement in patent law could be an effective way of both *ex ante* steering mechanisms or *ex post* control.<sup>353</sup> However, to effectively fulfill this function, the sanctions would have to be severe enough to act as an effectual deterrent from using genetic resources while adhering to the ABS laws of the country of origin.

Still, the disclosure of the origin/legal provenance of a genetic resource and the associated traditional knowledge in patent applications would represent only one way to ensure that the CBD access and benefit-sharing provisions and compliance with ABS legislation are observed. Not all or even the majority of the bioprospecting activities result in a patent application. Therefore, a combination of the different elements might prove a helpful way to make use of certificates of origin.

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<sup>350</sup> COM(2003) 821, p. 19.; IP/C/W/400/rev.1, p. 8-9.

<sup>351</sup> WIPO/GRTKF/IC/5/10, p. 32 et. seq.

<sup>352</sup> Ibid, p. 34.

<sup>353</sup> For the differentiation between both functions of a disclosure requirement *compare* Godt 2004, p. 208-210.

## 6.4 Special users and pre-CBD collections

Botanical gardens are in a special situation concerning genetic resources, because plant material plays a crucial role with regard to the traditional seed exchange between botanical gardens, which allows them to keep their collections up to date. The botanical gardens in German-speaking countries responded to Germany's responsibility which resulted from the CBD by adopting a Code of Conduct in 1997<sup>354</sup> and a standard material transfer agreement<sup>355</sup> to be used by members of the association of botanical gardens (VBG).<sup>356</sup> This procedure is associated with extra bureaucratic work. In order to minimize it, the botanical gardens that are registered as following the Code of Conduct can exchange plant material freely among themselves without have to sign a MTA. Only if material of other non-registered institutions is involved, does MTA have to be used.

On the European and international levels, there are a number of initiatives in this connection including the Code of Conduct which the British Kew Gardens developed. At the encouragement of German botanical gardens, the international initiative "International Plant Exchange Network" (IPEN) came into life.<sup>357</sup> Botanical gardens have special needs and also primarily exchange material among themselves. IPEN and other initiatives ensure that genetic material is exchanged only in cases in which non-commercial use is pursued. These existing systems should thus be supported by the new system of certificates of legal provenance. This would create the advantage of allowing existing systems to merge and the opportunity to benefit from their experience. A simple way of doing this would be e.g. to include all members of IPEN into a simplified procedure (see chapter 6), which would mean that they would obtain just one time a certificate, which is valid for all their non-commercial transactions, as in the CITES system.<sup>358</sup>

## 6.5 Form, effectiveness, practicality of a certificate

Any new system for tracking the flow of genetic resources using a certificate will have to fulfill a number of requirements in order to stand chances of being accepted and implemented successfully.

First, a certificate should be designed in a simple and comprehensive form, which makes it easy to use and minimizes problems, which might arise from the use.<sup>359</sup> Thus, a single harmonized certificate should be introduced, which limits the efforts of users. It should not be framed in a way which would prevent stakeholders from enjoying the flexibility needed in order to carry out their transactions.<sup>360</sup>

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<sup>354</sup> [http://www.botanik.uni-bonn.de/botgart/Verhaltenskodex\\_englisch.pdf](http://www.botanik.uni-bonn.de/botgart/Verhaltenskodex_englisch.pdf).

<sup>355</sup> [http://www.botanik.uni-bonn.de/botgart/MTA\\_english.pdf](http://www.botanik.uni-bonn.de/botgart/MTA_english.pdf)

<sup>356</sup> <http://www.biologie.uni-ulm.de/verband/>.

<sup>357</sup> Driesch et al. 2003.

<sup>358</sup> Another example for such an initiative is MOSAICC, which is a Code of Conduct for the use micro-organisms. MOSAICC stands for **M**icro-**O**rganisms **S**ustainable use and **A**ccess regulation **I**nternational **C**ode of **C**onduct. Compare <http://www.belspo.be/bccm/mosaicc/>.

<sup>359</sup> Laird 2004.

<sup>360</sup> COM(2003) 821, p. 5.

Second, the work load of administrations, which have to control them must be taken into account.

Third, the system has to work effectively, i.e. fulfill the functions foreseen and not allow or at least seek to prevent fraud.

Also, any overall system for tracking the flow of genetic resources should be created in a way that does not necessitate new international or national structures, does not duplicate work being undertaken under other international processes<sup>361</sup> and uses as little funds as possible. It was pointed out that if a requirement to submit documentary evidence of PIC for patent applicants was to be introduced, it would be facilitated by a clear, simple and harmonized system for certifying access such as a standard MTA.<sup>362</sup> Hereinafter, form, practicality and effectiveness of a certificate of origin will be discussed. In order to profit from the experience with existing international permit systems, the experience with CITES is presented first. Then, possible synergies and connections between the CITES permit system and a possible ABS certificate of legal provenance are discussed. Possible legal implications of a certificate follow as well as the consequence for scientific and economic actors that the introduction of a certificate system would have. Finally, we try to outline a potential model of how an international system of certificates of legal provenance.

### 6.5.1 The experience with CITES

The Convention on International Trade in Endangered Species of Wild Fauna and Flora represents an international system that makes use of a largely uniform permitting procedure in order to track international trade in endangered species.

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which came into force in 1975, regulates the global trade in threatened and endangered species. With its now 166 parties CITES enjoys broad membership. Generally speaking, it acts as a border guard, regulating the trade of threatened species as well as their parts and derivatives thereof across national boundaries. The level of trade restriction varies depending on the status of threat a species faces for which CITES provides three regulatory options in the form of three Appendices

**Appendix I** lists species threatened with extinction that are or may be affected by trade. Subject to narrow exceptions, Appendix I of the Convention prohibits international commercial trade of the species listed as well as of their readily recognizable parts and derivatives. Appendix I species may only be traded if both the exporting and the importing countries issues permits and consent to the international trade. An import permit may be issued only if the specimen is not to be used for primarily commercial purposes and if the import will be for purposes that are not detrimental to the survival of the species. In the case of a live animal or plant, the Scientific Authority must be satisfied that the proposed recipient is suitably equipped to house and care for it.

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<sup>361</sup> UNEP/CBD/COP/7/INF/37, p. 7.

<sup>362</sup> COM(2003) 821, p.20 ff.

Parties to the Convention have to designate Scientific and Management Authorities. For trade in Appendix I species, both the importing and the exporting nations' Scientific and Management Authorities must give their advice prior to issuance of the import and export permit.

**Appendix II** species are not yet threatened with extinction but might become threatened if trade in them is not strictly controlled and monitored to avoid exploitation incompatible with species survival. Trade in Appendix II species requires the issuance of an export permit but not of an import permit. The exporting state must receive the advice of its Scientific Authority that the export will not be detrimental to the species survival. The Management Authority has to confirm that the specimen was not obtained in breach of state laws and that the method of shipment minimizes the risk of injury, damages to health and cruel treatment.

Species are listed in **Appendix III** when a party currently protects the species under its domestic laws and seeks the international cooperation of the Parties to the Convention to control its international trade. For trade in Appendix III species only an export permit is required or a certificate of origin if the respective species does not originate in the country which has sought the respective CITES protection.

Experiences with the CITES permit and certification system can shed some light on a possible system of certificates under the CBD. The question of possible synergies between the CBD and CITES as well as what can be learnt from the permitting system of CITES has been discussed lately in different fora.<sup>363</sup> Key differences between the existing CITES permit and the envisaged certificate of legal provenance are outlined below.

	<b>CITES permit</b>	<b>Certificate of legal provenance</b>
Object of regulation	Involves live or dead specimen, their parts and derivatives and biological material in international trade	Applies to biological material, might later apply to progeny, derivatives, information
	May include or cover look-alike species as a precautionary measure	May need to incorporate mechanisms to deal with genetic resources from <i>ex-situ</i> sources
	Product is well described with the definition of the term 'specimen'	"Product" might be unknown (coded samples)

<sup>363</sup> Regional Workshop on the Synergies between the Convention on Biological Diversity and the CITES regarding access to genetic resources and distribution of benefits, The role of the certificates of origin, Preliminary report, 17-18 November 2003. See Ruiz et. al. 2003. Promoting CITES-CBD Cooperation and Synergy, Workshop 20-24 April 2004, Isle of Vilm, Germany. See BfN-Skripten 116, 2004.

	<b>CITES permit</b>	<b>Certificate of legal provenance</b>
Goal/objective	Aim is to prevent and/or mitigate the negative impacts of trade	Aim is to promote fairer and more equitable relationships between providers and users of genetic resources
	Conservation, sustainable use, maintenance of the role a species in its ecosystem	Fair and equitable sharing of benefits
	Impede unsustainable trade	Foster the exchange of genetic resources and benefit-sharing
Scope	Covers only one operation (except re-exports)	May cover multiple operations
	Role ends with the import into importing country	Applies to the flow/process of genetic resource use
	The regulated action starts and ends with trade	Regulation of access implies a process, not just a movement
Institutionalization	A government agency decides on compliance with criteria for export/import (non-detriment finding, legal acquisition)	A government agency would decide on compliance with PIC and arrangements on benefit-sharing
	Customs officers verify compliance	Other areas (e.g. patent offices) might be involved as well
	Person requesting the permit usually knows the value of the specimen	Person requesting the certificate will probably not know the value of the specimen (uncertainty)

Table 1: Comparison between the CITES permit and a certificate of legal provenance<sup>364</sup>

A number of conclusions can be drawn from the table. First, CITES' main purpose is precisely to prevent an activity (Appendix I specimen) or ensure sustainable commercial or non-commercial trade (Appendix II specimen),<sup>365</sup> while an international ABS regime should facilitate and foster access to genetic resources and ensure the equitable sharing of its bene-

<sup>364</sup> Lichtschein 2004.

<sup>365</sup> Ruiz et. al. 2003, p. 9. A different position is taken by the German Federal Agency for Nature Conservation, which emphasises that the aim is to support a sustainable use of the endangered species imported. Jelden 2004.

fits. Second, the CITES permit does usually only apply to a single shipment, i.e. the export/import of a specimen,<sup>366</sup> while a certificate of legal provenance as outlined above would possibly be used in a number of different frameworks.

However, important similarities exist, which make the longstanding experience with the CITES permit system valuable for designing a possible certificate of legal provenance. Both the CITES permit and a possible certificate of legal provenance serve to confirm officially that the material in question is imported/used according to legal rules. In both cases, national government authorities are in charge of issuing the document. Both documents are or shall be standardized in order to be internationally recognizable.

The issue how and in what form CITES permits and certificates shall be issued is an ongoing process of discussion at Conferences of the Parties, which has received a lot of attention and resulted in the pertinent resolutions being continuously revised.<sup>367</sup> The CITES system foresees different permits and certificates, i.e. export, re-export and import permits, pre-Convention certificates, certificates of origin, as well as a number of certificates that are not relevant for a comparison with a certificate under an ABS regime.<sup>368</sup> These permits and certificates are standardized according to detailed rules,<sup>369</sup> including a standard nomenclature to indicate the names of the species.<sup>370</sup> Further specifications apply in the EU, also regarding the control of commercial activities, monitoring, sanctions and customs controls.<sup>371</sup>

Generally, the import of specimens, which are included in Appendix-I of CITES requires both import and export permits, while only an export permit but no import permit is required for specimens listed in Appendix II and III of CITES. In the EU, the importer of Annex-I-species is required to present an import permit at the border customs office. The export of Appendix I and II specimens requires an export permit. A re-export certificate is required for the export of CITES-listed specimens that were previously imported, including items subsequently converted to manufactured goods. A so-called EU-certificate may be issued when evidence of legal provenance must be provided. When exporting specimens listed in Appendix I or II, the export permit or re-export certificate must be presented at the customs office. Finally, if a specimen was obtained prior to the CITES listing date of that species (collected from the wild or held in captivity) a pre-Convention certificate may be granted that will allow for the specimen to be exported. An important characteristic of a CITES permit/certificate is that it expires after six months and is then considered void.<sup>372</sup>

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<sup>366</sup> However, re-export and –import of species is not unusual.

<sup>367</sup> Wijnstekers 2003, Jelden 2004.

<sup>368</sup> Traveling-exhibition certificates, phytosanitary certificates, permits and certificates for species subject to quotas, permits and certificates for crocodylian species etc.

<sup>369</sup> Compare CITES Resolution Conf. 12.3. E.g. it is recommended that the standard form is used, that certificates and permits are numbered in a standardized form, and that a uniform code is used to identify the purpose of the transaction, the source of the specimens etc.

<sup>370</sup> Compare CITES Resolution Conf. 12.11.

<sup>371</sup> Council Regulation (EC) No. 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein, OJ L 61/1, 3.3.1997; Commission Regulation (EC) No. 1808/2001 of 30 August 2001 laying down detailed rules concerning the implementation of Council Regulation (EC) No. 338/97 on the protection of species of wild fauna and flora by regulating trade therein; OJ L 250/1, 19.9.2001.

<sup>372</sup> CITES Resolution Conf. 12.3.

Different simplified procedures apply to trade that has only a negligible impact on the conservation of the species concerned, e.g. where biological samples are required for the control of diseases or diagnostic purposes. Parties to CITES can maintain a register of persons and bodies that may benefit from the simplified procedure. Biological samples can then be labeled and no permit needs to be presented at the customs office.

Under Art. VIII para. 7 (a) CITES, Parties are required to submit annual reports on their international trade in species listed in the Annexes to the CITES Convention. This is an important mechanism for determining the volume of trade in a given species, the volume of trade involving a particular country and to discern trade infractions and inadequate enforcement of CITES and national regulations.<sup>373</sup> These reports are compiled by the UNEP-WCMC CITES Trade Database, which holds 6 million records of trade in wildlife.<sup>374</sup> More than 500000 records of trade in CITES-listed species are reported annually.<sup>375</sup> This enormous database can be accessed online by anyone.<sup>376</sup>

The Guidelines for the Parties for the preparation and submission of annual reports require data to be divided into two main categories: imports and exports including re-exports. As far as possible, the data in the report should record the actual trade that took place, i.e. the quantity of specimen that entered or left the country. If it is not possible to report the actual exports and re-exports, the data on such trade should come from each permit and certificate issued. The report should state clearly whether the data used for the records of imports and exports/re-exports are based on permits/certificates issued or on actual trade.<sup>377</sup> In order to monitor the existing trade, however, it is important to record the actual trade that took place, because permits might not have been used etc.<sup>378</sup>

From an institutional point of view, the most important actors regarding enforcement of CITES provisions are the national border customs offices. It is important to train the customs officials well to ensure that no CITES-listed species are imported without a valid permit.<sup>379</sup>

In addition to being a potential system of ABS certificates, CITES also regulates the trade in biological material, e.g. cell cultures. Therefore, from experience with CITES a number of interesting points can be learnt and a long list of possible synergies exists. Also, the experience of CITES shows that it is possible to regulate the export/import of such material. However, experts point out that the international trade in genetic material must be considered to be significant.<sup>380</sup> Thus a system of certificates would probably be more complicated and costly to install than the existing CITES system was.

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<sup>373</sup> UNEP-WCMC 2004a.

<sup>374</sup> UNEP-WCMC 2004a, p. 3.

<sup>375</sup> Ibid.

<sup>376</sup> This, however, is a recent development. Until X months ago, the database was accessible only by governments.

<sup>377</sup> CITES Notifications to the Parties No. 2002/022.

<sup>378</sup> Jelden 2004.

<sup>379</sup> Ibid.

<sup>380</sup> Ibid.

Compared to the CITES system, a certificate for genetic resources would not be time-limited to six months, since it would be used in different contexts which would usually exceed this time limit. However, a mechanism, which CITES is using, i.e. the labels for registered entities might be useful for an ABS system as well. It could be applied to scientific entities, which regularly export genetic resources for non-commercial purposes and institutions such as botanical gardens. As in the CITES context, such a labeling scheme would apply only to the transfer between two registered institutions.

In addition to the CITES system, a system of certificates for genetic resources shall also include pre-Convention certificates, in order to allow uniform control and enforcement. It could be used for ex-situ collection material, which is not covered by the CBD's access and benefit-sharing provisions. Also, certificates should differentiate between countries with an ABS legislation in force and countries which have no ABS legislation. Possible elements of a certificate of legal provenance, closely related to the CITES system, are listed in Annex 1 of this study.

With regard to the enforcement of the CITES Convention, sanctions are left to the Parties. However, the CITES system can function only if sanctions are established.<sup>381</sup> Thus, from the experience with CITES it can be inferred that a system of import/export control of genetic resources should include sanctions as well to work effectively.

### 6.5.2 Synergies between CITES and an ABS certificate system

The majority of states that are Parties to CITES are Parties to the CBD as well. Experts see a great potential for synergies between CITES and CBD in general,<sup>382</sup> and specifically for access and benefit-sharing<sup>383</sup> and an ABS certification system.<sup>384</sup> This relates to the international as well as the national level, to the issuing of permits and certificates, border controls, reporting etc. In some countries, administrations responsible for CITES and CBD already cooperate on the organizational and administrative level with regard to the issue of access and benefit-sharing.<sup>385</sup>

Furthermore, natural overlap between CITES and a future ABS regime can result from the fact that live organisms, particularly those with reproductive material can also be estimated to represent genetic material under the terms of the CBD.<sup>386</sup> Therefore, the question of synergies and cooperation with regard to the two (future) regimes might not merely be an option but a necessity, if rules regarding the same biological material are not duplicative or even conflicting. This relates in particular to the issue of captive-bred specimens.<sup>387</sup>

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<sup>381</sup> Ibid.

<sup>382</sup> See BfN 2004, Promoting CITES-CBD Cooperation and Synergy.

<sup>383</sup> Jenkins 2004.

<sup>384</sup> Jelden 2004.

<sup>385</sup> E.g. in Madagascar, Ramiarison 2004, p. 66s.

<sup>386</sup> Jenkins 2004, p. 194.

<sup>387</sup> Ibid, p. 195.

### 6.5.2.1 Permit and certificate system

It has been suggested that a single permit/certificate could cover both endangered species and genetic resources. This, however, would require harmonization of the CITES and the future ABS regime, which seems difficult to realize.<sup>388</sup> It would also entail legal questions, such as the relationship between the two Conventions the CITES Convention and an ABS protocol, respectively. While the majority of countries that are Parties of CITES are also Parties to the CBD, this is not always the case. Therefore, it is unlikely that an agreement could be reached regarding a possible harmonization of the permitting system.

Even without such a harmonized permitting system, many things can be learned from experience of the CITES permitting system. First, the advantage of a CITES permit is its comparative simplicity. This makes it easy to use. Second, the design of an international permit can be studied in the CITES system, e.g. the necessity of authorized signatures. Third, it can be seen that a harmonized system of permits can be handled effectively on the international level.

With regard to institutional synergies of the permitting and certification system under CITES and an ABS regime, it can be expected on the one hand that where the same national focal points/management authorities handle both CITES and CBD, this enhances synergies. On the other hand, different qualifications are required in order to issue a CITES permit as opposed to an ABS certificate. Thus, the administration responsible for CITES permitting would have to be especially trained to be able to handle ABS certificates or other institutions would have to be created for this purpose.

### 6.5.2.2 National border controls

With regard to border customs officials, it is to be expected that they will be responsible for controlling both CITES permits and CLPs. A different approach would be to designate special points of exit/entry, which would be in charge of controlling the export/import of genetic resources. As it is the case of CITES, it can be expected that national customs officers need special training to be able to handle certificates of legal provenance for genetic resources.

### 6.5.2.3 Reporting

It has been indicated that the field of enhancing scientific knowledge could be one to provide further synergies between CITES and the CBD.<sup>389</sup> This covers scientific and manage-

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<sup>388</sup> As Bloch (2001) points out, introducing a clause into a CITES permit that states the material should not be used to access genetic information represents a questionable approach.

<sup>389</sup> Ibid.

ment research, nomenclature, reporting, databases, including clearing house mechanisms, the use and analysis of information and may be a joint website covering these issues.<sup>390</sup>

Of these points especially the question of reporting and common databases deserves attention with regard to an ABS regime. Reporting requirements under CITES are regulated in detail by a number of CITES resolutions, decisions and notifications.<sup>391</sup> Most importantly, Parties to the Convention are obliged to submit an annual report on their yearly trade in endangered species.

Under an international ABS regime, reporting in relation to the proposed certificates of legal provenance could play an important role in order to monitor the export/import of genetic resources and their use, especially in patent applications. (This point will be elaborated further infra.) The CBD Clearing House Mechanism would most probably be responsible together with the CBD Secretariat to ensure the monitoring of the CLPs.

From a practical point of view, a common or harmonized reporting system of CITES and the ABS regime would save resources both at the national and international level. The existing CITES Trade Database provides an excellent and complex model of a system for summarizing and monitoring the data submitted by the CITES Parties. The extensive experience that the executing UNEP institution has gathered as a result of operating the CITES Trade Database in electronic form since 1981 could contribute to the effective monitoring of an ABS regime, while at the same time limiting the financial resources required.<sup>392</sup> Experts of the institution regard a common database system as feasible.<sup>393</sup>

Problems with regard to common reporting have been mentioned in regard to both different purposes of reporting<sup>394</sup> and the object of reporting, i.e. the question of what information has to be provided.<sup>395</sup> The first point relates to the different goals of CITES and the CBD, but less so in regard to a reporting system of ABS certificates. This problem exists in regard to all MEAs that want to enhance their cooperation. The second point would have to be tackled by the national administrations. Generally, dwindling resources represent a motivation for national governments to slenderize administration. The duplication of existing structures for reporting and enforcement could most probably be avoided.<sup>396</sup>

Another current obstacle for common reporting in the framework of the CBD and CITES can be seen in the different not harmonized reporting cycles, the lack of a contained and centralized database system and differences in the reporting format.<sup>397</sup> From this it can be inferred that a future reporting system under an international ABS regime should pay particular attention to harmonizing reporting requirements and possibly even reporting formats

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<sup>390</sup> Ibid.

<sup>391</sup> These include Resolution Conf 11.17, Decisions 9.31, 12.87, 11.37/11.89 and Notifications 2004/012, 2003/084 and 2002/022.

<sup>392</sup> The UNEP-World Conservation Monitoring Centre in Cambridge, UK, is commissioned by the CITES secretariat with maintaining a database on CITES permits issued.

<sup>393</sup> Caldwell 2004.

<sup>394</sup> Compare for the different purposes: UNEP-WCMC 2004b, p. 153.

<sup>395</sup> Young 2004, p. 53.

<sup>396</sup> Jelden 2004.

<sup>397</sup> Francois 2004, p. 71.

to achieve important synergies between CITES and a new regime. Benefits could include more rapid and accurate reporting and a better use of national capacities and financial resources in this field.<sup>398</sup>

#### 6.5.2.4 Enforcement and compliance

Enforcement and compliance have been pointed to as strategic competences of CITES, of which the CBD could profit.<sup>399</sup> This holds true especially for a new international regime on access and benefit-sharing. So far, little experience with enforcement and compliance issues exists in the CBD framework. An ABS regime will only be effective if it is properly enforced and if compliance with it is well monitored. Thus, a sharing of experiences from the CITES context should take place, when drawing up and implementing enforcement and compliance provisions of an international ABS regime.

#### 6.5.2.5 Costs for national administrations

The costs of introducing a system of certificates of legal provenance for national administrations is currently difficult to estimate. Comparing them to the costs under the CITES system is equally difficult, because the costs of the introduction of the CITES permit system are not being discussed internationally.<sup>400</sup> Generally, there are two possibilities for determining the fees for issuing permits for the national administration. They can either be based on the value of the goods imported/exported or based on the costs of the administration. The latter possibility was chosen by the German administration, which precisely calculated the costs for personnel (based on differentiated salaries for scientists etc.) and averaged them.<sup>401</sup> These calculations represent average costs compared to other EU countries. This form of calculation is easier for the importers to handle. Other countries, such as the Scandinavian countries use high fees also in order to limit trade in CITES-species. Currently, the fees for issuing permits cover the costs of the administration. Different models are used by the German states (Länder), which partly use value-based fees. Since there are many possible synergies with the CITES system, costs for tracking the flow of genetic resources by using certificates might be limited. However, additional initial costs such as the necessary training of customs personnel, additional software necessary for the monitoring and exchange of information etc. would inevitably accrue.

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<sup>398</sup> Ibid. See also the recommendations in UNEP-WCMC 2004b, p. 167-168.

<sup>399</sup> Lehmann 2004.

<sup>400</sup> Jelden 2004.

<sup>401</sup> The costs of CITES permits for importers and exports in Germany can be found under <http://www.bfn.de/04/0402.htm>.

### 6.5.2.6 Conclusions

Overall, it seems that CITES and a future ABS regime have a broad range of connections and possible synergies. However, the differences between the two should not be overlooked. The most important point for an ABS regime is to profit from the experience made within the framework of CITES with a functioning permitting system. This concerns among other things the information that should be contained in a certificate of legal provenance,<sup>402</sup> its form, as well as enforcement and monitoring. Especially with regard to the international reporting and database system, installing new structures would clearly mean a duplication of existing arrangements. In addition, existing systems such as IPEN for the botanical gardens should be integrated.

### 6.5.3 Key points regarding form and practicality

To sum up the above analysis, a number of points regarding the form and practicality of a certificate of legal provenance seem important. An international standardized form for a certificate of legal provenance should be developed. Like in the case of permits issued in CITES, certificates within an ABS system should be designed in a way that discourages fraud with the use of security paper, embossed seals and registered signatures. At the same time, it should be simple and easy to manage. In order to ascertain that the flow of genetic resources can be monitored effectively, such a system should specify the allowed use of the resource. Certificates of legal provenance should be monitored. A system of CLPs would also facilitate increasing security by allowing user countries at the point of entry into the country and other pertinent moments to check whether the certificate of legal provenance is a valid original document issued by the authorized body in the provider country.

## 6.6 Legal implications of a certificate of origin/source/ legal provenance

A certificate of legal provenance could be integrated into legally mandated processes relating to international transport of genetic materials, IPRs and controls on marketing and commercialization, so that users have a strong incentive to comply with these mechanisms.<sup>403</sup> A certificate will only be effective, if both user and provider states integrate it into their legal systems.

Depending on the different frameworks in which a certificate can be used, different legal implications result. Possible conflicts can arise on the national level, under European law and with international law. Besides possible conflicts – which should not be at the center of the debate as has been pointed out recently<sup>404</sup> – there also exist a multitude of other areas of

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<sup>402</sup> See Annex I for the proposed elements of a certificate of legal provenance.

<sup>403</sup> IUCN 2004b, p. 16.

<sup>404</sup> Statement of Heike Baumüller, ICTSD, Roundtable on the Practicality, Feasibility, and Cost of Certificates of Origin, Paris, UNESCO, 9-10 November 2004.

interaction with international law, e.g. with the United Nations Convention on the Law of the Sea (UNCLOS) and the Cartagena Protocol,<sup>405</sup> which will not be explored further here.

### 6.6.1 International law

A certificate of legal provenance can conflict with rules of international law depending on the different uses made.

#### 6.6.1.1 Import and export restrictions

Import and export regulations making use of a certificate of legal provenance could conflict with international trade law. A certificate could be used to control the import of genetic resources at border controls. This implies that genetic resources that are not accompanied by a certificate of legal provenance would be banned from being exported/imported. Such an export/import ban could infringe upon Art. III:4 of the General Agreement on Tariffs and Trade (GATT).

That would be the case if the import ban means that the genetic resources are accorded a treatment less favorable than national “like-products” in respect of laws, regulations and requirements affecting their internal sale. Art. III:4 GATT intends to forbid unequal treatment of imported products as compared to national products. This is also made clear by Note *Ad Article III* GATT, which explains that internal taxes, charges, regulations and laws, which apply to an imported product but are collected or enforced at the time or point of importation, shall be regarded as internal tax or charge. Pure import restrictions are covered by Art. XI GATT. The requirement to represent a certificate of legal provenance at the point of import would not be an internal regulation of genetic resources but a pure import restriction. Thus, not Art. III:4 GATT but Art. XI:1 GATT would be relevant to the import ban.

#### *Infringement of Art. XI:1 GATT (prohibition of quantitative restrictions)*

Art. XI:1 GATT aims at eliminating quantitative restrictions. It states that no prohibitions or restrictions other than duties, taxes or other charges shall be instituted by a Party to the GATT on the importation of any product. In addition, a ban of the import of genetic resources, because no certificate of legal provenance was presented at the point of import could infringe upon Art. I:1 GATT.

#### *Infringement of Art. I:1 GATT (most favored nation clause)*

Art. I:1 GATT is the so-called most-favored-nation-clause. It provides that regarding all duties, charges, rules and formalities in connection with importation and exportation any advantage granted to one party to the GATT has to be accorded to the like products of all other parties. If a certificate of legal provenance is demanded for genetic resources at the point of import, genetic resources for which the importer does not possess a certificate of

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<sup>405</sup> Compare Young 2004c, p. 279.

legal provenance would be treated differently than the genetic resources possessing a CLP. This would be prohibited under Art. XI:1 GATT, if genetic resources of legal provenance would be “like” genetic resources of non-legal provenance. The likeness of products has to be determined by their properties, end-uses, consumer tastes and tariff classification.<sup>406</sup> The origin of the product as well as environmental, social and other impacts of “products” are not taken into account, because they are considered to be not related to the product as such.

*Justification of export/import restrictions under Art. XX (b) GATT*

An import ban, which would violate Art. XI:1 and I:1 GATT could be justified under Art. XX GATT. Art. XX (b) GATT provides an exception for measures that are necessary to protect human, animal or plant life or health. The application of Art. XX GATT to an import ban for genetic resources that are not accompanied by a CLP is questionable on several accounts. First, the import and export restrictions are “extraterritorial” from the point of view of the import country. The restrictions are applied due to concerns over genetic resources in the exporting states. Impacts are not perceived in the import state. The Tuna/Dolphin I Panel rejected the application of the exception of Art. XX GATT to extra-jurisdictional cases. Later on in the Shrimp/Turtle case, the Appellate Body held that there was sufficient nexus between the migratory sea turtles and the US territory.<sup>407</sup> Genetic resources are not migratory, therefore it is uncertain whether the decision would also apply to an import ban under an international system of certificates of legal provenance. The ruling of the Appellate Body has been criticized because of the global nature of environmental problems, which should allow the protection of goods that are endangered globally if not domestically. Second, it is questionable whether the requirement to present a CLP in order to be allowed to import genetic resources would be necessary to protect animal or plant life or health. It could be argued that a certificate of legal provenance intends to ensure that national ABS regulations are enforced, that genetic resources will be protected from perceived “bio-piracy” and that a fair and equitable sharing of the benefits of the commercialization of genetic resources takes place. However, it is disputed whether this contributes directly to the protection of biodiversity. However, it contributes at least indirectly, by means of possible support of those, who are the custodians of biodiversity and by levying funds for biodiversity protection. But the primary goal of a system of CLPs would not be the protection of animal and plant health. Third, a measure has to be *necessary* to protect animal or plant life or health. Here, the “least-trade-restrictive” standard applies.<sup>408</sup> Following from what has been said concerning the usefulness of a system of certificate of legal provenance for the protection of animal and plant life and health, it seems rather questionable whether the provision can be deemed “necessary”. However, the Korea Beef and the Asbestos cases intro-

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<sup>406</sup> Working Party Report, Border Tax Adjustments, 2 December 1970, BISD 18S/97.

<sup>407</sup> Report of the Appellate Body, United States, Import Prohibition of Certain Shrimp and Shrimp Products, AB-2001-4 (Shrimp-Turtle II) at para. 133.

<sup>408</sup> Report of the Appellate Body, Korea –Measures affecting imports of fresh, chilled and frozen beef, AB 2000-8 (Korea Beef) at para. 166.

duced a public interest element into the “necessity” test, which could lead to finding export bans to be justified under Art. XX (b) GATT.<sup>409</sup>

#### *Justification of import/export restrictions under Art. XX (g) GATT*

Similar considerations relate to an exception under Art. XX (g) GATT, which allows measures relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production and consumption. While restriction on domestic production could result from a CLP system, which applies to the use of genetic resources in other contexts (such as patent applications, food and drug applications etc.), it is not obvious that the restriction relates to the conservation of the exhaustible natural resource, i.e., genetic resources, or rather to the use of the resource.

#### *Chapeau of Art. XX GATT*

Under the umbrella of Art. XX GATT, measures can be exempted if they are not “applied in manner which would constitute a means of arbitrary or unjustifiable discrimination between countries” or a “disguised restriction on international trade”. In the Shrimp Appellate Body decision, the Body held that multilateral action to tackle an environmental problem was preferable.<sup>410</sup> It can therefore be argued that a trade measure that is applied in the framework of an international ABS regime could not represent a means of arbitrary or unjustifiable discrimination. Accordingly, trade restrictions (i.e. import and export restrictions or bans) based on a lacking certificate of legal provenance would be justified under Art. XX GATT.

In the last ten years, an extensive discussion on possible conflicts between multilateral environmental agreements (MEAs) and the WTO has taken place. Recently, it has been stated that the likelihood of a conflict between WTO and MEA rules is increasing.<sup>411</sup> At the same time, declarations of the mutual backing of trade and environmental agreements receive broad assent. Paragraph 31 of the Doha Mandate provides that with a view to enhancing the mutual support of trade and environment, negotiations on the relationship between WTO rules and trade obligations in MEAs are agreed on.<sup>412</sup> It remains to be seen whether these will result in a solution that rules out that an MEA trade provision can be found to violate WTO rules. Up until such an agreement is made on the international level, it remains possible although highly improbable that a WTO dispute settlement body would find a trade provision under an MEA to infringe upon the GATT.

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<sup>409</sup> Report of the Appellate Body, Korea –Measures affecting imports of fresh, chilled and frozen beef, AB 2000-8 (Korea Beef) at 162. Report of the Appellate Body, European Communities – Measures affecting asbestos and asbestos containing products, AB 2000-11 (Asbestos) at 172.

<sup>410</sup> Report of the Appellate Body, United States, Import Prohibition of Certain Shrimp and Shrimp Products, AB-2001-4 (Shrimp-Turtle II) at para. 120-125.

<sup>411</sup> Tarasofsky 2004, p. 2.

<sup>412</sup> Doha WTO Ministerial Declaration, WT/MIN(01)/DEC/1.

#### 6.6.1.2 Transport regulations

Transport regulations, such as a provision that requires a certificate of legal provenance to be attached to genetic resources when these are transported would be covered by the WTO Agreement on Technical Barriers to Trade (TBT Agreement). According to Art. 2.2 of the TBT Agreement technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, while taking into account the risks non-fulfillment would create. Furthermore Art. 2.5 TBT Agreement provides that that where a technical regulation is adopted for a legitimate objective, and is in accordance with international standards, it shall be refutably presumed not to create an unnecessary obstacle to international trade. A regulation of the transport of genetic resources under an international regime using certificates of legal provenance would therefore not infringe upon the TBT Agreement.

#### 6.6.1.3 Registration of the use of genetic resources

The registration of the commercial use of genetic resources would be neutral with regard to international trade law, as long as imported products (i.e. genetic resources) would be accorded the kind of treatment no less favorable than that which is accorded to like products of national origin (Art III:4 GATT).

#### 6.6.1.4 Patent law

For the most part, the use of certificate of legal provenance is discussed in relation to disclosure requirements under patent law. Here, conflicts with international patent law and WTO law, namely the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) as well as the Patent Cooperation Treaty are being debated. Especially the question of the compatibility of a mandatory disclosure requirement in patent law, which could lead to a rejection of nullification of the patent right, is disputed. This question was not to be explored further in this study.

While many claim that a disclosure requirement regarding the origin/legal provenance of genetic resources would not infringe upon the TRIPS agreement, in addition concrete proposals have been brought forward that aim at harmonizing possible conflicts between international IPR law and a disclosure requirement.<sup>413</sup> Both a revision of the Patent Cooperation Treaty as well as a revision of the TRIPS agreement have been put forward.

### 6.6.2 European law

Conflicts could potential arise between a certificate of origin and rules of European law (again depending on the different uses made). The CBD has been ratified both by the Euro-

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<sup>413</sup> WIPO, Proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications, PCT/R/WG/4/13, 2003.

pean Community and its Member States. Council Decision 93/626/EEC on the approval by the European Economic Community of the CBD<sup>414</sup> refers to Art. 174 of the Treaty of the European Community (ECT),<sup>415</sup> which confers upon the community the competence to conclude international agreements within the sphere of environmental cooperation in accordance with the procedures of Art. 300 ECT.<sup>416</sup> Art. 300 ECT provides that agreements concluded under the conditions of that Article shall be binding on the institutions of the Community and on Member States.

Annex B to Council Decision 93/626/EEC contains a Declaration by the European Community on the competence of the Community alongside its Members States. It does not declare the extent of the competences as required by Art. 34 para. 3 of the CBD, but does explain Community competence by referring to relevant legal instruments adopted by the Community. It would thus seem that, barring a clear-cut division of competences, the Community must be presumed to have competence in areas in which it has adopted regulations or directives. It can furthermore be presumed that in areas in which the Community has adopted a regulation or directive, the provisions of the CBD covered by that legal instrument must be considered to be included in the part of the Agreement that is binding on the Community and its Member States by virtue of Art. Art. 300 of the Treaty of the European Community.<sup>417</sup>

The Community has the exclusive competence to regulate issues in a number of areas, which include trade, agriculture and fisheries. It has issued a number of regulations in fields which would be covered by the certificate of legal provenance, e.g. Council Regulation 1467/94 on conservation, characterization, collection and utilization of genetic resources.<sup>418</sup> Thus, it can be concluded that the EC has the competence to regulate a certificate of legal provenance, because it has already adopted regulations in this field; however, the possible regulation has to meet the requirements of the Treaty especially the fundamental freedoms as well as not infringe upon the principle of subsidiarity.

The legal competences the EC has to regulate in this field can be determined depending on how the instrument certificate of origin is classified.

The purpose of a certificate of origin is to introduce an international system documenting the flow of genetic resources by using certificates. The overall goal of a standardized system is envisioned to “in short, harmonise procedures for identifying the existence of PIC; protect the confidentiality of contracts; reduce transaction costs; facilitate tracking of gene flows; promote increased trade in genetic resources; and provide an incentive for countries of origin to develop more flexible ABS rules and procedures.”<sup>419</sup> The overall objectives, however, of an access and benefit sharing regime under the Convention on Biological Di-

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<sup>414</sup> Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity, OJ L 309/1, 13.12.1993.

<sup>415</sup> Formerly Art. 130R of the Treaty of Rome.

<sup>416</sup> Formerly Art. 228 of the Treaty of Rome.

<sup>417</sup> Hans W. Longva, 1999, chapter 4.

<sup>418</sup> Council Regulation (EC) No 1467/94 of 20 June 1994 on the conservation, characterization, collection and utilization of genetic resources in agriculture OJ L 159/1, 28/06/1994.

<sup>419</sup> Barber/Johnston/Tobin 2003, p. 38.

versity are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Art. 1 of the Convention).

Thus, a certificate of origin as an instrument of the access and benefit sharing regime predominantly affects environmental jurisdiction but as a by-product could also affect trade jurisdiction when used in connection with export and import activities.

An examination of the provisions of the Treaty dealing with trade and environmental protection shows that the Community has exclusive competence to regulate in the field of external trade with third countries and international organizations (Art. 133 ECT) but concurrent competence to regulate in the field of environmental protection (Art. 175 ECT).

According to the European Court of Justice, Article 133 ECT is relevant if the intention and purpose of the Treaty is exclusively external trade, otherwise Art. 133 ECT cannot be the legal basis of the Treaty. As an environmental provision, Art. 175 provides for an additional competence of the European Community but does not explicitly touch upon the competence of the Member States to act in this field (Art. 174 ECT). Art. 175 does not provide for harmonization of national laws. Evidently, Art. 175 is not a provision to harmonize national law, but an independent competence of the Community to establish minimum standards. This position is supported by the fact that Art. 176 clearly permits Member States to enact higher standards than those adopted by the Community, so long as those standards are consistent with the EC Treaty, notably Art. 28, 30, and 95.

Since the intention and purpose of the certificate of legal provenance is not external trade alone but environmental issues, Art. 133 ECT cannot serve as a legal basis. Therefore, a treaty would have to be based on other articles of the ECT or if the European Community has no competence in the field of regulation, the agreement has to be signed together with the Member States as a so-called “mixed agreement”.

Under Art. 176 ECT protective measures adopted pursuant to Article 175 shall not prevent any Member State from maintaining or introducing more stringent protective measures, provided that such measures are compatible with the Treaty and that they are notified to the Commission.

Thus, there are two possible options with regard to the adoption of an international ABS regime by the Member States. Either the Community itself ratifies the regime. In that case, the Member States would not be able to act individually. If the Community does not ratify the regime and as a consequence does not implement the ABS provisions by means of Community regulations, the Member States would be able to adopt implementing provisions themselves under Art. 176 ECT as more stringent protective measures for the protection of biodiversity. However, these measures would have to be compatible with the EC Treaty.

### 6.6.2.1 Import and export restrictions

Import and export restrictions with the use of a CLP could conflict with the EC Treaty provisions on the free movement of goods and services.

*Art. 28 EC-Treaty: Free movement of goods- prohibition of quantitative restrictions between Member States*

A certificate of legal provenance could be used as an import and export regulation and thus conflict with the prohibition of quantitative restrictions between Member States under Art. 28 ECT. Art. 28 of the ECT prohibits quantitative restrictions on imports and all measures having equivalent effect between Member States. Art. 29 ECT forbids quantitative restrictions on exports, and all measures having equivalent effect between Member States. Art. 30 ECT provides for exceptions, stating that the provisions of Art. 28 and 29 ECT shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. A certificate of legal provenance cannot be considered a quantitative restriction on import, because it does not set quotas for the import of genetic resources. But it could be seen as a measure with equivalent effect. The European Court of Justice (ECJ) has defined measures with equivalent effect in the Dassonville case as all trading rules enacted by Member States, which are capable of hindering, directly or indirectly, actually, or potentially, intra-community trade.<sup>420</sup>

This so-called Dassonville formula applied to the certificate of legal provenance shows that the certificate would be a measure with equivalent effect to quantitative restriction on intra-community trade if applied by the Member States individually. The certificate has to be presented when a product is being exported or imported. This way it can hinder or delay the border crossing of a product and can bring about further costs. The measure with equivalent effect can, however, be justified according to the Cassis de Dijon formula<sup>421</sup> if it applies in a general manner to the production and marketing of given products and if it is necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defense of the consumer.<sup>422</sup> The protection of the environment is also such a necessary requirement.<sup>423</sup>

Since the certificate of legal provenance can be seen as an instrument of environmental protection, it would be justified under the Cassis de Dijon formula since it would apply to all genetic resources in a general manner.

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<sup>420</sup> Judgment of the Court of 11 July 1974. Procureur du Roi v Benoît and Gustave Dassonville, Case 8-74; text can be found : [http://www.europa.eu.int/eur-lex/en/search/search\\_case.html](http://www.europa.eu.int/eur-lex/en/search/search_case.html).

<sup>421</sup> Judgment of the Court of 20 February 1979, Case 120/78, ECR 79/649.

<sup>422</sup> Judgment of the Court of 20 September 1988, Case 302/86, ECR 88/4607.

<sup>423</sup> Ibid.

The registration of the commercial use of genetic resources would also not infringe upon the Treaty, as long as imported products would be accorded a treatment no less favorable than that accorded to like products of national origin.

Accordingly, a violation of Art. 28 of the Treaty by means of the certificate cannot be found as long as the measure is proportional, which is the case with the certificate of legal provenance. This can be seen as a legitimate objective in achieving its proposed aim of safeguarding biological diversity. In addition, the adequateness cannot be questioned, because a milder, equally effective measure is not perceivable.

*Art. 49 ECT: Free movement of persons, services and capital*

A certificate of legal provenance could also affect the freedom of services guaranteed by Art. 49-55 of the ECT. A certificate could be a hindrance to the transportation business. However, transport services are exempted from the freedom of services, as clarified by Art. 70 et. seqq. of the Treaty. According to Art. 77, charges or dues may be levied at the border crossing but shall not exceed a reasonable level after taking into account the costs actually incurred thereby. A regulation concerning the certificate that obeys these norms, therefore, does not infringe upon the Treaty.

In sum, the introduction of a certificate of legal provenance would not infringe on European law.

### 6.6.3 German law

To exemplify legal issues that can come up under national law, a number of legal questions with regard to German law will be discussed here. Though there are no specific national laws in Germany which run counter to the introduction of the certificate of legal provenance,<sup>424</sup> the legal obligation to possess this certificate for the research into, the trade with or the commercialization of genetic resources is not unproblematic. The obligation may infringe upon the basic rights of the actors. Conflicts are possible with Art. 5 III, 1, 12 I, 14 and 3 I of the German Constitution.<sup>425</sup>

Art. 5 III, 1 of the Constitution guarantees the freedom of science and research. Introducing a certificate of origin as a prerequisite for scientists and researchers working with genetic resources acts as a restriction to Art. 5 III, 1 of the Constitution, because the work is only permissible if documents are presented. Art. 5 III, 1 of the Constitution provides a basic right that does not contain written possibilities for its limitations. But nevertheless, limitations are possible for the protection of rights that are mentioned in the Constitution. All basic rights have limitations. Taking into account this aspect, Art. 5 III, 1 of the Constitution GG can be restricted for the purpose of the protection of the environment, Art. 20 a of

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<sup>424</sup> Part 6 of the Law of the Protection of Trademarks and other Denominations („Gesetz über den Schutz von Marken und sonstigen Kennzeichnungen“) is not relevant. It refers to the protection of the geographical origin of a product as a trademark.

<sup>425</sup> Grundgesetz für die Bundesrepublik Deutschland of 23.05.1949.

the Constitution. The introduction of the legal obligation of presenting a certificate of origin before researching into genetic resources, has as an aim, *inter alia*, the conservation of the biodiversity and the protection of the environment, as protected by Art. 20a of the Constitution. The duty of obtaining a certificate of origin contributes to the protection of the environment, because it hinders the reckless exploitation of biodiversity.

Art. 12 GG (freedom of occupation) could possibly be violated, because the merchant of products consisting of genetic resources has to obtain the certificate of origin before commercialization could occur. In this case, commercialization would be restricted. The obligation to possess a certificate of origin would also affect the business of an importer of genetic resources. Completing the importation would depend on the presentation of the certificate of origin. Regarding Art. 12 GG, it is important to mention that if a company has to be registered before carrying out research activities, trade secrets may be disclosed. As a minimum, the registration office has information about the field in which the company is looking for new research results.

All these intrusions into the freedom of Art. 12 I GG describe a so-called barrier to the exercise of a profession:<sup>426</sup> It does not affect the choice of an occupation, but regulates the conditions of a specific job (in this case: merchant, importer, researcher). According to the adjudication of the German Constitutional Court, a legal infringement on this level is justified if reasonable arguments demand this course of action for the public welfare.<sup>427</sup> An infringement of Art. 12 I GG on this level can be justified easily. Taking into account this adjudication, the obligation to present the certificate of origin before doing a specific job is justified. This legal obligation would be introduced to assure the fair and equitable sharing of benefits arising from the use of genetic resources, which ultimately leads to the conservation of biodiversity and the environment. This aim contributes to the public welfare. The certificate of origin would be an appropriate and necessary means of reaching this aim, because there is no alternative that is as effective but less restricting. An intrusion in the form of a barrier to the exercise of a profession is an intrusion on the less restricting level possible. The prerequisite of a certificate of origin would also be proportional.

If a certificate of origin is necessary for obtaining permission to import products consisting of genetic resources, Art. 14 GG must be regarded: Art. 14 GG protects the property. Its protection includes the freedom to decide what to do with objects owned by a person. It covers the property in its existing dimensions, but not expectations or chances connected with the property. Taking into account the scope of Art. 14 GG, import restrictions imposed on products, which are part of someone's property, are infringements on Art. 14 GG in the form of a so-called restriction of the content and a definition of the limits of the right (Art. 14 I, 2 GG).<sup>428</sup> They do not withdraw concrete positions of property (expropriation), but define in an abstract way the content and limitations of property. If a certificate of origin were just a prerequisite for commercialization, the scope of Art. 14 GG would not be

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<sup>426</sup> In German: *Berufsausübungsschranke*.

<sup>427</sup> In German: *vernünftige Gründe des Allgemeinwohls*.

<sup>428</sup> In German: *Inhalts- und Schrankenbestimmung*.

ouched, because the commercialization is part of the expectations connected with property. It would not limit the property in its existing dimension.

Intrusions in the form of an “Inhalts- und Schrankenbestimmung” are justified when they are based on a law and when they are appropriate, necessary and proportional. A legal obligation to present a certificate of origin before importing genetic resources contributes to the protection of biodiversity and the environment and to the fair and equitable sharing of benefits. There is no alternative that is less restricting but as effective as the introduction of the certificate of origin. The obligation to have a certificate of origin for importing genetic resources is an infringement of Art. 14 GG, which does not have a serious affect on the protection of property. The import can still be made. The owner just has to obtain a document. According to Art. 14 II, 1 GG, the proprietary must respect the needs of the general public.

When a certificate of origin is required for importing genetic resources, the research and commercialization, another conflict with basic rights, can emerge: Art. 3 I GG may be infringed upon, because only actors with genetic resources are obliged to obtain the certificate of origin. Importers and researchers of other products are relieved of this duty. This may run counter to the principle of equal treatment of Art. 3 GG. However, Art. 3 GG does not demand equal treatment of everybody and everything, but only of equal persons and things. Different things can be handled in different ways. Products consisting of genetic resources differ from products that do not contain genetic resources. Therefore, it is not improper with regard to Art. 3 GG to demand a certificate of origin only of these actors who deal with genetic resources.

In sum, the introduction of a certificate of legal provenance would not infringe upon German law.

## **6.7 A possible model of a system of certificates of legal provenance**

As explained supra, certificates of legal provenance would be the preferable solution for a certificate to prove that ABS legislation has been observed. The certificate of legal provenance could be used in a number of frameworks, such as the application for a patent, for the export and import of genetic resources etc. A system of CLPs could thus provide an overall framework for tracking the resources, thereby preventing their use without the observance of the CBD and national/regional ABS legislation. A multilateral approach to the issue would have the advantage of providing a comprehensive system as opposed to a number of bilateral or unilateral measures.

The EC has already declared its willingness to contribute to finding a multilateral approach to the issue of disclosure in patent law. As the EC pointed out, multilateral action would be more effective as disclosure requirements would better achieve their purpose if implemented widely.<sup>429</sup> This does not only apply to patent applications but to all measures, which could make use of a certificate of legal provenance.

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<sup>429</sup> COM(2003) 821, p. 17.

Switzerland indicated an important point for disclosure requirement in patent law: If the source of a genetic resource or knowledge, innovations and practices, is merely declared in patent applications, states and other stakeholders interested in verifying whether they are named in patent applications would have to scrutinize the large number of patent applications filed annually worldwide.<sup>430</sup> Additionally, some patent offices do not publish patent applications at all or only after the expiration of a certain period of time; furthermore, it may take several years from the filing of a patent application to the granting of the patent and its publication. Thus, if patent applications are not published, the declaration of the source would not become publicly accessible until the patent is granted and published.<sup>431</sup> This issue could also be addressed by a multilateral approach with a focus on the monitoring of the genetic resources.

For a multilateral system to function, user countries would have to introduce legislation, which makes certain acts dependant on the presentation of a certificate of legal provenance. This would be foremost the widely discussed disclosure of legal provenance in patent application. It might prove equally effective to require a certificate of legal provenance in applications for permits by the food and drug administration, and in order to receive funds for R&D.

Practical problems, which are not only relevant for patent applications but also for other proposed measures, could thus be overcome by a system to document the flow of genetic resources through certificates, which we will call the CLP system hereinafter and outline below. To sum up the analysis *supra*, a system of certificates of legal provenance would make use of different existing frameworks such as border controls, patent law, R&D funding etc.

An important feature of the CLP system could be to cover *ex-situ* collections. This would be important in two ways: First, it would close possible loopholes in the system. Second, it would make the functioning of the system more effective, if all transferred material would be accompanied by a certificate. Of course, this would have to be introduced either by user countries or on a voluntary basis by the institutions involved. It would not be necessary to declare the origin of the resource, but sufficient to declare that the material was acquired legally. To foster scientific research, *ex-situ* collection, botanical gardens and universities should be covered by a simplified procedure. Like in the CITES system, they could receive a general, annual permit for scientific use only. Like in the CITES system, this certificate would apply to all resources used by the scientific institution. The origin of the resource would be documented, so if the institution intends to transfer it for commercial use, the country of origin would then have to issue a certificate of legal provenance after negotiating a MTA.

A system to track the flow of genetic resources was first proposed by *Tobin*.<sup>432</sup> A possible CLP model makes use of both national focal points in all states and the CBD clearing house mechanisms. The clearing house mechanisms of the CBD would be in charge of monitoring

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<sup>430</sup> PCT/R/WG/4/13, p. 13 (Submission by Switzerland).

<sup>431</sup> *Ibid.*

<sup>432</sup> Barber/Tobin/Johnston 2003, p. 38.

all certificates of legal provenance (a task that could be delegated from a practical point of view to the WCMC in Cambridge, which is also in charge of monitoring CITES). Under the international ABS regime, all states then would have to designate National Focal Points (as also required by the Bonn Guidelines). When a certificate is issued by a provider state, its National Focal Point is obliged to notify the Clearing House Mechanism (i.e. the WCMC) of the certificate. The monitoring centre maintains a database of certificates of legal provenance, which can be accessed by national authorities, such as patent offices, border authorities, the food and drug administration etc. At the same time, as proposed by Switzerland, the national authorities, especially patent offices will notify the WCMC when they receive an application for a patent based on or making use of genetic resources. This is documented in a second database, which is accessible by the National Focal Points. Whenever the monitoring centre receives a notification by a national authority that a certificate of legal provenance has been used, it informs the National Focal Point of the provider states, which issued the certificate. Thereby, the flow of genetic resources can be tracked.

However, such a system would be dependant on the adoption of national legislation in both provider and user countries. Provider countries would have to introduce certificates of legal provenance. It is noteworthy that they would not have to introduce ABS legislation, which is not intended by all provider countries. Rather, they would have to be able to certify that the genetic resource was acquired by the user legally. That could also mean that there were no specific legal requirements for obtaining the resource, except to receive a certificate. This step is necessary in order to prevent loopholes.

With regard to the general requirement that no new structures and funds shall be needed, the CLP system would be mostly built on existing institutions, i.e. National Focal Points, the Clearing House Mechanism of the CBD and national authorities such as patent offices, border authorities etc. However, some additional resource would be necessary, especially in order to enable the monitoring centre to execute the functions foreseen by the CLP system under an international regime. Especially installing and maintaining an additional database to track certificates of legal provenance would require additional financial means.

The CLP system has the following advantages:

- *Improving compliance.* A CLP system provides aims to stop the import and export of genetic resources that was not acquired in compliance with the CBD and ABS legislation. By an international system of CLP, user countries could contribute to the implementation of the CBD's access and benefit-sharing provisions and the compliance with national/regional ABS legislation.
- *Monitoring.* Through tracking the flow of genetic resources, their use could be monitored with the aim of ensuring the compliance with ABS laws. Even when the users do to not present the certificate of legal provenance at all points that national legislation requires them to, it can be deduced from later points, e.g. from the application for a patent it could be inferred that the genetic resource has been imported into that country at an earlier time.
- *Transparency.* It would provide both user and provider countries with information on the use of genetic resources, thereby contributing to transparency and trust build-

ing. In addition, it would allow an international overview of cases of ABS, and thereby contribute to more realistic expectations regarding benefits, while making clear the obligations of users.

- *Foster scientific use.* The simplified certificate procedure would allow scientific research to be excluded from the time-consuming and burdensome procedures that often exist for scientific as for commercial uses, thereby fostering research.

From a practical point of view, some drawbacks of this system have to be pointed out, which of course only represent a theoretical model:

- *Coverage.* In order for the system to function effectively, *all* important provider and user states would have to become Parties to the international ABS regime, which seems unrealistic. This is even more so, because only genetic resources acquired after the entry into force of an international ABS system would be covered. Considerable loopholes could result from the fact that probable non-Parties to the future regime are important intermediaries. “Back-dating” of genetic resources might occur.
- *Cost of implementation.* All user states would have to adopt stringent legislation in regard to the use of genetic resources, which could meet with their considerable resistance, especially due to perceived increased costs of scientific and/or commercial use of genetic resources. Even if, as predicted in chapter 7.7, costs would in fact be moderate for companies, political resistance might be considerable. At the same time, means to finance the monitoring mechanisms would have to be provided by the Parties of the international ABS regime.
- *Streamlined procedures are necessary.* By the same token, all provider states would have to adopt streamlined comprehensive ABS procedures that allow the issuing certificates of legal provenance without major bureaucratic burdens for the users.
- *Integration of international institutions is difficult.* It has been pointed out that a coordinated approach for the worldwide traceability of genetic resources is a difficult task, especially because it requires global agreement and acceptance of a highly integrated institutional and administrative system.<sup>433</sup> As has been pointed out even by the proponents of a system of CLPs, a main problem at international level will be development of clear concepts and definitions, which allows to institute a functioning system.<sup>434</sup>
- *Acceptance.* It can be questioned whether the idea of a certificate of legal provenance is really “well recognised and accepted.”<sup>435</sup> At least from the industry and scientific institutions many are not informed on the issue and purpose of a certificate of legal provenance. Considerable resistance can be expected from the economic actors towards such a system.

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<sup>433</sup> Ruiz et al. 2003, p. 5.

<sup>434</sup> Ibid, p. 7-8.

<sup>435</sup> Ibid, p. 7.

- *Benefits for biodiversity.* Finally, the important question whether the benefits of an international ABS regime would contribute to the *in-situ* conservation and sustainable use of genetic resources might remain unanswered.

Figure 4 graphically illustrates the described model for a CLP system.

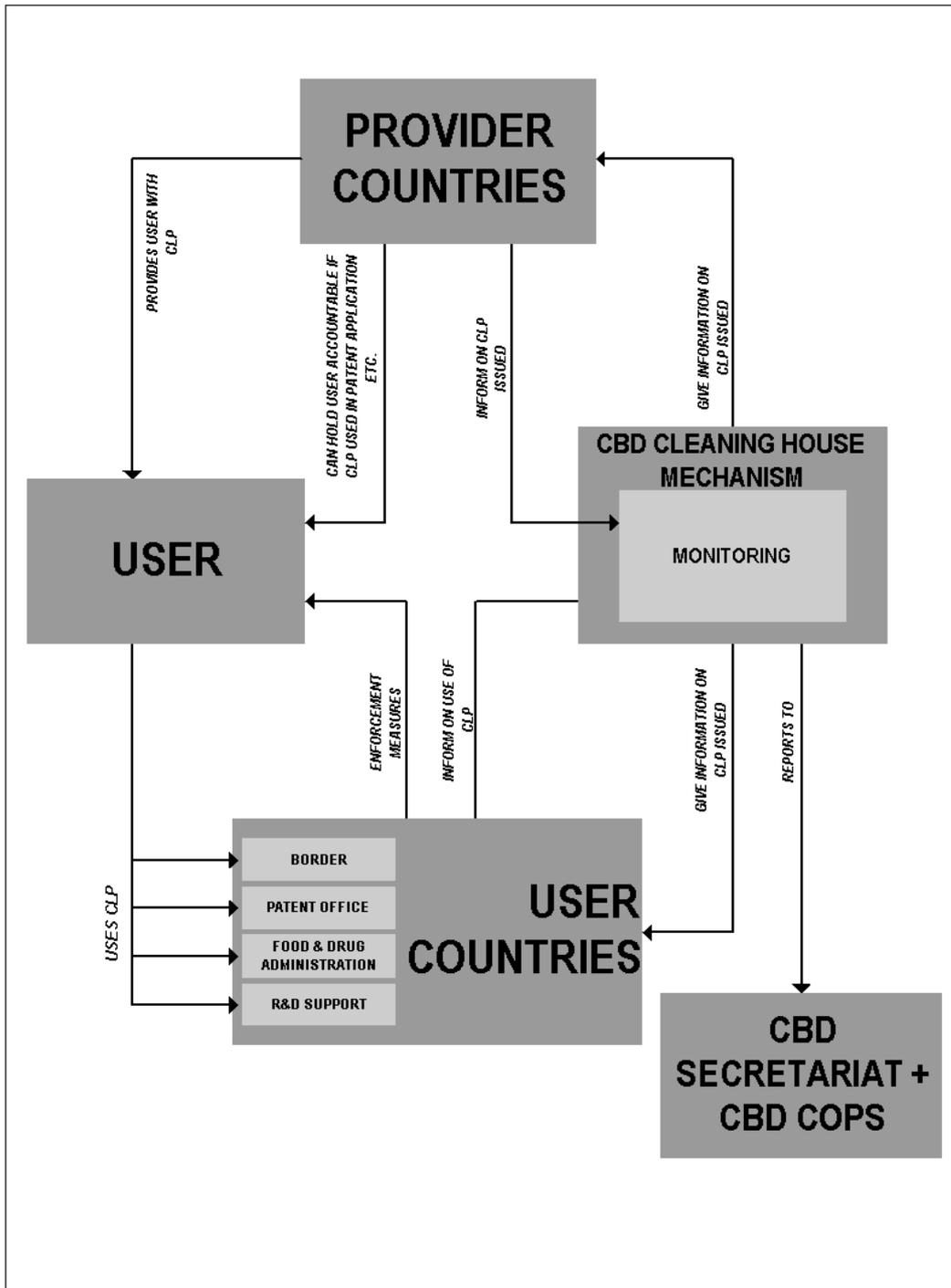


Figure 4: A model for a system of CLPs. Source: Öko-Institut.

## 6.8 Impacts of Certificates of Legal Provenance on economic and research actors

### 6.8.1 Framework of analysis and methodological considerations

The introduction of Certificates of Origin, Source or Legal Provenance can be expected to impact on companies and research institutions that utilize genetic resources, both in positive and negative ways.<sup>436</sup>

In order to analyze the impacts, a clear-cut framework of analysis needs to be established. In the following, we assume that from the pool of certification alternatives, it is Certificates of Legal Provenance that will be introduced (as the model that appears most effective to ensure ABS compliance). We also assume that these will be designed following the model of certificate of legal provenance. Concerning the framework for a CLP system, two of the outlined pillars will be emphasized:

1. Pillar 1 – Import/export regulations, i.e. the introduction of the duty of companies and research institutions to produce CLPs when importing and exporting genetic resources; and
2. Pillar 2 – Patent law, i.e. the introduction of a need to hand in a CLP when applying for a patent. The requirement to disclose the legal provenance of the genetic resource is assumed to be a self-standing requirement.<sup>437</sup> This means that the legal consequences of non-compliance lie outside the realm of patent law.<sup>438</sup>

These two pillars are not mutually exclusive, and in our model they are combined. We also assume that ex-situ collections (botanical gardens, gene banks, culture collections) will be included into the CLP system but will underlie a simplified procedure (cf. chapter 6.6.). As explained above, retroactive application of the certification system can only be introduced either on a voluntary basis or by user countries; it will not be considered here. This means that the submission of a CLP is only necessary for genetic resources acquired after the introduction of the system.

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<sup>436</sup> Specifying the impacts on “German” companies and universities is an exercise has its limits in a globalising context: a big part of formerly “German” companies especially in the pharmaceutical, cosmetics and agrochemicals sector today are part of larger multinational corporations, so that changes in German legislation might actually affect corporate headquarters in the US in the first place. Similarly, German universities are tied into international cooperation and exchange, so that changes in the legal set-up here affect foreign cooperation partners and vice versa.

<sup>437</sup> The self-standing requirement is chosen instead of a free-standing requirement, since the latter does not entail any consequences. This not only makes it a rather weak instrument, but is also creates no significant impacts to be analysed.

<sup>438</sup> The decision not to analyse a model where the legal consequences would lie within patent law, specifically where CLPs would be a formal prerequisite of patentability (cf. chapter 7.3.7.3) is motivated by the assessment that such a model to date seems unlikely. The reasons are the disapproval of major international actors as well as potential norm conflicts with international patent law.

The impacts to be analyzed cover both costs and benefits. The costs and benefits in this case are *transaction* costs and benefits. Transaction costs are costs other than the direct production costs – the costs of transforming inputs like genetic resources into outputs such as medicine, seed, or cosmetics – or transport costs.<sup>439</sup> Transaction costs generally encompass search and information costs, bargaining and decision costs, policing and enforcement costs. Transaction benefits are benefits other than those resulting from the immediate marketing of a product.<sup>440</sup> They cover among others gains of cooperation and exchange, benefits in terms of reputation, (inter-) organizational learning etc.

In the analysis, costs and benefits will in most cases not be monetarized. The impacts surveyed are restricted to those on companies and research institutions; costs and benefits on the national economic and social level are not specified.

### 6.8.2 Technical realisation of analysis

The analysis of impacts draws on literature review, on information gained in expert interviews and own calculations. It is substantiated by data from the user survey conducted by Bonn University in parallel to this study “Users of Genetic Resources in Germany, - Awareness, Participation and Positions regarding the Convention on Biological Diversity“ (in the following: Bonn User Survey).<sup>441</sup> Most of the transaction costs and benefits dealt with will not be monetarised.<sup>442</sup>

The 17 focused expert interviews were conducted with representatives of companies, research institutions, intermediaries, NGO representatives, the German Patent Office, patent lawyers, as well as administrations from countries that have introduced self-standing disclosure requirements in their national patent law. Among the corporate users of genetic resources, comments both from large companies and small and medium-sized enterprises (SMEs) as well as associations from different sectors – health, agriculture/seed, horticulture and cosmetics and other sectors that employ biotechnology – were taken into consideration. The research actors interviewed comprised universities and other state-funded research institutes. Finally, *ex-situ* collections (botanical gardens, gene banks, culture collections) as not-for-profit intermediaries and commercial brokers of genetic resources were approached.

With different foci, the following issues were inquired about in the expert interviews:

- Channels of genetic resource acquisition (direct access in countries of origin vs. acquisition through intermediaries);

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<sup>439</sup> See Ronald Coase (1937), the pioneer of transaction cost economics, still defined transaction costs relatively broadly as “the cost of using the price mechanism”.

<sup>440</sup> See Zajac/Olsen (1993) on the concept of “transactional value analysis”, which includes “transaction benefits” (ibid.: 133).

<sup>441</sup> Holm-Müller/Richerzhagen/Täuber 2005.

<sup>442</sup> Though transaction costs and benefits can in general be measured by adding all items relevant to the transaction, there are both practical limits to conduct it within this study, as well as theoretical limits of transaction cost measurement (Busse 2001: pp. 17). When there is no or no reliable data for individual items, substitute items have to be used, e.g. substituting the working costs of the company’s legal advisor by an average rate. For some transaction costs no data exists, not even useful substitutes, or they cannot be attributed to a specific transaction. When substitutes are employed, statistical errors occur and accumulate.

- Frequency of border crossing (pillar 1) and patent application (pillar 2) when acquiring/using genetic resources;
- Assessment of the impacts of CLPs on the respective corporation, research institution and intermediary. This included an estimation of monetary and non-monetary costs and benefits;
- Evaluation of technical-administrative consequences of self-standing disclosure requirement in patent law for patent offices; comparative estimation of a fine/penalty attached.

Also, knowledge of/familiarity with the discussion on Certificates of Legal Provenance was inquired, in order to get an impression of the public awareness of the instrument.

### 6.8.3 Impacts I: Costs

The following section describes expected negative impacts (costs) as well as expected positive impacts (benefits) linked to the introduction of a CLP system. A system based both on border controls and patent applications (as a self-standing requirement) has three pivots for CLPs:

- the conferral of the CLP when acquiring a genetic resource (either in the country of origin (in situ<sup>443</sup>/via own reproduction<sup>444</sup>), in some other country where the resources are reproduced i.e. cultivated by the user,<sup>445</sup> or via intermediaries inside or outside the country of origin<sup>446</sup>),
- the need to submit the CLP at border controls (pillar 1), and
- the need to submit the CLP at the patent office (pillar 2).

The three pivots are graphically represented in the diagram on the following page.

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<sup>443</sup> Genetic resources are acquired by German users like this in 22% of the cases (shares adapted from Bonn User Survey; multiple entries were possible).

<sup>444</sup> Genetic resources are acquired by German users like this in 4% of the cases (shares adapted from Bonn User Survey; multiple entries were possible).

<sup>445</sup> Genetic resources are acquired by German users like this in 6% of the cases (shares adapted from Bonn User Survey; multiple entries were possible).

<sup>446</sup> Genetic resources are acquired by German users like this in 68% of the cases, with 37% of intermediaries situated in the countries of origin (shares adapted from Bonn User Survey; multiple entries were possible).

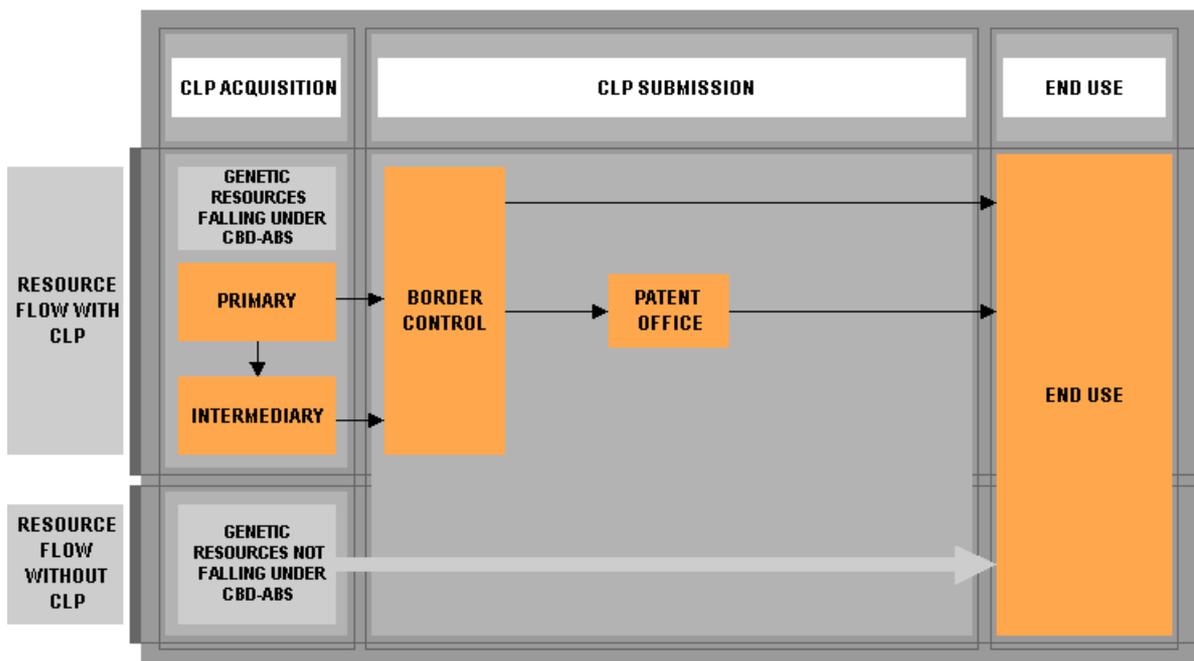


Figure 5: Pivots for CLPs in the genetic resource flow. Source: Öko-Institut.

### 6.8.3.1 Costs attached to the conferral of CLPs

Cost structures vary, depending on whether CLPs are conferred when acquiring a genetic resource under in-situ conditions in the country of origin (primary CLP acquisition) or when acquiring the genetic resource through intermediaries (secondary CLP acquisition).

#### *Primary CLP acquisition*

In the model described above, a Certificate of Legal Provenance (CLP) would be issued by the national authority in the country of origin when the user gains access under the prerequisites of the CBD, respectively under the relevant national access and benefit sharing provisions.<sup>447</sup> The certificate of legal provenance would proof the existence of an ABS agreement. In addition to this ABS agreement, which is required anyway, little additional costs or time would stem from the certificate, provided the provider countries would establish effective institutions. It has to be considered that providers would introduce an administrative fee for the certificate.

It needs to be noted that transaction costs that are caused by the ABS negotiations themselves are not object of discussion here.<sup>448</sup> By the same token, information costs (relating to

<sup>447</sup> The user also needs to conclude an ABS agreement with the Country of Origin when he reproduces a genetic resources outside the Country of Origin.

<sup>448</sup> OECD 2003, p. 26.

national ABS requirements, to the authority responsible for ABS and for the issuing of CLPs) would predominantly be implied by the ABS procedure itself rather than by the CLP system. On the contrary, the introduction of a certificate of legal provenance might contribute to the streamlining of procedures due to the need to identify clearly which government institution is responsible etc., thereby also easing requirements for access permits.

Users that do field collections and enter directly into ABS negotiations are rare especially among German companies; mostly universities and research institutions access genetic resources in situ (see Bonn User Survey). Across the sectors, most actors either receive their material via intermediaries (see below) – this applies especially to small and medium sized companies –, or they use material that does not fall under the CBD (see below). The results of the Bonn User Survey and the expert interviews thus confirm the results of an earlier Swiss government survey,<sup>449</sup> as well as the findings of Ten Kate/Laird of 1999,<sup>450</sup> which found that apart from some cases in the pharmaceutical and plant protection industry, companies are very rarely conducting first-hand bio-prospecting.<sup>451</sup> Among industry users, some codes of conduct on access and benefit sharing exist.

Public ex-situ collections would have to get the CLP along with PIC when acquiring autochthonous in-situ material abroad. Exchange of samples among the collections would underlie the simplified procedure. Material could only be passed on to commercial users after they have taken up ABS negotiations with the country of origin.

#### *Cases where primary access to genetic resources does not necessitate ABS and CLPs*

It is worth noting that a considerable amount of genetic resources used by industry and research institutions does not fall under access and benefit-sharing provisions, so that the awarding of a CLP in these cases would either be non-obligatory or without meaning. This is the case for all ex situ resources acquired before the CBD's entry into force (1993), for all Plant Genetic Resources for Food and Agriculture (PGRFA) listed in the International Seed Treaty's Annex, and for all genetic resources acquired from non-parties as well as from countries of origin without national ABS legislation. Farm animal genetic resources present a special case.

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<sup>449</sup> Blättig 1998, p. 6.

<sup>450</sup> Ten Kate/Laird 1999.

<sup>451</sup> See also the statement of the Biotechnology Industry Organisation (Bio), Bio 2004. For more background on bioprospecting cf. Garson 2004, Bremner 2004.

NON PARTIES	CBD PARTIES					
	WITHOUT ABS LAWS	GEN RES. PRE-CBD	GEN RES. UNDER CBD		ITPGR	
				PGRFA not in Annex I of ITPGR	PGRFA in Annex I of ITPGR	EX SITU
				PGRFA not in Annex I of ITPGR	PGRFA in Annex I of ITPGR	IN SITU
		All genetic resources except Plant Genetic Resources for Food and Agriculture (PGRFA)			PGRFA	

	ABS UNDER CBD		ABS UNDER ITPGR (MULTILATERAL SYSTEM)		OPTIONAL ABS UNDER CBD
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Figure 6: ABS provisions for different types of genetic resources. Source: Öko-Institut.

Genetic resources that were stored in *ex-situ collections* (botanical gardens, zoos, gene banks, bio-resource centers, private collections of industrial users and breeders etc.) before 1993 are exempted from the CBD's provisions, as the Convention does not apply retroactively. With regard to plant genetic resources alone this means that around 90% of the estimated 42 million herbarium specimens in botanic garden herbaria and 6.13 million accessions in the gardens' living collections do not fall under ABS provisions (BGCI 2001). In Germany's 102 botanical gardens, the estimated share of pre-CBD collections likewise reaches 75% to 90%, relating to approximately 550,000 to 650,000 living plant accessions (ibid.). The country's biggest national gene bank<sup>452</sup> for cultivated plants has some 150,000 accessions, most of them pre-dating the CBD's entry into force. Animal genetic resources in ex-situ collections, from specimens (in zoos) to cryo-conserved semen, embryos, oocytes, tissues etc.,<sup>453</sup> likewise legally do not necessitate access and benefit-sharing and would technically need no CLP if they were collected before 1993. The same applies to ex-situ stored cell cultures and microorganisms (culture collections), which are – unlike animal genetic resources<sup>454</sup> – being amply used by both research and industry. Finally, all pre-1993 material in private collections of industry and the breeding sector is not concerned.

Another field where the bilateral access and benefit-sharing system of the CBD does not apply to comprehensively is *plant genetic resources for food and agriculture*. The Interna-

<sup>452</sup> Genebank of the Institut für Pflanzengenetik und Kulturpflanzenforschung (IPK) in Gatersleben.

<sup>453</sup> The world's first DNA bank to preserve endangered animals, the "Frozen Ark" is now being built in the United Kingdom, by the London Natural History Museum, the Zoological Society of London and the Institute of Genetics at the University of Nottingham.

<sup>454</sup> So far, industry, at least, has not greatly explored animal genetic resources..

tional Treaty for Plant Genetic Resources (ITPGR or Seed Treaty) that entered into force in June 2004, specifies the CBD (*lex specialis*) for a list of 35 food and 29 forage crops.<sup>455</sup> Because of their agricultural importance, access to these plants, both in-situ and ex-situ, is facilitated for all parties to the Treaty. Since this multilateral system is also the basis of benefit-sharing, CLPs would technically be superfluous for the annex crops.<sup>456</sup>

Furthermore, CLPs would not be required for material that was acquired from *Non-Parties* (such as the US).<sup>457</sup> CBD Parties that have not (yet) transposed and specified the CBD's access and benefit sharing provisions into national legislation would however issue CLPs, based on the idea that a certificate of legal provenance can also certify that there was no national ABS legislation in force when the material was acquired.<sup>458</sup>

A special case are *Farm Animal Genetic Resources*. Here, access and benefit-sharing has not been a major issue so far.<sup>459</sup> For many years, access has been agreed between parties in bilateral transfer agreements, most of which were conducted between parties in industrialized countries.<sup>460</sup> It is argued that “[s]ince the owner determines to what extent genetic material is available to third parties and for what prices, the price of animals actually includes a benefit-sharing arrangement”.<sup>461</sup> However, this holds true above all under the conditions of industrialized agriculture. As gene flows of animal genetic resources from the (only rarely industrialized) agricultural systems of the southern hemisphere to the northern hemisphere are expected to grow, this situation might change. Formally, animal genetic resources fall under the CBD and its ABS provisions, unless the Parties – as sovereigns over their genetic resources – deliberately decide not to subject them to these rules.

Another special case are genetic materials originating from human samples. *Human genetic resources* are frequently used in the pharmaceutical industry and research, but are not covered by the CBD (Dec. II/11).

### *Secondary CLP acquisition*

As the Bonn User Survey shows, German industrial and academic users receive genetic resources in most cases via intermediaries, i.e. they do not acquire them directly at the country of origin's authorities. For the CLP model this implies that the certificate needs to be passed on as genetic resources change from the first to subsequent owners (secondary

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<sup>455</sup> Godt 2004, p. 204.

<sup>456</sup> This does not hold true, however, for those plant genetic resources for food and agriculture not listed in the annex.

<sup>457</sup> This applies to material that *originates* in the non-party country. Material which is stored in non-party collections and stems from countries of origin that are CBD parties, according to this model, would still need CLPs in the future: for exporting the resources out of the country of origin, for importing it from the non-party into other user countries, and finally for patent applications within CBD countries. The problem lies, however, in the possibility of misuse, i.e. when material is ubiquitous/not endemic and could be labelled as indigenous to the non-party, though it actually stems from a CBD provider country.

<sup>458</sup> Like in all other cases, the CLPs would state that the (de facto non-existent) legal requirements have been complied with.

<sup>459</sup> Musavaya/Zárate 2004.

<sup>460</sup> Kaal-Lansbergen/Hiemstra 2003.

<sup>461</sup> *Ibid.*, p. 3.

CLP acquisition). This might cause costs both on the side of the intermediaries (as brokers) and the recipients.

It is necessary to perceive the double relation between users and intermediaries of genetic resources: While German companies and research institutions/universities – as recipients of genetic resources – receive their material in most cases from intermediaries, many intermediaries themselves belong to the corporate or research sector.<sup>462</sup> There are basically two types of intermediaries: Non-commercial intermediaries can be public gene banks, botanical gardens, culture collections, universities in provider countries or user countries (e.g. departments involved in pre-breeding for the agricultural sector). Even individuals act as not-for-profit intermediaries – for example horticultural hobby breeders or university geneticists, who pass on their materials to colleagues for free. Commercial intermediaries are companies that pass on genetic resources at a market price. They are frequently highly specialized on specific material. Broker companies either form independent entities, or are vertically integrated into larger corporations that might be end users of the resources at the same time. Intermediaries pass on genetic resources in different forms: as raw material, as screened and processed material and even as patented substances and derivatives.

Given the possible double function of intermediaries<sup>463</sup> (a) and users<sup>464</sup> (b), we try to specify their respective costs induced by a CLP system.

*a) Costs for intermediaries*

As certificates would only be required for newly acquired material (no retroactive application), the technical problems for the intermediary involved in organizing and passing on a certificate should be limited. Here, a lot depends on the provider countries to implement simple and harmonized procedures – a step that might actually be promoted through a CLP system. In a transparent and functioning institutional set-up, the intermediary will have only minor extra administrative costs and time. However, these might accumulate in the case of professional intermediaries such as ex-situ collections. Therefore the simplified procedure is envisaged for their exchange among each other. In Germany, botanical gardens are estimated to pass on more than 100,000 seed samples, and to receive 48,000 samples in the annual seed exchange.<sup>465</sup> Some 60% of the samples received stem from foreign countries, of which again 45% are European. German Gardens receive less than 6% of the samples from Botanical Gardens in developing countries of the Southern Hemisphere.<sup>466</sup> Germany's major crop gene bank Gatersleben hands out 12-15,000 accessions yearly, the German Collection of Micro-organisms and Cell Cultures (DSMZ)<sup>467</sup> passes on some 15,000 samples. The cumulated administrative efforts might in the end lead to a (minor) increase of fees/prices for the recipients.

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<sup>462</sup> The most notable exception are state-funded ex-situ collections: They are non-commercial intermediaries without really belonging to the research sector.

<sup>463</sup> As donors (that might have received the material from other intermediaries/donors).

<sup>464</sup> As recipients (that might themselves act as donors after having worked on the material).

<sup>465</sup> Krebs et al. 2003.

<sup>466</sup> Asia 4%, South America and Africa max. 1% each, see Krebs et al. 2003.

<sup>467</sup> Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH.

More problematic cases would emerge if the intermediary does not have a certificate for the resource – because it was collected or given without the necessary CLP (which would de facto mean illegally).<sup>468</sup> An expert from the DSMZ – that serves as International Depository Authority for micro-organisms under the Budapest Treaty<sup>469</sup> – estimates that only 10% of the material offered to the collection by scientists (depositors) are presently accompanied by PIC. As PIC is the prerequisite for ABS and would thus also be a future prerequisite of a CLP, in a *static* view this could imply that in future the collection had to reject the other 90% of the samples offered. In this case the expert believes that the exchange of microbiological samples would be curbed severely and research hampered. The relatively poor result regarding PIC could be due to lacking knowledge on the CBD requirements and the national procedures. Gene banks frequently report difficulties to determine the country of origin of major parts of their accessions.<sup>470</sup> Though this problem is less virulent for the resources acquired after 1992, very often the documentation systems have only been improved recently. By means of avoiding obligatory retroactive application, this problem could be reduced.

Also academic researchers fear that some of their sources might dry up – either due to the administrative extra effort for the donor, or because of the still practiced habit to collect samples for scientific uses without ABS. While a CLP certainly is exactly meant to stop illegal resource acquisition, it should not hamper access unnecessarily.

A simplified procedure for registered institutions with non-commercial interest like in the CITES-system could thus prevent all those costs involved in the CLP conferral between registered institutions (state-run ex situ collections, universities etc.).<sup>471</sup>

A foundation for a possible future CLP system in the realm of non-commercial intermediaries, specifically of ex-situ collections, is laid by their current practices regarding ABS. A number of botanical gardens have introduced voluntary provisions relating to ABS in the past years.<sup>472</sup> In Germany, an expert estimates, that already two thirds of all botanical gar-

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<sup>468</sup> Such resources acquired before the introduction of a CLP would not obligatorily require a CLP.

<sup>469</sup> Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1981. To achieve patent protection for an invention, a full disclosure of the process in question must be given to enable a person skilled in the art to practice the invention. This is usually done through means of a written description. As biological material involved in biotechnological inventions cannot be described in such a way that they are “reworkable”, patent offices of most countries require that the organism must be deposited with a recognized, independent, public culture collection (<http://www.dsmz.de/patents/genbuda.htm>).

<sup>470</sup> The reason for this is often that the samples that have been passed on time and again through numerous collections.

<sup>471</sup> This would mean that a scientific institution could receive a yearly certificate for all resources under their collection, which allows them to import/export genetic resources. This certificate could neither be used for the transfer to commercial users nor for patent applications or other commercial uses. Thus, if a commercial use of the material is intended, a separate certificate of legal provenance would have to be issued by the source country for the same resource. As long as the resource would be used only for non-commercial purposes, it can be transferred accompanied by the “general” certificate issued for the scientific organisation.

<sup>472</sup> E.g. the Code of Conduct adopted by the German ‘Verband Botanischer Gärten’ ([http://www.botanik.uni-bonn.de/botgart/Verhaltenscodex\\_englisch.pdf](http://www.botanik.uni-bonn.de/botgart/Verhaltenscodex_englisch.pdf)) as well as the respective model agreement on the supply of plant material by Botanic Gardens ([http://www.botanik.uni-bonn.de/botgart/MTA\\_englisch.pdf](http://www.botanik.uni-bonn.de/botgart/MTA_englisch.pdf)). Internationally, Botanic Gardens Conservation International (BGCI) provided principles on access to genetic resources and benefit-sharing that may serve as a framework for more specific codes ([http://www.bgci.org.uk/botanic\\_gardens/access\\_to\\_genetic\\_resources.html](http://www.bgci.org.uk/botanic_gardens/access_to_genetic_resources.html)). The International Plant Exchange Network (IPEN) has developed such a Code of Conduct for materials (<http://www.bgci.org.uk/files/2/795/ipencodeofconduct.doc>).

dens ask the users of their material not to use it commercially except when an ABS agreement is concluded with the country of origin. By signing a Material Transfer Agreement, the user commits to complying with this obligation; however, no verification and enforcement mechanism exists. The botanical gardens frequently pursue restrictive policies towards industrial users. At the same time, industry has traditionally rarely sought genetic resources from botanical gardens. The most frequent users of botanical garden materials are other botanical gardens. University departments (as potentially non-commercial users) are often obliged by Botanical Gardens to sign the same commitment as industry when receiving accessions – i.e. to notify the country of origin when their work results in commercial gains. For in-situ and ex-situ access to microbial genetic resources (MGRs) a code of conduct and a model Material Transfer Agreement have been developed by the WFCC<sup>473</sup> and by the European Union project MOSAICC.<sup>474</sup> Crop gene banks have not yet been subject to the requirement of benefit sharing while the International Treaty of Plant Genetic Resources for Food and Agriculture (formerly: International Undertaking) was pending.<sup>475</sup> With its entry into force, ABS clauses in Material Transfer Agreements might become necessary for plants not cited in the ITPGR-Annex.

#### *b) Costs for Recipients*

The immediate costs for recipients of genetic resources would mainly consist of a possible (though probably marginal) increase of fees/prices when intermediaries shift costs to users.

Indirect costs might arise when the tracking system leads to a thinning out of the exchange of those genetic resources that were not acquired in accordance with the CBD, respectively national ABS legislation. These indirect costs, that have the form of foregone research benefits and that are extremely difficult to quantify,<sup>476</sup> could be quite substantial and could lead to a shift of research and development into other areas.<sup>477</sup> However, as the objective of the CLP system is exactly to improve ABS implementation, these costs are to accept.

#### 6.8.3.2 Costs attached to the submission of CLPs

In our model, CLP need to be submitted at two pivots: when importing and exporting, and when applying for patents.

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<sup>473</sup> WFCC (World Federation for Culture Collections) 1999.

<sup>474</sup> MOSAICC = Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct. <http://www.belspo.be/bccm/mosaicc/docs/code.pdf>

<sup>475</sup> Cf. Resolution 3 of Nairobi Final Act, which was passed when the CBD was signed. It states that access to ex-situ collections of PGRFA not acquired in accordance with the CBD needs to be tackled separately. The respective adaptation of the International Undertaking (IU) for Plant Genetic Resources to the CBD was decided on in FAO Resolution 7/93.

<sup>476</sup> Cf. Visser et al. 2000.

<sup>477</sup> GBF 1998, p. 13.

### *Importing and exporting genetic resources*

Once a company, research institute or other user/intermediary has acquired a genetic resource in accordance with the CLP system (see above, chapter 6.7), border crossing will require no further costs. The existing CLPs will only have to be submitted along with other customs declaration information when the genetic material is imported or exported. In order to guarantee an efficient procedure at borders, customs staff would need to be trained.

### *Patent application*

Technological and legal developments have increased the patenting of products and processes that were developed on the basis of genetic resources: In the past two decades (1980-2004), the European Patent Office as a major international patenting institution has received (at least) 76,471 applications for European and world patents based on plant, animal or microbial resources and another 17,594 on pharmaceuticals using genetic engineering, among which at least a portion is based again on non-human genetic resources. A total of 10,202 European Patents (added up with the pharmaceuticals: 10,289) have been granted. The tendency is increasingly rising. Though this trend is strongly opposed,<sup>478</sup> patents as a potential (though not always certain) source of revenues and added value are perceived as an important starting point for benefit-sharing. It has to be noted, however, that only a fraction of genetic resources that are taken from a provider country and yield benefits, actually form the basis of a patent application.

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<sup>478</sup> Institut für ökologische Wirtschaftsforschung et al. 2004, Sharma 2003, Brand/Kalcsics 2002, Koechlin 1998, Shiva 1997, Crucible Group 1994 etc.

1980 – June 2004	Patent applications		Patents granted
	European Patent (EP) and World Patent (WO) applications <sup>479</sup>	European Patent (EP) applications <sup>480</sup>	Granted European Patents
Genetic Engineering <sup>481</sup>	39,935	26,476	5,381
Plants <sup>482</sup>	3,828	2,570	415
Plants, genetically modified <sup>483</sup>	3,183	2,155	269
Extracts <sup>484</sup>	7,539	4,929	1,820
Gene sequences of plants <sup>485</sup>	1,262	816	101
Animals <sup>486</sup>	3,130	1,717	145
Animals, genetically modified <sup>487</sup>	2,351	1,320	87
Medicine with genetic engineering <sup>488</sup>	17,594	11,184	2,071
<b>Total</b>	<b>78,822</b>	<b>51,167</b>	<b>10,289</b>

Table 2: Patent applications at EPO and patents granted by EPO. Source: adapted from Ruth Tippe, Kein Patent auf Leben e.V. (<http://www.keinpatent.de/Statistik.html>).

The obligation to submit a CLP when filing a patent application would induce economic costs. Their amount depends both on (a) the costs of compliance, and (b) the costs of non-compliance such as legal sanctions. The latter will be analyzed, but will not be accounted for in the impact analysis, since legal compliance is imputed from a normative point of view.

<sup>479</sup> Double counts are eliminated: WO and EP are all applications, except those EPs (Euro PCT), which were already published as WO- applications.

<sup>480</sup> I.e. applications that are/were examined at the EPA (including those that have been rejected or withdrawn during the examination, and those that were awarded patents).

<sup>481</sup> Classification C12N015 within the EPA patent database.

<sup>482</sup> Classification A01H.

<sup>483</sup> Classification A01H + C12N015.

<sup>484</sup> Classification A61K35.

<sup>485</sup> Classification C12N01529.

<sup>486</sup> Classification A01K67.

<sup>487</sup> Classification A01K67 + C12N015.

<sup>488</sup> Classification A61K + C12N015.

### *a) Costs of compliance*

According to our model users are in possession of a CLP from the moment on when they legally acquire a genetic resource. They are not obliged to declare the legal provenance retroactively for resources that they already work with or have acquired earlier and stored in collections, even if these underlie ABS requirements. In order to keep this potential loophole small, incentives to declare legal provenance of genetic resources gained prior to the cut-off date voluntarily should be contemplated in order to improve the tracking system. Costs are minimal for users that have accessed the genetic resource in accordance with the provider country's ABS legislation and thus are in possession of a CLP. They merely have to attach the CLP to the patent application. The number of annual applications of biopatents is limited even for big corporations; this effort is certainly negligible. For example, in 2003 the number of patent applications at the EPA for European and World Patents on genetically modified animals totaled 222, those on genetically modified 207, on plant genes 107.<sup>489</sup>

In addition, if the original CLP acquisition and subsequent passing on were conducted lawfully, patent litigation which is costly for the users and initiated by for example provider countries would be prevented.

When introducing CLPs for patent applications, a potential second source of costs of compliance might be an increase of procedural fees at Patent Offices.<sup>490</sup> This seems unlikely, though, for the Patent Offices extra costs and time would be limited once the CLPs had been accounted for in the standard procedures. Technically, there seem to be no major hurdles: A CLP would be required like other documentation; a verification would not be necessary. The Patent Office would merely need to send a (standardized) notification to the country of origin as well as to the monitoring center under the clearing house mechanism of the CBD. The procedure would resemble the customary notification of the inventor through patent offices in the 'naming of the inventor' procedure.

### *b) Costs of non-compliance*

Regarding the costs of non-compliance, formal sanctions as well as litigation have to be considered. Several forms of formal sanctions have been proposed, among others the refusal of a patent. The following considerations, for the reasons stated above, focus on sanctions independent of the validity of a patent (so-called self-standing requirements). These sanctions would possibly consist of an administrative fine or a – probably monetary – penalty (under criminal law). Their objective is to encourage users of genetic resources to comply with the CBD, respectively to discourage them from violating provider countries' ABS legislation. It is obvious, however, that in order to be truly effective a sanction needs to exceed the opportunity costs of compliance for the patent applicant; the sanction tied to non-compliance must be more 'expensive' than the process of legally acquiring a CLP. Determining the height of opportunity costs, however, is difficult, since it varies with different

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<sup>489</sup> Information Ruth Tippe/Kein Patent auf Leben e.V.

<sup>490</sup> Generally, the scale of fees is fixed by the legislator, not by the Patent Office itself.

economic actors and patent applications: for example, it varies with the applicant's company size (multinational vs. SME), with the industry sector (pharmaceutical vs. seed vs. natural cosmetics industry etc.), individual turn-over and market share, and above all with the potential value of the patent.<sup>491</sup> Opportunity costs again differ between industry and universities: The risk of foregoing economic benefits of a patent might amount to less with academic institutions, and as state-funded institutions they are certainly under higher pressure to comply with national law (here: patent-related disclosure requirements). Due to the latter aspect, a relatively low fine could in fact disadvantage academic actors more so than companies. Taking a look at the state practice takes one further only up to a point: The self-standing disclosure clause in Norwegian patent law, which imposes a penalty under the Criminal Act (for the forging of documents), is considered a success – patent applicants are reported to disclose the country of origin or source of a genetic resource, if they know it. However, there are two hooks to this perception: First, the patent office cannot verify whether the applicant really does not know the country of origin/source if he states so. Second, in a number of cases it is technically possible to withhold the fact that the patented object, e.g. a gene sequence, is derived from a natural genetic resource. The sequence only needs to be synthesized and afterwards be declared to have been developed synthetically all along. In the case of synthetic material, no country of origin needs to be disclosed at all. The present absence of court cases is therefore no reliable evidence for the implementation success of the clause. As to the severity of the penalty, the lack of precedents implies that the amount itself is still unclear.

#### 6.8.4 Impact II: Benefits

Apart from the potential costs associated with a CLP system, a majority of experts interviewed in the course of this study perceive benefits, too. Though none of these benefits consist of immediate income opportunities on the part of the users (the focus of this analysis), most of them have very tangible monetary aspects to them.

##### 6.8.4.1 Heightened sensitivity

Especially non-company interviewees emphasized that CLPs could be a means of sensitizing all actors involved to the obligation of benefit sharing, as required by the CBD. This would be directed at companies, but also at (patent) lawyers and at scientists, among others at researchers from countries of origin giving away native resources without PIC.<sup>492</sup> By increasing knowledge, but also by providing a means of verification, certificates could support compliance to benefit sharing provisions. Though the CLP system was not always seen as an optimal solution by the experts – because of loopholes on the one hand and costs on the other –, most interviewees recognized the legitimacy of benefit sharing. Some stressed that now the users and user countries were under obligation to make a contribution.

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<sup>491</sup> For this reason, linking the fine to the actual revenues induced by the patent seems advisable.

<sup>492</sup> Bättig 1997, p. 2.

#### 6.8.4.2 Reduced transaction and direct costs

An international CLP that substitutes national provisions (such as the Norwegian and Danish certificate of origin in patent law), information and negotiation costs of economic and research actors relating to national would reduce ABS legislation and procedures.

Depending on the exact design of the patent related free-standing disclosure requirement, direct costs for users might be decreased instead of increased: It would be possible to establish positive sanctions instead of negative ones: As an incentive, those applicants that provide a CLP could be granted a reduction of patenting fees.<sup>493</sup> From a public policy perspective such a measure would have the disadvantage of debiting public budgets. The measure would also provoke civil society protests as it might work as a general incentive for biopatenting.

#### 6.8.4.3 Legal security

A recent article in *Nature* stated that: “A clear title document for each compound discovered would be an important element of an [ABS] agreement. Advocates envision a document that would follow compounds around like a passport, stating where they came from and who holds rights on them. Bioprospectors say that this arrangement could help entice drug companies back into the game.”<sup>494</sup> As can be seen from this statement, a prominent benefit is perceived in legal security; along with the establishment of a CLP system internationally harmonized procedures would be introduced. They would help to clarify who the authorized institutions on-site to be consulted are. Unintended breaches of law that might be sued at a later point would thus be reduced. Once a company or research institution has acquired a certificate, it does not run the risk of its patents to be challenged before patent offices’ boards of appeal. Also, when a CLP for a genetic resource exists, the respective patent can not be contested on ABS grounds. Costs arising from the acquisition and submission of CLPs would therefore probably be (over-) compensated by evaded litigation costs; and the security that patents are not contestable for ABS reasons would hedge research and development investment. This is all the more valid as provider countries and international civil society – as potential plaintiffs – are highly sensitized to the issues of access and benefit sharing and “bio-piracy”.

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<sup>493</sup> Godt, 2004, p. 210.

<sup>494</sup> Dalton 2004, p. 600.

### 6.8.5 Summary

The total costs determined for the German research sector appear calculable: Generally, costs would only accumulate for those genetic resources underlying the CBD and having been acquired after a future deadline (no retroactive implementation).

The crucial ‘pivot’ of *CLP acquisition*, when a genetic resource is taken under in-situ conditions (primary CLP acquisition), is relevant only for a small percentage of companies and scientists. Costs related to this pivot would be minor, provided that the institutionalization of CLP issuing in the provider countries is transparent and functions. In order to ensure this, the international CLP regime should go hand in hand with procedural standards. Also, making available means for capacity building in developing countries and economies in transition are very advisable. When a genetic resource is not taken under in situ conditions, but rather is received via an intermediary (secondary CLP acquisition), which is standard for a lot scientific work and most industrial sectors including the breeding sector in Germany, users have to anticipate a slight increase of costs. In order to avoid cumulated administrative burdens, particularly public ex-situ collections and non-commercial users should be subjected to a simplified procedure.

The pivot of *CLP submission at border controls* would incur no specific further costs for companies, academic research teams or ex-situ collections, once the customs procedures would have been adapted. In order to grant effective implementation of the import/export regulations, funds needs to be earmarked for the training of customs staff.

The pivot of *CLP submission at patent applications*, again, does not appear to bring about substantial costs for genetic resource users. If a CLP has already been obtained once, this merely needs to be submitted along with the patent application. A rise in procedural patent fees on the grounds of CLPs is neither likely nor would it have prohibitive effects on applicants. Since compliance to disclosure requirements is the legislator’s goal, costs linked to non-compliance – sanctions tied to the non-submittal of CLPs (fees, fines, penalties) – are not included in the cost-benefit analysis. It becomes clear, however, that the amount of these costs is crucial for the success of the instrument. A low sanction (low opportunity costs of compliance) might not discourage a user from non-compliance/evading the CLP system.

*Public costs*, though not analyzed above, can be expected to be limited, too. These costs would cover the adaptation of national import/export regulations and patent application procedures in both user and provider countries, clarification of competence structures and capacity building in provider countries (NFP, customs, patent offices) as well as setting up an international monitoring system. As user countries would benefit from an effective CLP system, too, the provision of funds to support capacity building in provider countries would be appropriate. Since especially commercial users profit from a smoothly working system, they might be mobilized to financially support these efforts. A further item of costs would be awareness raising, both among users and within provider country authorities and universities.

## 7 Conclusions

Since its entry into force in 1993, the CBD has not fully achieved one of its three main purposes: The fair and equitable sharing of the benefits of the use of genetic resources. The Bonn Guidelines represented a major achievement in clarifying the obligations of users and provider (states) but are criticised as a non-binding instrument.

The Terms of Reference for the negotiation of the international ABS regime identify some new elements for the ABS regime. Of these, many are so far not clearly defined. If a comprehensive regime is the goal of the negotiations, terms like genetic resources, access and derivatives will have to be defined in a way that facilitates the harmonization of national ABS legislation and coherent international rules.

The Terms of Reference for the negotiation of the international regime do not include means of linking access and benefit-sharing to the conservation and sustainable use of biodiversity. A biodiversity trust fund or a number of national funds could be useful means for ensuring a contribution of access and benefit-sharing to the conservation and sustainable use of biodiversity world-wide.

Included in the new “elements” of the international ABS regime are the so-called certificates of origin/source/legal provenance, which were discussed extensively above. In conclusion, a certificate of legal provenance would represent a model that would benefit most both provider states, user countries and users. The latter could be sure that they have complied with all relevant legislation. Institutions in user countries which implement user measures (such as disclosure requirements), e.g. patent offices, would not have to examine certificates but could limit themselves to ensuring that they were legally issued with the help of a monitoring system. Provider countries would be able to ensure that a certificate of legal provenance is issued only if all legislation has been complied with. Provider countries would profit from the increased benefit-sharing taking place.

The CLP system described would allow for a number of synergies with the existing CITES system. Thereby costs for countries involved could be limited. From a practical point of view, CITES equally provides important insights on how such a system could function. In sum, it can be estimated that the practical implementation of a system of certificates of legal provenance would be feasible and not terribly expensive. From a legal point of view, a certificate of legal provenance could conflict with international trade law. Such conflicts exist between a number of MEAs and have been discussed widely in the past years, both in the framework of the WTO (such as the Committee on Trade and Environment) and MEAs. With regard to an international ABS regime that makes use of certificates of origin, similar questions would arise as soon as export/import regulations and/or restrictions are included. It can not be said that a system of certificates of legal provenance would be admissible in any case under international law. On the other hand, trade measures under MEAs can be seen as justified under Art. XX GATT, since they are based on a multilateral approach. Generally, it remains to be seen whether the Doha Round will clarify this relationship in general.

Overall, a coherent system for tracking the use of genetic resources world-wide is feasible in theory. The analysis leads to the finding that a certificate of legal provenance could be used in a number of contexts in the user countries to ensure that legislation in the provider countries is respected. This includes but is not limited to the disclosure of origin/source/legal provenance in patent applications and the need to present a certificate when importing/exporting genetic resources.

Existing systems of certificates for ex-situ collections such as IPEN have proven to be valuable and should be integrated into a future system of certificates. Botanical gardens have special needs and also mostly exchange among themselves. A number of initiatives ensures that genetic material is exchanged only where non-commercial use is made of it.

Without requiring a retroactive application of the certificates, they could cover genetic resources from ex-situ collections, by simply stating in the CLP that these resources were acquired prior to the entry into force of the CBD. This could close a loophole in a CLP system, because *all* genetic resources from Parties to the regime will require a certificate, which ensures that the resource was obtained observing ABS rules. Alternatively, ex-situ collections could issue a certificate of legal provenance. Currently, many ex-situ collections use standard MTAs. These existing systems should thus be supported through a simplified procedure by certificates of legal provenance. This would create the advantage of allowing existing systems to merge and the opportunity to benefit from their experience.

There are two important reasons why a system of CLPs should not be overestimated in its ability to harmonize ABS requirements and ensure benefit-sharing with the providers respectively provider countries of genetic resources: First, the system would only work effectively if *all* provider states would introduce ABS legislation related to the certificates of legal provenance. Second, the certificate of legal provenance legislation would have to cover as many aspects of the use as possible if it is to ensure that it provides security to the providers.

From the point of view of the users of genetic resources, a certificate of legal provenance would not only entail costs but also major benefits. First, they would be provided with legal certainty with regard to their use of the resources, a point that many users consider unsatisfactory under the current system. Second, they could use the CLPs at any given time to prove their legal use of genetic resources to the international public and thereby protect themselves from accusations of “bio-piracy”. Third, the issuing of CLPs would require simple and consistent procedures in provider countries that users would probably profit from.

## 8 List of Acronyms and Abbreviations

ABS	Access to Genetic Resources and Benefit-sharing
AGR	Access to genetic resources
ASEAN	Association of South East Asian Nations
Bonn Guidelines	Bonn Guidelines
CARB	Access to Biodiversity Resources Commission
CBD	Convention on Biological Diversity
CEMAT	State Council on the Environment, Science and Technology
CGIAR	Consultative Group on International Agricultural Research
CITES	Convention on International Trade in Endangered Species
CLP	Certificate of Legal Provenance
CONAGEBIO	National Commission for the Management of Biodiversity
COP	Conference of the Parties
CPT	Pastoral Land Commission
DA	Department of Agriculture
DENR	Department of Environment and Natural Resources
EC	European Community
ECJ	European Court of Justice
ECT	Treaty of the European Community
EO	Executive Order
EPA	Environmental Protection Authority
EPC	European Patent Convention
EU	European Union
FAO	Food and Agriculture Organisation
GATT	General Agreement on Tariffs and Trade

GR	Genetic Resources
GTA	Amazon Working Group
GTZ	Gesellschaft für Technische Zusammenarbeit (Germany)
IACO	International Civil Aviation Organization
IBAMA	Brazilian Institute for the Environment and Natural Renewable Resources
IEPA	Institute of Scientific and Technological Research of Amapá
IMO	International Maritime Organization
IP	Intellectual Property
IPEN	International Plant Exchange Network
IPR	Intellectual Property Rights
ITPGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture
IUCN	International Union for Conservation of Nature and Natural Resources
MAT	Mutually agreed terms
MEA	Multilateral Environmental Agreement
MTA	material transfer agreement
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organisation
OAU	Organization of African Unity
OCEAP	Organization of Cooperatives
OECD	Organisation for Economic Cooperation and Development
OJ	Official Journal
PBR	People Biodiversity Register
PCSD	Palawan Council for Sustainable Development
PDSA	Sustainable Development Program of Amapá
PGRFA	Plant Genetic Resources for Food and Ag-

	riculture
PIC	Prior informed consent
RECIEL	Review of European Community and International Environmental Law
R&D	Research and Development
SEMA	State Secretary of the Environment, Science and Technology
SINAC	National System of Conservation Areas
TBT	Technical Barriers to Trade
TK	Traditional Knowledge
TOR	Terms of Reference
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNEP	United Nations Environmental Programme
UPOV	Union for the Protection of New Varieties of Plants
WCMC	World Conservation Monitoring Centre
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation



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## 10 Annex 1: National definitions

Information on existing national definitions or other relevant definitions of the following terms: access to genetic resources, benefit sharing, commercialization, derivatives, provider, user, stakeholder, ex situ collection, and voluntary nature (as contained in annex II of document UNEP/CBD/COP/6/INF/4).

Term in English	Term in German	Definition
Access to genetic resources	Zugang zu genetischen Ressourcen	No definition in German law, since the term is not used in German Law. Related terms like conservation of genetic diversity are used in § 1 para. 1 no. 4 TierZG or origin and function of genetic Material in Part II of Annex 1 to § 4 of the Genetic Engineering Law (GenTG).
Benefit-sharing	Vorteilsausgleich/Gewinnbeteiligung	No specific definition in German law, but contained in other German acts for example: § 12 no.1 Railway Crossroads Law (EBKrG).
Derivatives	Derivate	No specific definition in German Law but used in § 1 of the Annex 1 to the Cosmetics Regulation (KosmetikV).
Commercialization	Kommerzialisierung/Vermarktung	No specific definition in German law, but contained in German law for example: § 2 a no.1 Wine Regulation (WeinV), § 1 Laying Hen Registration Law (LegRegG).
Provider	Anbieter	No specific definition. Definition of provider in

		the Federal Income Tax Law (EstG). In § 80 EstG provider in the legal sense of this law is defined as provider of retirement provision contracts and the utilities named in § 82 para. 2 of this law.
User	Nutzer	No specific definition. Definition of user in the Federal Garden Plot Holder Law (BKleingG). According to § 1 para. 1 BKleingG user in the legal sense of this law is a garden plot holder. The term is also used in other German laws for example: Art. 3 para. 2 no. 3 Wild Animal Species Agreement Law (Wild-TArtÜbkG).
Stakeholder	Interessenvertreter	No specific definition. No definition in German law but contained for example in § 70 Bye Law of the Lower House of German Parliament (BTGO).
Ex-situ collection	Ex-situ Sammlung	No definition or usage of the term in German law.
Voluntary nature	Freiwillig, freiwilliger Art	Definition of voluntary nature in § 1 sec.1 of the Voluntary Nature Activity Order (EhrBetätV), accordingly voluntary nature in the legal sense of § 118 a of the third book of the Social Security Code (SGB) is an activity which is per-

		<p>formed free of charge, serves the common welfare and which is done at an organisation, that is performing activities without commercial proposition, which are in the public interest or non-profit, or facilitating beneficent or church purposes.</p> <p>The term is also used in other German laws for example: § 40 sec. 1, 2 and 3 of the Seed Circulation Law (SaatgVerkG).</p>
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## **11 Annex 2: Information to be included in a certificate of legal provenance<sup>495</sup>**

- a) The full name and the logo of the Convention
- b) The complete name and address of the Management Authority issuing the permit
- c) A unique control number
- d) The complete names and addresses of the exporter and importer
- e) The scientific name of the genetic resource in accordance with a standard nomenclature to be adopted
- f) The description of the genetic resource
- g) The intended use of the genetic resource (scientific/commercial)
- h) The source of the genetic resource
- i) The quantity of the genetic resource
- j) The date of issue (and – where relevant - the date of expiry)
- k) The name of the signatory and his/her handwritten signature
- l) The embossed seal or ink stamp of the Management Authority
- m) The actual quantity exported, certified by the stamp or seal and signature of the authority that carried out the inspection at the time of the exportation
- n) A statement that the specimen originates in the country that issued the certificate
- o) A statement that the resources are of legal provenance
- p) If applicable: a statement that the genetic resources were acquired before the entry into force of the CBD

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<sup>495</sup> Based on the model of a CITES permit.

## 12 Annex 3: Comparative table of national and regional ABS provisions

Tabelle 12.1 Comparison of national ABS provisions

	Costa Rica <sup>496</sup>	Andean Community	Asean <sup>498</sup>	OAU <sup>499</sup>	South Af- rica <sup>500</sup>	India <sup>501</sup>	Philippines <sup>502</sup>	Brazil <sup>503</sup>	Australia/
State sovereignty over GR	2	5	1	Intro.			1.1.		
Covers GR	7 no. 2; 25; 26	1	3, 4	1	1; 3; 80	2	2.1. p)	7; 9	schedule
Covers biol. Resources	7 no. 9	1	3, 4	1, 2	1; 2; 80	2	2.1. g) 9.1.2)		Schedule; 9; 24
Covers derivatives			3,	1, 2; 8; 64	1; 80	2	2.1. m)		
Covers TK	7, no. 2; 6	7	3, 4	2	1	3		7	
Human genetic resources	4	4	4	Intro.	80	2		3	schedule

<sup>496</sup> Costa Rica, The Biodiversity Law, 1998.

<sup>497</sup> Andean Community Commission, Decision 391: Common Regime on Access to Genetic Resources, 1996.

<sup>498</sup> Asean, The Asean Framework Agreement on Access to Biological and Genetic Resources (draft), 2000.

<sup>499</sup> OAU Model Law: African Model Legislation - for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, 2000.

<sup>500</sup> South Africa: Biodiversity Bill, 2004.

<sup>501</sup> India: The Biological Diversity Bill, 2002.

<sup>502</sup> Philippines: Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources, 1996 Administrative Order No. 96-20

<sup>503</sup> Brazil: Provisional measure on access to genetic resources and traditional knowledge, 2001 (*Not: Amapa*).

<sup>504</sup> Australia: The Biodiscovery Bill of Queensland, draft.

	Costa Rica <sup>496</sup>	Andean Commu	Asean <sup>498</sup>	OUA <sup>499</sup>	South Af-	India <sup>501</sup>	Philip-pines <sup>502</sup>	Bra-zil <sup>503</sup>	Austra-lia/
ex-cluded									
Exclu-sion of tradi-tional use of GR/for own con-sump-tion	4	4	4	21		7	3.1.b)	4	
Facili-tates access		9				41		21	3
Pro-ected areas	22-43; 58-61	6 <sup>th</sup> cont. prov.		3	1; 11; 39		4		24
ex situ collec-tions covered	7 Nr. 1, 7; 69	1	4; 11	2				7, 15; 18; 19	
limits to the use of GR		24, 45		15				5	
Restric-tions on IPRs for GR	78 ;80	2 <sup>nd</sup> cont. prov.	4	9		6			
Permis-sion	7 no. 27; 69	16		7, 13	81	3, 19		16	10; 12

	Costa Rica <sup>496</sup>	Andean Commu	Asean <sup>498</sup>	OUA <sup>499</sup>	South Af-	India <sup>501</sup>	Philip-pines <sup>502</sup>	Bra-zil <sup>503</sup>	Austra-lia/
Regu-lates prior in-formed consent	65		10; 8	5	82		2.1. w) 7	11;14; 16	
Regu-lates access	63	16;17; 18	10	3	82		2.1. e) 8.1.4)	16	11
Envir. impacts	7 no. 18; 92 seq.	18	13	15	91	24	6.1.4.	5, 6	44
ABS contract state/us er		35	11	7	82		8 15.1.	13; 27	33
ABS contract lo-cals/use r		35	11	7	82	19		27	
Publi-cation of ac-cess right	67	38		6		19			27
Differ-ence commer-cial/scie ntific use	71			11, 12			8	16, 19	54

	Costa Rica <sup>496</sup>	Andean Commu	Asean <sup>498</sup>	OAU <sup>499</sup>	South Af-	India <sup>501</sup>	Philip-pines <sup>502</sup>	Bra-zil <sup>503</sup>	Austra-lia/
Rights of communities (e.g. to prevent access)	66			16-23			5	9	
Regulates benefit sharing	76		11	12; 22	83	21	8	24-29	34, schedule
Mandatory monetary benefits	76		11	12					
Money for biodiversity issues	41	1 <sup>st</sup> cont. prov.	12		85	26	16	33	
Information about research		17	11	8			8	19, 22	
Certificate of origin	71								
Samples for the provider country		17	11	8			8	19	30

	<b>Costa Rica<sup>496</sup></b>	<b>Andean Commu</b>	<b>Asean<sup>498</sup></b>	<b>OUA<sup>499</sup></b>	<b>South Af-</b>	<b>India<sup>501</sup></b>	<b>Philip-pines<sup>502</sup></b>	<b>Bra-zil<sup>503</sup></b>	<b>Austra-lia/</b>
Enforce- ment provi- sions	112	46		67	101; 102	55	14	26; 30	50

### 13 Annex 4: Comparative table of ABS agreements

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
<b>Kani</b>	India	Trichopodaceae	The Kani people	50% share of license fee	Not all members of the Kani tribe involved in negotiations	<b>no</b>
			The Indian Tropical Botanic Garden and Research Institute (TBGRI)	50% of the royalties of sale	Need of multi-stakeholder approach	
			Arya Vaidya Pharmacy Ltd.	Training of Kani	No protection from patents outside of India	
				Increased income from the sale of the plant		
<b>Kava</b>		Papaveraceae	Kava growers in the Pacific islands	No relevant direct benefits		<b>No</b>
			Herbal industry companies, e.g. L'Oreal, Shiseido	Possibly increased local demand, additional employment and income for local		
<b>Hoodia</b>	South Africa	Hoodia gordonii (Asclepiaceae)	The San	8% of milestones payments (est. US\$ 10 mill.)	Benefits are limited to monetary benefits which hinge on product sales	<b>Yes</b>

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			Council for Scientific and Industrial Research	6% Royalties (percentage not published) overall less than 0.03% of proceeds from sales		
			Phytopharm plc.	So far: US\$ 33,000 to San Hoodia Benefit Sharing Trust		
			Pfizer Inc.	Plant extraction facility built		
<b>MSI-Cancer<sup>505</sup></b>	Philippines	Marine organisms	Marine Science Institute, University of the Philippines	Annual bioprospecting fee US\$ 200 <sup>506</sup>	Benefits will accrue only in the case of successful commercialization	<b>Commercial research agreement based on EO 247</b>
			University of Utah	5% of net revenue on invention, licenses, royalties, or other commercialization to Department of Agriculture	Benefits for indigenous communities not defined	
			Philippine Department of Agriculture	Training of government representatives		
			Wyeth-Ayerst	Information campaign for communi-		

<sup>505</sup> Swiderska/Daño/Dubois 2001.

<sup>506</sup> Payable to Interagency Committee for Biological and Genetic Resources for the duration of the agreement.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
				ties on protection/conservation of coastal resources		
				If inventions are derived: training in marine-related discipline for qualified candidate of the community		
<b>INBio</b> <sup>507</sup>	Costa Rica	Plants, insects, micro-organisms	National Institute of Biodiversity of Costa Rica (INBio)	Research funds of US\$ 1 mill. (partly paid to Costa Rica's conservation program)	Lack of transparency and information	INBio-Merck agreement governed by Costa Rican law
			Merck & Co Inc.	Laboratory equipment and materials	No compensation of stakeholders	
				Royalties on products developed	Mostly strengthening national research capacities	
				Establishment of new facilities in Costa Rica		
				Training of personnel		
				No monetary benefits for indigenous communities		

<sup>507</sup> Columbia University 1999, pp. 18 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
				Training for locals to become parataxonomists		
<b>NCI-UNIP</b> <sup>508</sup>	Brazil	Plant samples	National Cancer Institute	Monetary benefits for source country	Flexibility in an uncertain legal situation	yes
			Universidade Paulista	Training of scientists, provision of bioassay material for source country	Technology transfer and training are the only benefits if no bioactive compounds are discovered	
				Joint patent protection for invention developed collaboratively		
				Repatriation of results		
				Re-supply of license or monetary compensation		
<b>MMA-BioAndes</b> <sup>509</sup>	Colombia	drugs	BioAndes	Complex monetary benefit-sharing system, concerning royalty payment, taxes and income from sale, to pay to	1 <sup>st</sup> application rejected in any Andean pact country	Agreement was not finalized

<sup>508</sup> Columbia University 1999, pp. 24 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
				the state		
			Colombian Ministry of the Environment (MMA)	Deposition of specimens	Invoked reasons not clearly linked to Decision 319	
				Technology transfer to Colombian company		
				Training of Colombian scientists		
				Joint research		
				Infrastructure and capacity building		
<b>NCI-MBG<sup>510</sup></b>	Cameroon	Ancistrocladus korupensis	National Cancer Institute, US	Provision of test results, equipment, infrastructure support and technologies to host country	Lack of coordination among the parties	yes
			Missouri Botanical Garden, US	Research exchange with University of Yaounde and state		
			University of Yaounde	Payment of royalties to the state		

<sup>509</sup> Columbia University 1999, pp. 34 seq.

<sup>510</sup> Columbia University 1999, pp.45 seq; Laird/Lisinge 1998.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			Indigenous communities in southwest Cameroon	Seek the host country as the first source of raw materials found to be commercially valuable		
			Government of Cameroon	Training of local communities and of the University of Yaounde		
			Purdue University			
<b>Prunus africana</b> <sup>511</sup>	Cameroon	Prunus Africana (Pygeum)	Plantecam-Medicam Company	Higher payment per collected kg for the village	Decline of unsustainable harvesting since signing the agreement	yes
			Bakweri Villages	Training of village in harvesting and financing	Land tenure is important factor	
			Ministry of Forests and Environment	Capacity and institution-building in village		
			Mount Cameroon Project	Upgrading of infrastructure of village		
<b>USP-SIDR</b> <sup>512</sup>	Fiji	Marine and terrestrial organisms	University of South Pacific (USP)	60% of third persons licensing fees for USP	Only proportionate sharing of fees, no exact amount	

<sup>511</sup> Columbia University 1999, pp. 45 seq; Laird/ Lisinge 1998.

<sup>512</sup> Columbia University 1999, pp. 51 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			University of Strathclyde (SIDR)	60% of net income accrued be commercialization for USP	Multi-level sharing agreement (local and national level)	
			County of Verata	Joint research for USP		
				Joint patents for USP		
				100 % of the portion of extract license fees received by USP to Verata		
				Training of staff and workshops in Verata		
				Management of village based enterprises		
<b>Yellowstone-Diversa</b> <sup>513</sup>	US	Genetic resources in the geothermal waters of the park	Yellowstone National Park	Annual payment of US \$ 20.000 for 5 years to Yellowstone	Channeling of all proceeds to Park, for purpose of research and conservation, inequitable	yes
			Diversa Corporation	US \$ 28.000 to WFED	In case of no returns: costs of park for project not covered	

<sup>513</sup> Columbia University 1999, pp. 61 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			World Foundation for Environment and Development (WFED)	In-kind services and resources valued at US \$ 375.000 to park	Difficult to respect rights of all stakeholders in decentralized administrative system	
				0.5 to 10 % of proceeds resulting from commercialization to park	Reversion of the paid fees to the state makes stakeholders feel alienated	
				Collaborative research with park		
<b>Zimbabwe</b> <sup>514</sup>	Zimbabwe	swartzia madagascariensis.	University of Lausanne		Suppliers of TK not involved	
			US based pharmaceutical company		Agreement not addresses genetic resources	
			University of Zimbabwe			
<b>Procter &amp; Gamble</b> <sup>515</sup>	Kenya	Extremophiles	Kenya Wildlife Service	No agreement	Illegal extraction of biological resources with huge industrial potential	-
			Procter & Gamble			

<sup>514</sup> Chishakwe/Young 2003.

<sup>515</sup> Mbaria 2004.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			Genencor International Inc			
<b>Suriname ICBG-program</b> <sup>516</sup>	Suriname (Dutch Guiana)	Drugs	International Cooperative Biodiversity Group (ICBG)	Royalties for Suriname (depending on potential product sales, level of development, potential costs, extent of Contribution of ethnobotanical knowledge)	Multifaceted benefits because of different interest of the parties	yes
			Conservation International (non governmental conservation organization)	Up-front compensation to pay in fund for Suriname's people	Equitable sharing is incentive for cooperation and conservation	
			Pharmaceutical company owned by the government	Support staff for local community	Source country must have opportunity to participate in bioprospecting	
			Missouri Botanical Garden	Technology transfer to Suriname	Communication among all parties essential	
			American pharmaceutical company		Important long-term relationships	
			Local tribal people			

<sup>516</sup> Guérin-McManus et al. 1998.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
<b>Novartis-UZACHI</b> <sup>517</sup>	Switzerland	Micro-fungi	Novartis (Sandoz)	Technology and know-how transfer to Oaxaca	Capacity building in local Communities essential	yes
			4 Mexican Communities in Oaxaca (UAZCHI)	Salaries for persons working at the laboratory for four years	Common decision-making	
				Annual payment of US \$ 10.000 to Communities	Non-monetary benefits more important than monetary	
				Sample fees for communities	Little intervention of national authorities	
				“Success-fee” for communities		
<b>BDCP</b> <sup>518</sup>	Nigeria	drugs	Shaman Pharmaceuticals Inc	Workshops and training programs for Nigerian scientists	Community decision-making of villages	yes
			The Healing Forest Conservancy	Supplies for schools and botanical collections	Trust fund involved	
			Bioresources Development and Conservation	Laboratory equipment for Nigerian		

<sup>517</sup> Baruffol 2003.

<sup>518</sup> Moran 1998.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			Program (BDCP)	scientists		
			Local Communities	US \$ 200.000 to different stakeholders		
				Laboratory results to communities		
<b>Calanolide<sup>519</sup></b>	Malaysia	Calophyllum lanigerum. var. austrocoriaceum.	National Cancer Institute	Royalties, shared between the actors, coordinated by the SMP	Use of letter of intent, letter of collection and memorandum of understanding	yes
		Calophyllum teysmannii var. innophylloide.	Medichem Research	Technology transfer to Sarawak	Growing capacity of source countries for involvement in research	
			State Government of Sarawak	Training of Sarawak's scientists		
			Sarawak Medichem Pharmaceuticals (SMP)	Joint research between Sarawak scientists and Medichem		
			University of Illinois at Chicago	Intellectual property under joint venture		

<sup>519</sup> ten Kate Wells Adrian, The access and benefit-sharing policies of the United States National Cancer Institute: A comparative account of the discovery and development of the drugs Calanolide and Topotecan, 1998.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
<b>Topotecan</b> <sup>520</sup>	India	Camptothecin	National Cancer Institute	Payments to supplier of natural Camptothecin	Original supplies not under agreement	yes
			Smith-Kline Beecham	Research funding of collaborating institutions		
				Access to expertise of collaborating institutions		
<b>UC Davis</b> <sup>521</sup>	Mali	<i>Oryza longistaminata</i>	University of California at Davis	Royalties from companies if they commercialize a product to UC Davis	Fund established	yes
	Philippines		International Rice Research Institute	Access to the gene for provider country	Sharing benefits without legal obligation	
			Stanford University			
			2 agricultural biotechnology companies			
<b>Burkina Faso</b> <sup>522</sup>	Burkina Faso	Cereals (sorghum, millet, maize)	National and foreign institutes	No agreement concluded	In spite of some hurdles, Burkina Faso is in need for a national ABS	no

<sup>520</sup> Ten Kate/Wells 1998.

<sup>521</sup> ten Kate/Collis 1998.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
					strategy	
<b>Lebanon</b> <sup>523</sup>	Lebanon	Indigenous plants, water, soil	Lebanese Agricultural Research Institute	No agreement concluded	National ABS law is drafted and yet difficulties in implementation can be foreseen	no
			American University of Beirut			
<b>Panax vietnamensis</b> <sup>524</sup>	Vietnam	Herbaceous plant	Nature's Way	5-30 year investment in cultivation in the area, 70 % of the total produced goes to Nature's Way, 30 % to Government  Nature's Way would reimburse Government for the cost of labour, material etc., 25 % of the budget goes to re-establishing plant in its natural habitat	Little awareness of the government to benefit-sharing with local communities,  Bureaucracy major threat to regulatory system for natural products,  difference between botanical medicine companies and pharmaceutical industry must be clear prior to drafting of access and benefit-sharing legislation	
			REM Ventures			

<sup>522</sup> Wynberg 2004, pp. 19 seq.

<sup>523</sup> Wynberg 2004, pp. 27 seq.

<sup>524</sup> ten Kate/Laird/Burningham, 1999, pp. 112 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			People's Committee of Kon Tum Province			
			Government of Vietnam			
<b>Pipa horticultural Co. Ltd<sup>525</sup></b>	China	Chinese plant resources	Piroche Plants Inc. in joint venture with	Piroche Plants contributes 90 % of the joint venture capital and NGBSS 10 %; Distribution of benefits: 50 % of profit for further development of Pipa 10 % Piroche Plants 10 % NGBSS 10 % Pipa staff 20 % support conservation activities	Joint venture defines only monetary benefits and their sharing, but these have been invested so as to give rise to a range of non-monetary benefits; 20% of the profits dedicated to conservation have not been distributed yet	yes
			Pipa Horticultural Company Ltd (Pipa) established by Nanjing Botanical Garden Service Station (NBGSS)			

<sup>525</sup> Kerry ten Kate, 1999, pp. 158 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
<b>Lutte Biologique contre les Locustes et le Sauteriaux, Locust Control Programme LUBILO-SA<sup>526</sup></b>	Niger and several other African Countries	Metarhizium funghi	Biopesticide Programme of the Commonwealth Agricultural Bureau International (CABI) Bioscience	Access to mycoinsecticide technology; royalties generated from the sale of Green muscle the derivated product; capacity building through research and training programme; research funding; environmental safety; benefits to farmers	Chances of developing effective products can be greatly increased if access to genetic resources, local research skills, and overseas expertise and funding are pooled between several source countries; benefit-sharing aspirations have to be assessed against other economic considerations, esp. prospective commercial licenses	yes
			Comité Inter-Etats pour la Lutte contre la Secheresse dans le Sahel (CILSS)			
			German development agency (GTZ)			
			Plant Health Management Division of the			

<sup>526</sup> Kerry ten Kate, 1999, pp. 217 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			International Insitute of Tropical Agriculture (IITA)			
			Biological Control Products SA (BCP)			
<b>Latin American International Co-operative Biodiversity Group (ICBG)<sup>527</sup></b>	Argentina; Chile; Mexico	Xerophytic plants and associated microorganisms	University of Arizona	<p>Payment of quaterly salaries to partners in Argentina, Mexico and Chile, funding of collection trips, royalties in the event product is commercialized,</p> <p>University of Arizona is required to distribute the royalty benefits from future licensed products through establishment of trust funds for local conservation and development projects in the source countries,</p> <p>Non-monetary benefits :</p> <p>Equipment and materials; know-how</p>	<p>Cost of research and development for natural product pesticides are greater than those for synthetic ones; costly fees for access, demand for high royalty rates, bureaucratic and lengthy procedures serve to put companies off this method of research,</p> <p>Companies are increasingly wary of entering into partnerships involving access to genetic resources,</p> <p>Companies will only look favourably on insti-</p>	yes

<sup>527</sup> Kerry ten Kate, 1999, pp. 224 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
				and training; re-search collaboration, database management system; conservation, sustainable sourcing	tutions of high scientific caliber, offering samples of high quality, based in countries where it is possible to obtain unequivocal PIC	
			Hansen's Disease Center			
			Universidad Nacional de Mexico			
			Pontifica Universidad Catolica de Chile			
			American Home Products Cooperation (Wyeth-Ayerst & American Cynamid Co)			
			Universidad Nacional de la Patagonia			
			Instituto de Recursos Biologicos de Argentina			
<b>New England Bio-</b>	China, Vietnam,	Restriction	New England Biolabs Inc.,	Providing the partner laboratory with		yes

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
<b>labs (NEB)<sup>528</sup></b>	Protugal, Cameroon, Uganda, Nicaragua	Enzymes	Massachusetts, USA	equipment and money to pay the salaries of the staff,  Joint research and training between NEB and its partners, acknowledgment on patents and other publications		
			Partner laboratories in China, Vietnam, Protugal, Cameroon, Uganda, Nicaragua	NEB pays 5 % of the royalties on sales of enzymes found by partner laboratories to them,  Establishment and partly funding of private foundation NEBF that is supporting scientific research for environmental projects in developing countries		
<b>Yawanawa and Aveda Corporation Bixa orellana Project<sup>529</sup></b>	Brazil	Bixa orellana	Yawanawa tribe represented through Organizacao dos Agricultores e Extractivistas Yawanawa do Rio Gregorio	Package of benefits to improve the community's ownership over the means of production, through development of bixa supply industry and also diminish		yes

<sup>528</sup> Kerry ten Kate, 1999, pp. 257 seq.

<sup>529</sup> ten Kate/Laird/Waddington, 1999, pp. 281 seq.

Case	Country	Type of genetic resource	Actors	Benefits	Lessons learned	Legally binding agreement
			(OAEYRG)	the community's level of dependence on external goods;  Conservation impacts: production and processing of bixa conducted in environmentally sound manner		
			Aveda Corporation			
			FUNAI the Brazilian federal government agency under Ministry of Justice			
<b>Conservation International (CI) and Croda Inc.</b> <sup>530</sup>	Guatemala	Cohune palm (Orbignya cohune)	Conservation International-Guatemala (CIG)	Promotion of sustainable and alternative source of income based on the forest resource, for communities living around Maya Biosphere Reserve in Guatemala; payment per supply of processed oil, receiving of a margin on sale of products to end product manufactur-	Green marketing valuable tool to tie commercialization of natural products to benefits for local communities;  Importance of local partnerships: directly source from community-based enterprises instead of sourc-	yes

<sup>530</sup> ten Kate/Laird/Morris, 1999, pp. 287 seq.

<b>Case</b>	<b>Country</b>	<b>Type of genetic resource</b>	<b>Actors</b>	<b>Benefits</b>	<b>Lessons learned</b>	<b>Legally binding agreement</b>
				ers; conservation of esp. crozco palms, development of local industry; training and capacity building	ing raw materials from developing countries	
			Industria Petenera de Corozo (INPECO)			
			EcoMaya, SA			
			Croda Incorporated (New Jersey)			
			Conservation International-Conservation Enterprise Department (CED); Washington D.C., USA			