

Ute Feit, Franziska Wolff (eds.)

**European Regional Meeting on an  
Internationally Recognized Certificate  
of Origin/ Source/ Legal Provenance**

Report of an international workshop hosted by the  
German Federal Agency for Nature Conservation,  
Isle of Vilm, Germany, 24-29 October 2006





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## **Introduction to the meeting**

UTE FEIT

Bundesamt für Naturschutz / Federal Agency for Nature Conservation

### **1. The European Regional Meeting on an Internationally Recognized Certificate of Origin/Source/Legal Provenance**

One of the major results of the 8<sup>th</sup> Conference of Parties of the Convention on Biological Diversity (COP 8, March 2006, Curitiba) concerning ABS was the decision of the CBD parties to finalize the negotiations of an international ABS regime before the year 2010.

One element that is considered promising as a potential component of an international regime is a certificate of origin, source or legal provenance. The Parties to the Convention on Biological Diversity (CBD) agreed, in Decision VIII/5 C, paragraph 1, to establish a Technical Expert Group (TEG) to explore and elaborate possible options for the form, intent and functioning of an internationally recognised certificate of origin/source/legal provenance and to analyse its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention. The TEG on Certificates will meet in January 2007 in Lima, Peru. It shall provide technical input to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing and will operate in accordance with specific terms of reference.

These terms include the following aspects: to consider the possible rationale, objectives and the need for an internationally recognised certificate of origin/source/legal provenance; to define the potential characteristics and features of different options as well as to analyze the distinctions between the options and implications of each of the options for achieving the objectives of Article 15 and 8(j) of the CBD. The terms of reference include furthermore identifying associated implementation challenges, including the practicality, feasibility, costs and benefits of the different options, including mutual supportiveness and compatibility with the CBD and other international agreements.

### **2. Purpose of the meeting**

In preparation of the upcoming events, the German Federal Agency for Nature Conservation in collaboration with the Finnish EU Presidency organized a European Regional Meeting on an Internationally Recognized Certificate of Origin/Source/Legal Provenance. The meeting took place at the International Academy for Nature Conservation on the Isle of Vilm, Germany, from October 24-29, 2006.

### **3. Participants and activities**

The workshop was addressed to ABS Experts of the public and the private sector. 42 participants out of eleven EU countries, plus Mexico and Canada supported the meeting with comprehensive presentations, statements and contributions to the discussions. Among the participants there were ABS Experts from the CBD Secretariat, European ministries/ABS National Focal Points, NGOs and several of the officially nominated ABS Experts of the upcoming Technical Expert Group on Certificates. In addition, to bring in any possible practical implications according to an ABS Certificate in time, additionally representatives from the following four user sectors of genetic resources participated as well: ex-situ collections, pharmaceutical industry, seed Industry and academic research.

#### **4. Key issues**

The goal of the expert meeting was to provide and exchange available information on certificates of origin/source/legal provenance to support the negotiation process with technical advice. A certificate could potentially be relevant to the whole chain of the ABS process by bringing more transparency to transactions related to genetic resources and facilitating the monitoring of national ABS laws. However, core issues of this new concept still require a careful evaluation: exactly what should be certified, the relationship of such certificate with the CBD objectives of conservation and sustainable use, its practicality and cost effectiveness, its potential relationship to disclosure of origin requirements in patent applications etc.

Therefore, at the meeting several presentations were held on basic legal and technical information, each highlighting different key aspects such as economic impacts, international law or traditional knowledge. In addition, results of former workshops on the subject such as the Paris Roundtable on Certificates in 2004 as well as different submissions by CBD parties on certificates were taken into account. Other presentations dealt with organisational aspects of a certificate system under a comparative perspective. Participants examined possible synergies between the Standard Material Transfer Agreement under the FAO Treaty, the CITES Certificate System, or the notification mechanism of the Basel Convention as well as the Science Commons Project. One section of the meeting tackled implementation challenges of European governments involving the user sectors of genetic resources within their countries, and the last section gave an overview of implementation challenges of an internationally recognized certificate of some key users. The meeting involved users of genetic resources in order to offer a platform to bring in their views, proposals and concerns at an early stage of the negotiation process.

#### **5. Outcomes**

The meeting was not intended to result in agreed-on outcomes, but helped to more thoroughly tackle a number of issues related to a certificate system. It became clear that while the discussion of certificates is fairly advanced there are still basic questions unanswered. Most fundamentally, the question gained emphasis during the meeting of what the exact purpose of a certificate was, i.e. what problem it should help solving, and to what extent the certificate designs presently under discussion indeed tackled this problem. The issue was also raised whether the present concepts provide sufficient incentives to enhance users' compliance with ABS provisions. A number of presentations showed that in technically designing certificates we can learn from other agreements that have established notification or documentation systems – ranging from the International Treaty on Plant Genetic Resources, to CITES and the Basel Convention on waste shipments.

When discussing implementation challenges for European countries, the value of empirical data on genetic resource use and the need for respective industry transparency were emphasised. The inputs of representatives of various user sectors made it clear that the conditions within the sectors differ substantially, raising the question of whether certificates should be implemented in sector specific ways.

In particular, delimitating non-commercial from commercial uses of genetic resources was considered both necessary and difficult. In the concluding working group sessions, participants highlighted that the discussion on certificates should not preclude development of other solutions or tools, including user country measures. They also developed tentative outlines of a two-tiered certificate system that provides

different procedures for the commercial and non-commercial use of genetic resources. More detailed discussion results can be read up on in the meeting's summary.

#### **6. Documentation of the meeting**

The meeting resulted in the documentation at hand. Its main contents are a summary of the meeting and abstracts of the presentations given. The summary focuses on the discussions that followed the expert presentations; the content of the presentations is available through the respective abstracts. The abstracts contain as final paragraph conclusions or recommendations that the speakers developed with a view to the deliberations of the Group of Technical Experts.

## Summary of the meeting

FRANZISKA WOLFF

Öko-Institut / Institute for Applied Ecology

The following summary is intended to give an impression of the discussions led at the European Regional Meeting on an internationally recognized certificate of origin/source/legal provenance which took place on 24-29 October 2006 on the Isle of Vilm, Germany. Its purpose is not to present any agreed-on positions, as the goal of the meeting was restricted to exchanging opinions. The summary is based on notes of the meeting taken by the author. As such, it may not fully reflect the opinions, concerns, and proposals of all participants. The author has endeavoured to take into account the comments received from participants following circulation of a preliminary draft.

### Opening of the meeting

The meeting was opened by SIMONE IRSFELD from the German Ministry for Environment, Nature and Nuclear Safety and by MARINA VON WEISSENBERG, representative of the Finnish EU Presidency, who welcomed the participants and outlined the upcoming process on access and benefit-sharing (ABS) issues till the 10<sup>th</sup> Conference of CBD parties (COP-10).

### I. Background

In a first session that served to establish the background to the informal expert meeting, MATTHIAS BUCK from the European Commission, DG Environment, gave an overview of the outcomes of COP-8 relating to ABS and summarized the Technical Expert Group's mandate (see Abstract at page 23). Buck stressed that the Group's mandate was relatively broad, also touching upon some genuinely political questions. However, the experts selected for this group and the process of nomination seemed to indicate that parties were truly interested to use this group as an opportunity to engage in the necessary technical discussion.. In the ensuing debate, participants reflected to what extent consideration of the actual need for a certificate was a political as opposed to technical issue. Several aspects of the ABS negotiation history were debated. Among others, it was mentioned that the idea of certificates had emerged in the CITES context and that often the ABS negotiations were seen as politically linked to negotiations on protected areas.

VALERIE NORMAND from the CBD Secretariat gave an overview of issues for consideration in relation to an internationally recognized certificate, based on submissions<sup>1</sup> received by the Secretariat in preparation for the meeting of the Group of Technical Experts (GTE) on an Internationally Recognized Certificate of Origin/Source/Legal Provenance, as well as on available literature and the outcomes of past workshops (see Abstract at page 26). She mentioned that to date seven parties, one non-party and several stakeholders had made submissions. The selection of experts and observers had been concluded and preparations were ongoing for the GTE meeting at 22-25 January in Lima, Peru. In the discussion different aspects of the GTE mandate were picked up. As regards the scope of the certificate and the

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<sup>1</sup> Document UNEP/CBD/GTE-ABS/1/3, available at <http://www.biodiv.org/doc/meetings/abs/absgte-01/official/absgte-01-03-en.pdf>

question to which genetic resources it would apply (resources acquired pre CBD, post CBD, post introduction of the certificate), it was said to be extremely difficult to determine the time when a genetic resource was acquired, while it was easier to establish when it was actually used. A debate emerged on whether there was a need to more clearly define what a genetic resource was. With regard to the potential characteristics and features of such a certificate, participants discussed whether it suffices to control the certificate in user countries or whether ‘checkpoints’ should also be established in provider countries, taking into account that users are also situated in provider countries. Also, a participant underlined that the certificate would best be linked to checkpoints that are immediately related to commercialization. This would not be the case with patent offices, considering that in average only 5-10% of all patent applications lead to a commercial product. Processes to verify certificates would need to take into consideration changes of intent in the use of the resource: a plant may first be accessed as biological resource and only later be used as a genetic resource. Similarly, a genetic resource that is first accessed without a commercial intent may later in the chain be used for commercial purposes. Such changes in form or use can take place already in the provider countries. When looking into the distinctions between the options of certificate of origin/source/legal provenance, the new suggestion of a ‘certificate of compliance’ was noted with interest. However, it was not further gone into what exactly the differences were to a certificate of legal provenance and what implications such a proposal would have.

In order to feed into the present meeting the results of the 2004 ‘Paris Roundtable on Practicality, Feasibility and Costs of Certificates of Origin’ that had been hosted by UNU-IAS, in co-operation with the Institut du Développement Durable et des Relations Internationales (IDDRI) and the Centre for Philosophy of Law, Catholic University of Louvain, CHRISTINE FRISON from the Catholic University of Louvain presented the Roundtables’ conclusions (see Abstract at page 32). In the ensuing discussion, there was agreement that many issues flagged at the Roundtable were still relevant. However, participants who had also taken part in the Roundtable underscored that the Roundtable’s conclusions had not been negotiated and had not generally been consented upon. In particular, the very value of a certificate had been left outside the Paris debate. Also, the question whether or not pre-CBD and pre-certificate material should be included in a system of certificates had remained contentious. As regards the Roundtable’s composition, it was mentioned that the commercial sector had been underrepresented, and that many lessons had been taken from the ex situ sector. In the context of the Roundtable’s debate on the relation between a certificate and WTO provisions, the need was stated to better combine trade and ABS expertise. The question was asked but answered in the negative whether the Roundtable had fleshed out the idea of a multilateral ABS regime, as it is known in the context of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), in the sense of referring to the ITPGRFA’s Standard Material Transfer Agreement as a model for a certificate system.

In his presentation, JOSÉ CARLOS FERNÁNDEZ UGALDE from the Instituto Nacional de Ecología, Mexico, made concrete suggestions for building a system of certificates of origin. In the model, free exchange of genetic resources was foreseen with only minimum ‘book keeping’ standards up to certain checkpoints. Only if such checkpoints were reached, fully-fledged certificates giving evidence of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) would become necessary (see Abstract at page 40). In the debate, a number of participants supported the idea of a ‘free exchange area’ for non-commercial purposes and underlined that a lot of both academic and industrial research did not yield commercial benefits. However, the interface between the free exchange area and commercial use would need to be

clearly defined. The speaker clarified that free exchange would still presuppose that material could be traced back. Advantages and disadvantages of patent offices as checkpoints were discussed, as well as potential loopholes in the system. Ex situ collections and the use of genetic information rather than of the physical resource were mentioned as potential loopholes. Another issue debated was how relevant the differences were between certificates of origin, source and legal provenance, and to what extent they were complementary. While it was appreciated that the system was simple, a critic pointed out that it did not always take into account market realities. In particular, the question was posed what guarantee commercial users would have that, in case the product development promised to become commercially interesting and they needed a fully-fledged PIC/MAT, the country of origin/source would actually issue the certificate.

## **II. Basic legal and technical information concerning certificates of origin/ source/ legal provenance**

The second section of the European Regional Meeting dealt with basic legal and technical issues with regard to certificates of origin/ source/ legal provenance. An introductory talk was given by MIRIAM DROSS from the Öko-Institut, who elaborated the different certificate concepts and related legal issues, in particular trade law (cf. Abstract at page 45).<sup>2</sup> She also entered into the link between certificates and disclosure obligations in patent law and concluded that there were still more questions than answers with regard to both certificates and disclosure requirements. After the presentation, participants agreed that there was a need to be consistent in the use of terms and concepts. A major part of the discussion focused on disclosure obligations. Potential competitiveness impacts of introducing a self-standing disclosure obligation were debated, if other major user countries did not adopt a likewise provision. However, it was pointed out that such concerns seem unfounded: a patent granted in one jurisdiction does not provide protection in other jurisdictions. If a disclosure requirement is established in one jurisdiction, all patents protected under the respective system will be affected. A company that refrains from filing a patent in one jurisdiction will not enjoy protection of its intellectual property in the respective markets. If there were competitiveness effects at all, they would be positive, i.e. in favour of companies operating in markets in which disclosure requirements apply.

TOMME YOUNG spoke on the integration of a certificate into the international legal context and especially on possible uses for and components of a certificate of origin/ source/ legal provenance in a functional ABS Regime. She pointed out that those users who avoided ABS compliance in the first place would not be sufficiently motivated to comply by the presently discussed forms of a certificate system. She hence made a strong point to design certificates in a way so that they constituted an incentive instead of a disincentive for users to comply with ABS (see Abstract at page 48). In the discussion, many participants endorsed an incentive based approach as very promising to tackle non-compliance. However, it was also critically inquired whether such incentives to users, if afforded by provider countries, would not reduce the amount of benefits accruing to the provider countries. Should they be afforded by user countries, a participant pointed out, the incentives might be more effectively spent when directly devoted to biodiversity conservation in provider countries instead of subsidizing users. The need was appreciated to clarify the expectations towards the system of certificates.

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<sup>2</sup> The presentation was based on Dross, Miriam/ Wolff, Franziska (2005): New Elements of the International Regime on Access and Benefit-Sharing of Genetic Resources – the Role of Certificates of Origin. BfN-Skripten 127. Bonn. Available at <http://www.bfn.de/fileadmin/MDB/documents/skript127.pdf>

In her presentation on the economic impacts and implications of certificates of origin, CARMEN RICHERZHAGEN, from the German Development Institut (DIE), summarized open questions with regard to a certificate scheme and suggested a multi-objective scheme to tackle these (see Abstract at page 52). Referring to insights from the economics of information, she suggested that certificates may increase the value of a genetic resource, once passport data, biological information etc. are provided along with the certificate. Participants discussed the value of such biological information and to what extent it might make certificates more attractive for users. It was pointed out that biological information was only obtained in the process of analysing the genetic resource but was not available when accessing the resource.

ANA MARÍA PACON, from the Catholic University of Peru, discussed possible effects of a certificate on the disclosure of origin process in patent applications. Resuming the state of debate on disclosure requirements, she observed that the use of certificates was linked to the same questions regarding the triggers and problems, as in the case of disclosure requirements, but raised some additional questions, too (see Abstract at page 55). In the ensuing debate, an expert stated that disclosure of origin was not usually very costly for patent applicants, referring to the findings of a 1998 survey on disclosure of origin in patent applications using biological source material (cf. UNEP/CBD/COP/4/Inf.30). It was discussed whether the ABS debate would be further ahead if the negotiation of the Bonn Guidelines had focused on disclosure obligations. The debate on disclosure has been developing for some time and there were convergences. A participant stressed that it was now necessary to introduce an international disclosure obligation and to link the international certificate to it.

The next contribution was on implications if a system of certificates was to cover traditional knowledge (TK), and was made by NICOLAS BRAHY from the University of Louven. Brahy distinguished between TK 'in situ' (tacit knowledge in communities) and TK 'ex situ' (codified knowledge in databases). Based on this distinction, he developed his reflections on how a certificate could account of TK (cf. Abstract at page 66). Participants recognized the subject matter's intrinsic complexity. One difficulty discussed was what exactly would be the content of a certificate, and how a certificate could account of traditional knowledge without at the same time bringing the traditional knowledge into the public domain and hence 'devaluing' it. As an alternative to keeping TK secret it was suggested to deliberately putting it in the public domain, e.g. through databases, and claiming rights on it. Databases would facilitate access to TK. At the same time, they would make possible control over such access. Brahy advocated focussing on the protection of those parts of TK for which protection was feasible instead of achieving little progress by aiming at a very broad coverage of TK protection. Another strand of the discussion was about whether the problem of TK misappropriation should not be solved above all in the provider countries, or whether an international approach was preferable.

The presentation by JEAN-FRÉDÉRIC MORIN from McGill University, Canada, concerned the consistency of a certification scheme with international law, and especially the WTO Agreements (see Abstract at page 72).<sup>3</sup> Based on a set of assumptions (namely, that a certification scheme would be mandatory, product based, built on a providers' as opposed to global standards, and would be used for importation rather than patenting), he elaborated that the scheme would be likely to conflict with GATT Art. I, III, XI

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<sup>3</sup> In his presentation, Morin pointed to a respective paper produced jointly with Sélim Louafi from the Institut du développement durable et des relations internationales. It can be found at [http://www.iddri.org/iddri/telecharge/biodiv/certif\\_sl-jfm\\_04-11.pdf](http://www.iddri.org/iddri/telecharge/biodiv/certif_sl-jfm_04-11.pdf)

as well as TBT Art. 2. Morin presented an international regime and a WTO waiver as potential solutions. In the ensuing debate, participants discussed to what extent the basic assumptions were indeed applicable to the concept of an internationally recognized certificate of origin/ source/ legal provenance. Among others, it was argued that the certificate was intended to be an international and not a unilateral approach. A participant inquired whether the nature of certificates of origin was not substantively different from those certification schemes critically discussed in the WTO context, as those generally relate to the quality of a product or its underlying production process (and might hence be constructed as a Product and Production Measure/ PPM standards). The representative of the European Commission pointed out that the hypothetical 'ABS certification scheme' discussed in the presentation deviated from what was currently discussed in the CBD under the heading of 'internationally recognised ABS certificates'. An internationally recognised ABS certificate as currently discussed in the CBD would not raise concerns under WTO law

### **III. Organisational aspects of a certificate system under a comparative perspective**

The third workshop section aimed at conveying lessons from other, partly related policy fields in which certificates, registers, or further control mechanisms are employed. FRANZISKA WOLFF from the Öko-Institut presented the Standard Material Transfer Agreement (SMTA) under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (see Abstract at page 73). The SMTA's function differs from that of a certificate of origin/ source/ legal provenance in that it internationally standardizes access and benefit sharing for specific genetic resources. However, the SMTA 'follows' a genetic resource in a way that is similar to options discussed for a system of certificates. In the discussion, several questions on the International Treaty and the SMTA were clarified, and the relation was inquired in more depth between certificates and the SMTA. One participant saw the major difference between the two documents in that the SMTA was a private contract while certificates of origin/ source/ legal provenance were conceptualized as governmental documents. Despite this difference, several experts perceived the SMTA system as a potential model in that it was clear and comparatively simple. Especially, the multilateral trust account was considered exemplary. The trust receives the benefit sharing payments that are then to be allocated to farmers (as stewards of agrobiodiversity) in developing countries and countries with economies in transition. One participant stated that, although a certificate should not be 'added' to the SMTA, in the long run (sector specific) SMTAs might be considered as an option for ABS under the CBD. It was also stated that there were parallels between the ITPGRFA's ABS system and the 'sectoral' systems that evolve or are being discussed under the CBD (e.g. academia, botanic gardens) with regard to 'free exchange areas'.

IRINA SPOTTE from the German Bundesamt für Naturschutz (BfN) gave an introduction to the existing certification system under the Convention on International Trade of Endangered Species of Wild Fauna and Flora (CITES) (see Abstract at page 86). She explained that a 'certificate of origin' was also one of several CITES documents and elaborated on parallels to and differences vis-à-vis the certificate of origin/ source/ legal provenance concepts discussed in the CBD context. The speaker also mentioned the simplified procedure for the exchange of scientific material. She concluded by drawing attention to the fact that several core terms that are used in both CITES and CBD terminology actually have different meanings, including 'country of origin'; 'source'/'country of source'; and 'derivatives'.



Existing control mechanisms with regard to the shipment of waste and animals were discussed by TILMAN BAEHR from the Ministry of Urban Development and Environment, Hamburg. He set out core provisions of the Basel Convention and described the respective notification procedures and tracking systems for waste shipments. In addition, he briefly outlined the EU system of veterinary and zootechnical checks (Council Regulation 136/2004) (see Abstract at page 90). The discussion focussed on the Basel Convention. A participant inquired whether transactions to third parties needed to be tracked under the system, and Baehr explained that this posed no problem in practice. Regarding the control of whether the declared end use had been complied with, it was explained that the exporting country's obligation ends once the export country confirms that the declared use is fulfilled. When asked whether there was one central registry or decentralised records of competent authorities, Baehr explained that within Germany there were more than 30 different competent authorities. They pass on information to the German focal point which then sends annual reports to the Basel Convention Secretariat and the European Commission. The documentation system is an electronic one, but complex interfaces and user acceptance had caused technical difficulties when the system was introduced. Baehr noticed that the system's effectiveness was impaired by the non-participation of the USA in the Basel Convention.

MATTHIAS BUCK (in his personal capacity) presented his reflections on a Standard MTA for the exchange of biological research material that was currently developed in the context of the so called "Science Commons Project" on. This project aims at lowering transaction costs in the transfer of biological research material through a standardised MTA and by establishing a system that directly and automatically links information on concluded MTAs to a system of information exchange via the internet. Thereby, it will be quick and easy to retrieve and track information on biological research material and associated licensing conditions set out in MTAs.. Buck discussed the implications of this system, which is scheduled to operate by the end of 2006, for an international system to track genetic resources, associated user conditions and traditional knowledge (see Abstract at page 94). In the discussion it was pointed out that once a commercial transaction took place, recipients might still need to get back to the original provider to obtain broader terms of use than provided in the original PIC. Overall, however, the on-line brokerage would make it easier to spot cases of non-compliance. A number of questions were raised relating to potential effects on competition, the link to existing identification systems of genetic resources as well as technical and cost aspects.

#### **IV. Implementation challenges of an international certificate in European countries<sup>4</sup>**

The next session concerned implementation challenges of a certificate of origin/ source/ legal provenance expected to arise for governments in Europe. It was opened by CARMEN RICHERZHAGEN from the German Development Institute (DIE) and KARIN HOLM-MÜLLER, University of Bonn who presented a survey carried out among German users of genetic resources (see Abstract at page 101).<sup>5</sup> A major result was that in general, German users are poorly informed about CBD and ABS regulations. The survey also indicated that use of genetic resources was in most cases targeted towards the creation of marketable

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<sup>4</sup> The talk of SARAH HERNANDEZ (Ministry of Ecology and Sustainable Development, France) on a survey on the economic valuation of the use of genetic resources in France had to be cancelled. The abstract of her presentation, however, can be found at p. 113.

<sup>5</sup> Holm-Müller, Karin/ Richerzhagen, Carmen/ Täuber, Sabine (2005): Users of Genetic Resources in Germany - Awareness, Participation and Positions regarding the Convention on Biological Diversity. BfN - Skripten 126, available at [http://www.abs.biodiv-chm.de/de/data/BfN\\_Skript\\_126.pdf](http://www.abs.biodiv-chm.de/de/data/BfN_Skript_126.pdf)

products, rather than towards non-commercial or basic research. Users did not regard as problematic the costs of benefit-sharing. In the discussion, participants appreciated the usefulness of primary data and called for more such information, especially on users' preferences regarding certificates of origin/ source/ legal provenance. Several methodological questions were raised. Participants also asked whether the researchers had tried to find out why users did not respond to the questionnaire, and one reason given by non-respondents was concern about what would happen with their data. Asked whether they had inquired in the questionnaire about the provider countries of genetic resources, Richerzhagen replied in the affirmative but explained that the question had only rarely been answered. One expert recommended clarifying in the survey the role of botanical gardens as both users and providers of genetic resources.

Following this debate, MILENA ROUNDÁ, consultant to the Czech Ministry of the Environment (UNEP/GEF Project Coordinator) presented the results of two research projects, namely a) a UNEP/GEF project on Biodiversity Enabling Activities which included a survey on the Czech Republic's genetic resources and an analysis of their status, and b) a case study into the legal aspects of ABS in the Czech Republic (see Abstract at page 104). Participants expressed their interest in the Czech examples to share benefits by reintroducing genetic resources such as the Przewalski Horse and the Tarout cypress into their countries of origin, after they had been obtained and conserved in Czech institutions. On inquiry, Roundá confirmed that an overview would be annexed to the projects' report on how different sectors chose to implement the Bonn Guidelines. It was generally acknowledged to be useful to learn what information was needed for ABS capacity building in European countries.

CHRISTINE FRISON from the Centre for Philosophy of Law of the Catholic University of Louvain, and CLAIRE COLLIN, Ministry of Environment, Belgium, presented a survey of Belgian users of genetic resources (see Abstract at page 106). Its main objectives were to assess Belgian users' knowledge of the CBD as well as the degree of adoption of the ABS provisions contained in the CBD and Bonn Guidelines, and to give an overview of the institutional models and practices of genetic resource exchange. In the discussion, the value of empirical data was stressed once again. The question was raised to what extent the survey was overlapping with the German user survey, thus making possible a comparative analysis between the German and Belgian user sectors. While there was no systematic link between the two surveys, Frison confirmed that it would be interesting to make such a comparison, possibly including further surveys from third countries.

## **V. Implementation challenges of an international certificate for key users**

After the previous session had tackled the challenges of implementing an internationally recognized Certificate for state actors, this section served to analyse implementation challenges for users of genetic resources. The user groups included academic research, the pharmaceutical and agricultural/seed industries, and ex-situ collections.

SUSETTE BIBER-KLEMM from the Swiss Academy of Science and SUSANNE REYES-KNOCHE from the German Research Foundation (DFG) discussed the implementation of an international certificate from the perspective of academic research. First, Biber-Klemm presented a good practice compilation on ABS for academic research which the Swiss Academy of Science had published on the basis of a survey and

participatory methods.<sup>6</sup> She described the desirability to design a streamlined and standardized ABS procedure for academic research, and proposed a two tier system. In its first tier concerning academic research it would require a streamlined MTA containing the necessary basic information and agreements regarding academic research only (see Abstract at page 115). Afterwards, Reyes-Knoche presented an overview of the ABS related activities of the German Research Foundation (DFG) and its Committee on Biodiversity Research. The DFG activities go a step beyond rising awareness concerning ABS implementation: the DFG is working on drafting guidelines for researchers applying for DFG funding to conduct biodiversity-related basic research projects abroad. In this context it is being discussed to what extent the applicant has to provide evidence of his knowledge of the provider country's ABS provisions. Already now, funding applications for research projects without the perspective of getting the necessary research permits – including e.g. PIC – are not successful. Like the previous speaker, Reyes-Knoche stressed that a system of certificates should distinguish between commercial and non-commercial research (see Abstract at page 118). In the joint discussion of the two presentations, it was pointed out that basic research was not required to share benefits anyway and that the Bonn Guidelines specified already that material for non-commercial taxonomic research should be accessible on facilitated terms. On the other hand, participants stressed that the lines between commercial and non-commercial research had become blurred as the scientific community was more and more aware of the potential commercial value of their work. They are also increasingly applying for patents even if they are not interested in commercialising results. It was observed that there were intentional 'changes in intent' when research results on genetic resources originally acquired for non-commercial research were sold to companies. However, there were also unintended effects if those research results, once published, were used for commercial purposes without the researcher's knowledge or the provider country's PIC/MAT. An example was given where a company, on the basis of academic information published, had been able to build a molecule which had the same effects as a frog poison described in the publication, without needing to synthesize the poison. It was finally discussed whether it is possible for researchers to come up with an individual solution instead of waiting for obligatory measures from the legislator. A participant suggested that provision of PIC and MAT might not be necessary at the very beginning of the access process, but only once commercial benefits accrue; the previous process could be limited to basic record keeping.

Turning the discussion to industrial users, FLORIAN KERN from SPRU/ Science and Technology Policy Research at the University of Sussex presented an empirical analysis of access and benefit-sharing in the pharmaceutical industry (see Abstract at page 121).<sup>7</sup> On the basis of this analysis, he concluded that voluntary business measures had proven inappropriate to safeguard access and benefit-sharing in the pharmaceutical industry and hence advocated an internationally binding protocol. In the following, the level of ABS implementation in the pharmaceutical industry and the industry's involvement with the CBD processes were discussed. Several participants stated the need to act, should the observations on lacking ABS implementation be correct. One comment questioned the methodology used. An analytical difficulty pointed out by the speaker was the verification of whether companies indeed fully implemented

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<sup>6</sup> Swiss Academy of Science (2006): Access and Benefit Sharing. Good Practice for academic research on genetic resources. Available at [http://abs.scnat.ch/downloads/ABS\\_Brochure.pdf](http://abs.scnat.ch/downloads/ABS_Brochure.pdf)

<sup>7</sup> The presentation was based on Busch, Fabian/Kern, Florian (2005): Governing Biodiversity. The Realisation of Access and Benefit Sharing under the Convention on Biological Diversity, available at [http://dspace.ruc.dk/bitstream/1800/1148/1/Busch\\_Kern+Governing+Biodiversity.pdf](http://dspace.ruc.dk/bitstream/1800/1148/1/Busch_Kern+Governing+Biodiversity.pdf)

national ABS provisions. Voluntary codes, to the extent they existed, did not yet imply that companies actually complied with them. On the other hand, lack of a code or explicit company policy did not automatically preclude that staff actually carried out ABS. Some discussion emerged on the unclear distinction between genetic resources and biological material, and to what extent this unclear distinction obscured whether companies violated ABS or not. Even if companies did not use genetic resources directly, many of them used derivatives, e.g. in synthetic substances. Awareness was another issue raised: while some argued more public awareness would change the negotiation process, others stressed that biopiracy did gain a lot of public attention but still benefits were not fairly shared. A participant highlighted that awareness was not enough to achieve the CBD's objectives. Rather, rules were necessary to correct the market distortions with regard to the public good biodiversity. Some perceived the lack of mandatory legislation in the provider countries as crucial, others the lack of user country legislation.

A pharmaceutical industry input on certificates of origin/source/ legal provenance was then given by IVAN HJERTMAN, from IP Interface AB, Sweden (see Abstract at page 124). The presentation was based on submissions of the European Federation of Pharmaceutical Industries and Associations and of the British Pharma Group. Hjertman assured the audience of the pharmaceutical industry's support for the CBD and its objectives. Clarifying that the mandate with regard to an internationally recognised certificate was not to negotiate but rather to discuss such a certificate, he raised questions to consider in the discussion on such a certificate. In the discussion, participants expressed their wish for more concrete recommendations and more concrete proactive suggestions by the pharmaceutical companies regarding implementing ABS. Instancing red wine, as potentially included in the concept of 'derivatives' of a genetic resource, the discussion sprang up on what triggers or should trigger ABS. A participant underlined that the CBD definition of genetic resources with its reference to functional units of heredity was sufficiently clear. Another expert added that active components were benefits produced on the basis of genetic resources and in his opinion should enter the ABS chain. A further expert called on industry to be more transparent in how they used genetic resources. When asked whether industry would not prefer an international certificate to different national schemes with a view to transaction costs, Hjertman said that any international certificate system needed to allow some national flexibility. A final point raised concerned the pharmaceutical industry's trend of moving away from utilising genetic resources and how this trend might impact on the flow of benefit-sharing.

Representing the ex-situ sector,<sup>8</sup> ANDREAS GRÖGER, from Munich Botanic Garden, and KATE DAVIS, Royal Botanic Gardens, Kew, elaborated the view of botanic gardens on an internationally recognized certificate. Gröger pointed out in his talk that the transfers of genetic resources between botanic gardens in provider and in user countries by far outweighed transfers between botanic gardens and industry users. Nevertheless, those latter transfers needed to be dealt with carefully. He presented the International Plant Exchange Network (IPEN) as one way to handle the interface between commercial and non-commercial use and explained how ABS requirements are accounted for in the IPEN Material Transfer Agreement (see Abstract at page 127). Subsequently, Davis portrayed the use of biological material and genetic resources in large ex situ collections institutions containing a range of specimens<sup>9</sup> and with diverse biodiversity research programmes. Against this backdrop she discussed practical issues and concerns for

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<sup>8</sup> The presentation of PHILIPPE DESMETH (BCCM) on ABS in the case of microbial resources and on the MOSAICS System had to be called off. An abstract is nevertheless available at page 130.

<sup>9</sup> e.g. herbarium and other preserved specimens, frozen seeds and DNA as well as living collections.

collections with regard to certificates (see Abstract at page 139). In the discussion following the two inputs, various technical issues regarding IPEN were clarified, including that IPEN does not distinguish pre- and post-CBD material, i.e. handles pre-CBD material as if acquired after the coming into force of the CBD. Furthermore, the differences between the IPEN Code of Conduct and the Principles on Access to Genetic Resources and Benefit-Sharing were specified: whereas the Principles provide guidance for botanical institutions developing a CBD-compliant ABS policy covering the use of all specimens at the institution, IPEN represents a fully-fledged, CBD-compliant exchange and documentation system for living plant material in particular. IPEN attempts more intensely to fence off botanic garden's use of material from commercial use, while the Principles state that institutions should prepare a transparent policy on commercialisation. The Principles and IPEN are not mutually exclusive. Participants inquired what could be done to increase participation in IPEN and learned that the major problem was lack of resources to promote the system. Costs for joining IPEN merely encompassed the costs of computer documentation and of decision-making. An expert asked whether the DNA sequence databases to which institutions provide sequence data as a requirement when publishing taxonomic analyses could potentially work with this data and take patents out on it. Davis replied that when they sent on information to DNA databases, information linking the sequence data to the country of origin was also supplied (if known). It was pointed out that botanic gardens added value to biological material and carried fiduciary obligations.

KEES NOOME from Limagrain Advanta, Netherlands, discussed potential consequences of a certificate of origin/ source/ legal provenance for the seed business (see Abstract at page 142). While for crops covered by Annex-I of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture individual certificates were not applicable – there was only one ‘origin’: the Multilateral System –, he critically discussed feasibility of a certificate for plant genetic resources for food and agriculture which are not part of the Multilateral System. Participants debated whether a certificate would help to reduce distrust of provider countries and thus facilitate further talks on ABS, or whether the full implementation of national ABS laws should precede consideration of a certificate. Noome agreed with bilateral ABS for crop species which have a single identifiable country of origin but could only consider a multilateral ABS approach for species with multiple countries of origin. In this, he was supported by a participant who advocated promoting the idea of multilateral ABS in CBD context. As regards benefit-sharing, a simple flat-rate approach like that of the FAO International Treaty was discussed where a specific type of commercialisation requires payment of a fixed percentage of the gross sales. It was argued that non-parties would not likewise ‘tax’ their users, so that competition problems between Parties and non-Parties might be expected. Also, allocation of the multilateral benefit-sharing funds was seen as a sensitive issue, and the respective experiences of the FAO International Treaty were considered useful.

## **VI. Summary and way forward**

A final session was dedicated to group discussions on individual issues considered relevant for the conceptualization and implementation of certificates of origin/ source/ legal provenance. Three working groups were established to tackle a) the rationale, objective, and need of a certificate; b) implementation challenges, in particular costs/ minimizing costs and benefits/ incentives; and c) the demarcation of commercial and non-commercial research. The objective of the working group session was to raise questions and impulses for the Technical Group of Experts to tackle, however, without the need for agreement.

The WORKING GROUP ON THE RATIONALE, OBJECTIVE, AND NEED OF A CERTIFICATE was motivated by the fundamental question of ‘why a certificate?’. They felt that as the debates had taken a turn towards implementation and technical questions, the focus on this basic question had been lost. In the session, participants discussed two problems: i) What is the problem that needs tackling, and what are its causes? And ii) What are the means to tackle the problem? With regard to the nature of the problem (i), lacking implementation of and compliance with ABS were seen as the core problem. Various causes of this problem were identified. Legally, a lack was observed of ABS provisions at national level, both in provider and user countries. National provisions were crucial as international treaties such as the CBD did not constitute legal obligations for private users. Even if such national level ABS provisions were in place, they would be difficult or even impossible to enforce. Infringements of ABS provisions by users were seen as another part of the problem. Technically, the problem was seen to be caused by the fact that in some cases there was no single country of origin and by the difficulty to link a genetic resource to its country of origin. Apart from ABS compliance, the weak link between ABS and the other goals of the CBD was identified as a problem. With regard to the second question (ii), the means to tackle the (implementation/compliance) problem, several options were discussed (without any being singled out). One option was implementation of ABS provisions at national level, not only by provider countries but also by user countries. The other option was a multilateral harmonisation of ABS standards at international level. Minimum standards or a model law were seen as possible ways to realise the latter. ‘In-between’ the national and international option, a hybrid regime was outlined which basically kept the bilateral ABS approach but had multilateral ‘niches’ for specific sectors (beyond the niche presently constituted by the FAO International Treaty). A certificate was finally identified as one solution among others. Participants formulated several requirements for a certificate: it should be designed in a way that it transmitted *compliance* data (i.e. compliance with PIC; MAT, and/or Art. 8j); it should also be designed to promote compliance with conservation in situ and hence ascertain the origin of a genetic resource. Questions that the TGE should consider with regard to a certificate included: what is the added value of a certificate as opposed to proving PIC and MAT *without* a certificate? And to what extent can existing documents be used to prove origin/ source (such as phytosanitary documents), for example when a provider country/ country of origin has no ABS laws so that a certificate could not document ABS compliance? It was agreed that the debate on certificates should not preclude development of other solutions and tools.

The WORKING GROUP ON IMPLEMENTATION CHALLENGES, COSTS AND BENEFITS had worked on the question of how a certificate could be cost-effective and create incentives to comply with ABS. In their discussion, they developed a fully-fledged ABS model, based on two different certificates, which would minimise costs. The basis of their deliberations was an assumed ‘typical’ chain of use which started with the collection of material, its transboundary shipment and research on it. These steps were followed by scientific publications, application of IPRs and the commercial introduction of a product. In this chain of use, costs were held to emerge for providers as well as for users in relation with obtaining PIC and MAC, tracing of material, verification of the legal right to provide access, enforcement of a certificate, and identification to ensure a link between certificate and material. The core proposal was to induce the ABS process at the latest possible stage by avoiding any detailed per-specimen tracing of the genetic resources in the stages before. This could only be done if it was agreed in advance what the source of the material was. Access and benefit-sharing would be carried out bilaterally, if there was only one country of origin.

It would be conducted in a multilateral way, if more than one country of origin existed, and the shared benefits would flow into a multilateral fund. The question of whether a genetic resource had only one or multiple countries of origin would be settled through building an inventory of all species per country and comparing the entries. By building such an inventory, the parties would contribute to the implementation of Art. 7 and Art. 17 CBD on the collection and exchange of information on parties' biological diversity. Countries would have a positive incentive to contribute 'their' species to the inventory, as the inventory decided on bilateral vs. 'shared' multilateral ABS. Geographical regions could act as one unitary country of origin. If this was done, none of the costs of tracing, verification and identification would be necessary, as for a given species it would always be clear who is the provider to negotiate ABS with. As regards certificates, the group suggested to differentiate between one certificate or 'permit' necessary for those uses before commercialisation ('permit I' or 'PIC-light'), applied to a batch of specimens collected at one time with the PIC of a given set of providers, in essence a coordinated and simplified collecting/export permit, and one for using a genetic resource commercially ('permit II'). Permit-I would forbid the user to commercialize and to apply for IPRs. For this permit, neither ABS nor the inventory would be needed. Possibly, a fee could be required for access to the genetic resource at the moment of collection, but this would not be an upfront payment for future commercialisation. This permit would be useful for non-commercial uses, e.g. by gene banks, universities, etc. A second permit would be necessary for the next stage, i.e. if/ when a user is interested in commercialisation. Only now the genuine ABS process would start. The inventory would be necessary in order to clarify whether the ABS procedure was a bilateral or a multilateral one and who to negotiate ABS with. Both permits could have a unique number and would be registered in a data base, so that it would be possible to check for them.

When the Working Group presented their results to the plenary, many participants were favourably impressed by the model. Still, a number of critical enquiries were made. Among others, it was argued that an inventory was complex and too expensive for poor countries, especially if those were rich in biodiversity. Funding would need to be provided for setting up the inventory. A participant observed that the model contains a potential to cheat, as companies after the 'permit I' procedure might not apply for 'permit II', i.e. not to carry out the ABS procedure proper, but might still use the information obtained. In reply, it was argued that companies were under a contractual obligation and that there was a normative inclination to fulfil contractual obligations, especially if these were towards governments. If companies violated the contracts, they acted illegal and risked their licence to operate. One expert wondered what would happen if a provider country rejects to give 'permit II' after a company had already invested in product development. It was argued that this would increase the incentive for companies to negotiate 'permit II' early enough. Other experts mentioned that the issue of derivatives and related knowledge still needed to be tackled. Also, the question was asked of how the multilaterally shared benefits would be used; it was recommended to allocate the money to the in-situ conservation and sustainable use of biodiversity, in particular to the local stewards of biodiversity. An expert inquired about the implications of the model for micro-organism inventories, and a further participant asked whether indigenous peoples would have the right to reject access. With regard to the latter question, it was argued that this should be made possible in the permit-I procedure, depending on national legislation.

The WORKING GROUP ON THE DEMARCATION OF COMMERCIAL AND NON-COMMERCIAL RESEARCH had developed a quite similar, two-tier system with special treatment for non-commercial research. They argued that, as a start, it would be necessary to properly define 'research for non-commercial purposes'.

They suggested borrowing the existing definition used in the Uniform Biological Material Transfer Agreement (UBMTA). The regime for research for non-commercial purposes would offer facilitated access through a system of simplified permitting (similar to ‘permit I’ in the above model) and would postpone PIC and MAT till later. Exchange of genetic resources for non-commercial purposes among researchers would accordingly be facilitated. Documentation obligations would be restricted to minimum documentation standards as they are common e.g. in IPEN and MOSAIIC. Benefit-sharing would be non-monetary and could include, among others, the exchange of good practice and cooperation with host country. If a change of intent from a non-commercial to commercial use of the resource occurred, the user would need to negotiate PIC and MAT with the country of origin. At the stage of commercialisation, checkpoints would be necessary at which PIC and MAT would need to be proven. The group pointed out that national laws were necessary to implement this two-tier system. In the discussion, participants praised the focus on sharing non-monetary benefits and suggested to include this aspect into the model developed by the Working Group on Costs and Benefits, too. The major difference between the two models were seen in the latter’s focus on non-commercial exchange and non-monetary benefits.

The meeting was concluded with the organizers thanking the experts for their interesting contributions and fruitful debates.



# I. Background

## Overview of the outcomes of the Eighth Conference of the Parties to the CBD on access and benefit-sharing

MATTHIAS BUCK<sup>10</sup>  
EU Commission, DG Environment

### 1. Introduction

The Eighth Conference of the Parties (COP8) to the UN Convention on Biological Diversity (CBD) took place from 20-31 March 2006 in Curitiba, Brazil. Access and benefit-sharing (ABS) was regarded as the politically most important issue on a very broad agenda, not least, because the government of Brazil, as host of COP8, had publicly made progress on ABS the central criteria for success or failure of COP8.

Negotiations at COP8 had been preceded by the 3<sup>rd</sup> and 4<sup>th</sup> meetings of the ABS Working Group, the group which conducts the ABS negotiations. These meetings had been highly polarised, not allowing for constructive discussions. ABS WG3 had added additional items to an already long list of elements to be considered for inclusion in the international ABS regime.

At ABS WG4 in January 2006, in Granada, the chair made a major effort to push parties towards text-based negotiations. Eventually, she presented a text that, by its title and structure, appeared to prejudge some of the key issues in the negotiations (eg, one or more instruments; binding or non-legally binding character). Few delegations were prepared for this approach. As a result, the chair's text was not negotiated but converted into a long shopping list of square bracketed text that reflects the diverse priorities of parties present at the meeting. Eventually, it was possible to find agreement at ABS WG4 to "transmit" the so called "Granada Annex" to COP8, together with a recommendation that the work of the ABS Working Group should be continued between COP8 and COP9 in 2008.

Against this background, COP8 had to tackle two main challenges:

*First*, it had to decide *which status to accord to the "Granada Annex"* in the future ABS negotiations.

*Secondly*, and closely related, the COP needed to determine *how to continue the ABS negotiations* between COP8 and COP9.

Other important issues to be addressed included:

*Thirdly*, the contentious issue of how to facilitate the effective *participation of indigenous and local communities* in the elaboration and negotiation of the international ABS regime, a task explicitly required in the original negotiating mandate of the ABS Working Group (see Decision VII719, D Paragraph 6).

*Fourthly*, COP8 had to decide on *how to conduct technical work during the intersessional period*, particularly regarding the idea of a certificate of origin/ source/ legal provenance as one potential element of an international ABS regime.

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<sup>10</sup> Policy officer in the Environment Directorate-General of the European Commission. The views presented here are personal and do not reflect official positions of the European Commission.

In the following, I briefly describe how the COP8 decision on ABS (Decision VIII/4) addresses these issues.

## **2. Status of the Granada text**

Central here is paragraph 2 of Decision VIII/4, Section A: The Granada Annex was, without modifications, converted into an annex to Section A of Decision VIII/4 and is transmitted to ABS WG5 "for the purposes of continuing to elaborate and negotiate" the international ABS regime in accordance with the original negotiating mandate of Decision VII/19.

This aspect is a success for parties that had welcomed the chair's text in Granada and in Curitiba. There are, however, two major qualifiers in the decision:

*Firstly*, a non-numbered "footer" to paragraph 2 clarifies that the annex reflects the range of views held by parties at ABS WG4. This gives recognition to the fact that the annex in its current form does not constitute a negotiated document.

*Secondly*, the remaining elements of paragraph 2 all serve to keep the ABS negotiations open and responsive to input from (i) the outcomes of the TEG on the internationally recognised ABS certificate, (ii) a progress report on the gap analysis and the matrix, and (iii) other inputs submitted by parties, such as, for example, information on the status of genetic resources under national law as sought by paragraph 10 of this part of the decision.

## **3. How to continue the ABS negotiations between COP8 and COP9**

Before and at COP8, there was general agreement that the ABS negotiations should be continued. The question was, however, under which terms this should happen. Once views began to converge on the status of the Granada Annex (see above), negotiations on the structure of the intersessional work picked up momentum.

Most importantly, paragraph 6 sets a deadline for the ABS negotiations in the CBD framework. Its finely balanced wording is the outcome of many hours of work. The ABS Working Group is instructed to "complete its work at the earliest possible time before the tenth meeting of the Conference of the Parties", which will likely take place in 2010. I will not dwell on the intricacies of this wording but only emphasise that it reflects a clear and strong commitment by all parties to move the negotiations forward, at rapid pace. COP10 might seem far away today. However, in reality it is very close, given the complexity of the tasks and the few intersessional meetings ahead. Between COP8 and COP9 the ABS WG will meet only twice, the first time from 10-14 September 2007.

Parties at COP8 were conscious of their high level of ambition. To make best use of the two meetings of the ABS WG before COP9, they designated two co-chairs for this group, on the understanding that these will take on an active role during the whole intersessional period, for example, through consultations with key players or regional groups. Beyond this, the COP8 decision provides only few structure or guidance on the organisation of the intersessional work. This is strengthening the role of the co-chairs, as it provides them with a lot of leeway and flexibility on how to move the negotiations forward.

#### **4. Participation of indigenous representatives in the ABS negotiations**

As said before, the original mandate of the ABS negotiations foresees that representatives of indigenous and local communities should be able to effectively participate in the elaboration and negotiation of the international ABS regime. Against this background, much negotiating time and energy was spent on finding a way to enable such participation without blurring the principled distinction between parties and observers in the negotiating process. Eventually, parties managed to adopt a compromise text (decision VIII/5, C paragraph 6 and 7) that "invites chairpersons" in the ABS negotiations to facilitate the participation of indigenous representatives in "proceedings" of the ABS negotiations.

This language provides chairpersons with the necessary flexibility to experiment with forms of indigenous participation that go beyond current practice and gather practical experience on what works and what not. Overall, the decision sends a clear signal that indigenous representatives are regarded as a special group of stakeholders in the negotiations but stays in line with the "CBD-tradition" to base the participation of non-state observers on practice rather than on formal rules of procedure.

The good outcome on this issue as well as the energy and time devoted to it, went, however, largely unnoticed. Not least, because a few indigenous representatives were highly critical of the result.

#### **5. The internationally recognised ABS certificate**

At last, some words on the way in which the COP8 decision refers to the internationally recognised ABS certificate of origin/ source/ legal provenance. Without doubt, this is the most concrete substantive outcome on ABS of COP8.

Over the past three years, there has been quite some academic and political debate about the potential role of such a certificate in an international ABS regime. Before and during COP8, there was a clear sense that parties wanted to look at this potential instrument in-depth, at technical level. There was also no appetite to re-open the respective recommendation coming from ABS WG4 in Granada that recommended to COP8 to establish a technical expert group to look into the pros and cons of different options of a potential ABS certificate. The only discussion that took place on this issue, related to the number of experts that should attend the technical expert group and the process of selecting these experts.

Considering the relatively broad mandate of the certificates expert group, it is comforting to see that the process of nominating and selecting experts went smoothly and without the political problems that some, including myself, had expected in advance. The group of experts selected for this meeting seems well suited to engage in the necessary technical discussion. To me this shows that parties are truly interested in making best use of the opportunity offered by the certificate expert group. This is a promising signal that will hopefully reflect positively on the tone and approach of ABS WG5 in September 2007.

## **Overview of the different submissions by parties on an international certificate for the Technical Expert Groups**

VALERIE NORMAND  
Secretariat of the CBD

### **Abstract**

The presentation gives an overview of issues for consideration in relation to an internationally recognized certificate of origin/source/legal provenance. It is based on contributions received by the Secretariat in preparation for the meeting of the Group of Technical Experts on an internationally recognized certificate of origin/source/legal provenance to be held in Lima, Peru, from 22 to 25 January 2007. Available literature as well as the outcomes of past workshops on the issue of the certificate of origin/source/legal provenance are also taken into consideration. Following an overview of the main developments relating to access and benefit-sharing at the eighth meeting of the Conference of the Parties, the presentation covers issues relating to the potential rationale, need and objectives for an internationally recognized certificate of origin/source/legal provenance; the distinction between the options of certificate of origin, source and legal provenance; potential characteristics and features of an internationally recognized certificate; and finally, implementation challenges, including the practicality, feasibility, costs and benefits of such a certificate system.

## Overview of issues raised in relation to:

- Possible rationale, need and objectives for an internationally recognised certificate
- Distinctions between the options of the certificate of origin/source/legal provenance
- Potential characteristics and features
- Implementation challenges

### 1. Rationale, objectives and need

- To ensure traceability of genetic resources and increase transparency
- To ensure compliance with CBD ABS provisions and access requirements
- To provide legal certainty and predictability for users
- Large variety of users of genetic resources (GR) to be borne in mind

### 2. Distinction between options of certificate of origin/source/legal provenance

#### *Certificate of origin*

- Country of origin of genetic resources possesses genetic resources *in situ* (Art. 2 of CBD)
  - Issued by CNA of country of origin?

#### *Certificate of source*

- Country of origin or countries that have acquired genetic resources in accordance with CBD (Art. 15.3)
  - Issued by CNA of country of origin or source country?

#### *Certificate of legal provenance*

- Evidence that resource accessed in conformity with access requirements of the provider country and in accordance with Art. 15
  - Could only be issued by countries which have established legal requirements for access
  - Combination of these has been suggested

#### *Certificate of compliance*

- New proposal

### 3. Distinction between options of certificate of origin/source/legal provenance

#### *Certificate system and traditional knowledge*

- The issue of whether or not a certificate system should cover traditional knowledge associated with GR has not yet been closely examined

### 4. Potential characteristics and features

#### *Nature:*

- Voluntary or mandatory
  - Some have suggested that it could be voluntary or subject to national legislation
  - Others have suggested that it must be supported by a legally binding regime in order to be effective

## **5. Potential characteristics and features**

*Scope:*

- To coincide with scope of CBD?
  - It has been argued that since many transboundary transfers of genetic resources are outside the scope of the CBD e.g. material accessed prior to entry into force of CBD
  - Consequently, no system of certificates could comprehensively cover all transfers of GR

## **6. Potential characteristics and features**

*Scope:*

- Will the certificate apply to a genetic resource acquired after the CBD came into force but before the new system is implemented?
- Will the certificate apply to genetic resources found in countries which have not regulated ABS?
- How can genetic resources covered by the system be distinguished from GR that are not?
- Will biological materials, such as chemical extracts and essential oils, be freely useable without a certificate?

## **7. Potential characteristics and features**

*Scope:*

- Will the system cover genetic resources and knowledge/information derived?
  - Some argue that certificate could only be attached to physical property
  - Others argue that it should apply to GR and information or knowledge derived from these resources

## **8. Potential characteristics and features**

*Scope:*

- Will the system cover genetic resources and knowledge/information derived?
  - Some argue that certificate could only be attached to physical property
  - Others argue that it should apply to GR and information or knowledge derived from these resources

## **9. Potential characteristics and features**

*Scope:*

- Will the system cover traditional knowledge associated with genetic resources?

## **10. Potential characteristics and features**

*Form*

- Paper, code, virtual online system?
- Internationally recognised format – not necessarily standardized
- Simple, homogeneous, practical
- Security measures for the verification of its authenticity
- Easily verifiable
- Entail low administrative costs

## **11. Potential characteristics and features**

### *Information contained in the certificate*

- Particulars of provider and user and ILC
- Country of origin, user country
- Details of GR or TK
- Details of approved use of GR and restrictions on use
- Period of the agreement
- Conditions of transfer of rights to third parties
- Details of issuing authorities
- Taxonomic identification
- Issuing date
- Information for the identification of the material

## **12. Potential characteristics and features**

### *Subject matter*

- Access contract, collection activity, all samples of a specific species, individual sample?

## **13. Potential characteristics and features**

### *Process*

- Issued by competent authority of the provider country at time access is granted if requirements met
  - Basic common requirements to be developed
- Verified at check points or controls in user countries
- To accompany genetic resource and derived info or only the genetic resource

## **14. Potential characteristics and features**

### *Controls*

- Border
- Commercial
  - Patent offices
  - Registration points of other commercial application processes
- Non-commercial
  - Publication of scientific papers
  - Applications for research funding

## **15. Potential characteristics and features**

### *Institutional measures*

- National
  - Establishment of CNA and institutional mechanisms
  - Establishment of mechanisms of verification and monitoring in user countries
- International
  - International registry containing info on all certificates issued could serve as CHM

- Certificates issued notified and entered in database

## 16. Potential characteristics and features

### *Compliance*

- Mechanisms of sanction and compensation to address situations of non-compliance
  - e.g: User does not obtain certificate or contravenes obligations attached to the certificate

## 17. Implementation challenges

### *Benefits*

- Greater transparency, legal certainty and mutual trust between providers and users
- Evidence that GR obtained with PIC of CNA in provider country
- Facilitating the application of user measures
- Creating incentives for compliance with ABS requirements of provider countries
- Facilitating monitoring of ABS arrangements through the establishment of a central registry or CHM

## 18. Implementation challenges

### *Costs*

- Difficult to assess, may impact differently on different institutions
- Costs related to establishment of infrastructure at national and international levels
- Steps to minimise costs
  - Using existing tracking procedures
  - Using existing human resources, infrastructure and control points
  - Minimising creation of new levels of bureaucracy
  - Promoting consolidation of existing permitting requirements with any new certificate system
  - Promoting paperless system
  - Establishing minimum standard requirements for issuance of a certificate

## 19. Implementation challenges

### *Feasibility, practicality, costs and benefits*

- Pilot projects country and sector-based
- Fact based assessment of:
  - Volume of materials covered by such a system
  - Life-cycle analysis of specimens and certificates
  - Models for developing electronic certificates
  - Legal impediment to adopting this in individual countries
  - Personnel and system needs for both users and providers to implement and maintain the system.



## **20. Implementation challenges**

*Compatibility with other international agreements, such as*

- FAO ITPGRFA
  - WTO Agreements
  - WIPO Conventions and Treaties
- Will depend on the scope, design and application of such a system

# Conclusions of the Paris Roundtable 2004 on Practicality, Feasibility and Cost of Certificates of Origin

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## Report of the 2<sup>nd</sup> Paris Roundtable on ABS Governance, 9-10, November 2004: Practicality, Feasibility and Cost of Certificates of Origin<sup>12</sup>

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The 2<sup>nd</sup> Paris Roundtable on ABS Governance, held from the 9-10 of November 2004, brought together over fifty experts from states, international and regional institutions, academia, NGO's and civil society to discuss the issue of certificates of origin and their practicality feasibility and cost as a tool for ABS governance. The roundtable is the second annual roundtable on ABS governance organized by the Biodiplomacy Initiative of the United Nations University – Institute of Advanced Studies (UNU-IAS), the Institut de Développement Durable et des Relations Internationales (IDDRI), and the Centre de Philosophie du Droit, of the University of Louvain (CPDR), as part of their collaborative research and outreach ABS Governance Program (discussed further below).

Proposals for establishment of an international standardized system of certificates of origin to document genetic resource transfers are attractive due to their apparent simplicity. However, if certificates are to play a significant role in international ABS governance they will need to be a part of a simplified and transparent permitting system for access which links access with mutually agreed terms on benefit sharing; secures traceability in the flow of genetic resources, including transfers to third (and subsequent...) parties; provides mechanisms for ensuring accountability and enforcement of ABS rights and agreements; and facilitates the monitoring and prevention of illicit commercial and industrial use.

Some of the key questions facing regulators include the potential nature and scope of any regime; whether any regime should be of origin, source or legal provenance, or any mixture of these; how to deal with pre-CBD and pre-certificate collections; and how to avoid undue restrictions of basic research. Development and implementation of any certification system will require attention to divergent uses and users of genetic resources and to a range of potential providers of resources and associated knowledge, and further research into the implications of certification for protection of rights over traditional knowledge.

### 1. Introduction

The 2<sup>nd</sup> Paris Roundtable on the Governance of Access and Benefit-Sharing (ABS) organized by United Nations University-Institute of Advanced Studies (UNU-IAS), the Institut du Développement Durable et

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<sup>11</sup> While Christine Frison presented conclusions of the Paris Roundtable at the European Regional Meeting, the below report was written by Tom Dedeurwaerdere (CPDR), Sélim Louafi, (IDDRI), Carmen Richerzhagen (UNU-IAS), and Brendan Tobin (UNU-IAS).

<sup>12</sup> This summary is based upon the notes of the rapporteurs and authors. The summary is further informed by the comments of participants on an earlier draft of the summary. It is not however a consensus document and does not necessarily reflect the opinions, concerns or proposals of all participants.

des Relations Internationales (IDDRI) and the Centre for Philosophy of Law (CPDR), Catholic University of Louvain was held from the 9-10 of November 2004 at UNESCO in Paris. The roundtable, which focused on the practicality, feasibility and costs of certificates of origin, was chaired by Professor A. H. Zakri, Director of UNU-IAS and Laurence Tubiana, Director of IDDRI.

The Paris roundtable brought together a wide range of experts from both developed and developing countries working on the issue of ABS governance, regulation of biological resource flows, intellectual property rights (IPR) and trade, including representatives of national governments, the European Union, the Group of Like-Minded Megadiverse Countries, industry, international organizations including the World Intellectual Property Right Organization (WIPO), the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and the World Customs Union, representatives of indigenous peoples and non-governmental organizations as well as experts from academia.

The Paris roundtable was divided into four sessions focusing on:

1. The potential role of certificates of origin in ABS governance,
2. Challenges in developing an international certificate of origin system,
3. Certificates of origin and disclosure of origin, and
4. Certificates of origin and international trade rules.

Interest in the potential role of certificates of origin in the development of any international regime on ABS has increased since the 7th Conference of the Parties (COP VII) of the Convention on Biological Diversity (CBD). A number of research projects are now under way to prepare reports on this issue with a view to informing the work of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing in 2005. These include a study on the role of certificates of origin initiated by the German Federal Environment Ministry and the Federal Agency for Nature Conservation as well as work by the Smithsonian Institution, which was presented at the roundtable. Likewise, IDDRI prepared a preliminary report on the relationship between certificates of origin and WTO. Copies were distributed at the roundtable. A special issue on ABS, including the issues of certificates of origin and traditional knowledge, has been prepared by CPDR and will be published in *Ecological Economics* in spring 2005.

UNU-IAS has prepared a comparative study of procedures for documenting collections of biological and genetic resources in a number of major herbaria, genebanks, museums and microbial collections, with case studies from the Royals Botanic Gardens Kew, the Smithsonian Institution, the Instituto Nacional de Biodiversidad (INBio) in Costa Rica, and a number of microbiological collections. The preliminary results of this study highlighted the opportunities and difficulties of documenting genetic resource flows.

## **2. The potential role of certificates of origin in ABS governance and experiences in certification**

The rationale for a certificate of origin is to build bridges between national and international jurisdictions as well as between providers and users of resources. Certificates of origin can potentially provide evidence of legal title to use resources, simplify and harmonize existing ABS procedures and ensure compliance with ABS law and policy. As an instrument of a traceability system certificates of origin can help to monitor the trade and movement of resources and discourage unapproved and illegal use of genetic resources.

During the workshop it was argued that one economic justification for certificate schemes was their ability to provide legal certainty for user of genetic materials for those doing the expensive and lengthy process of commercial research and development. By increasing the certainty of their value, a certificate scheme would create incentives for the provision of genetic resources, create a known link to benefit-sharing provisions, and support conservation. It was also suggested that a certificate of origin can convert simple commodities into differentiated products through the provision of information to users.

A well developed certificate system has the potential to facilitate access if it reduces the number of permits and forms needed for research, collecting, and export. Existing procedures for these activities involve approval processes and permitting procedures involving numerous steps and ministries in most countries.<sup>13</sup> This complex system creates numerous entry points and potentially inconsistent benefit-sharing concerns and obligations.

However, most requests for access to genetic resources are not for commercial purposes. As a majority of genetic and biological resource use is not for commercial industrial purposes, for example 95% of resource use in Mexico is for basic non-commercial research, it is necessary to ask whether a certificate system will add to the bureaucracy and costs of managing ABS systems or help to rationalize it. If it is the latter this will require political will in provider countries to streamline processes and overcome existing tensions amongst government departments for control over access issues.

Experience in CITES and the World Customs Organization suggests that a computerized, paperless and centrally administered system would be preferable. CITES are currently examining how to move from a system of authorized signatures/seals, special paper or stamps to an electronic system. One concern, of course relates to how to support such a system. If there were a means for cost recovery for certificate administration by provider countries, these costs should not be so high that they will serve as a disincentive for basic research, which forms the vast majority of all access requests.

Unlike in the case of CITES the material covered by a certificate may change substantially during research and development activity through processing, breeding and refinement. This makes the transfer of certificates a potentially difficult process. Flexibility within the scheme is needed to adapt to changing circumstances.

Experience in CITES also emphasizes the need for capacity-building, awareness raising and consideration of security issues. These concerns will have to be addressed should a certificate system be developed.

It was pointed out during the roundtable that promoting more value added research and development activities in provider countries would make it easier to certify the resources being accessed. This issue linked helped to highlight the fact that any certification scheme is only one tool amongst a range of potential measures which together will make up an international ABS regime.

### **3. Challenges in developing an international certificate of origin system**

The concept of ABS promoted by the CBD poses some serious challenges for policy relevant research. Indeed, it combines in one framework issues of conservation of biological diversity and issues of equity and property rights, which are usually dealt with in separate disciplines and regulated in distinct political

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<sup>13</sup> The different steps include (but are not limited to) overall research permits, collecting permits, use permits (Material Transfer Agreements), movement and export permits.

institutions. So any progress on the creation of a system of certificates of origin that could foster the implementation of the ABS requirements depends on furthering fruitful collaboration between disciplines and involvement of relevant stakeholders in the discussion.

Users of genetic resources from the public sector stressed that a system, whether involving certificates or other mechanisms, needs to ensure traceability, transparency and tractability in order to be effective. Any system needs to protect the interests of resource providers without being restrictive and preventing desired flows of genetic resources for scientific purposes linked to the conservation and sustainable use objectives of the CBD. Participants noted the importance of access to genetic resources for food security and the need to create commercial opportunities from which benefits may flow.

One challenge will be how to develop a clear system that provides certainty for all new genetic resource collections and flows, while finding acceptable mechanisms to support the transboundary movement of both pre-CBD and pre-ABS collected specimens, each which are bound by different obligations. One possible model that would develop this type of comprehensive coverage would be a creative use of Certificates of Origin (for new collections), Certificates of Source (for pre-CBD materials) and Certificates of Legal Provenance (for post-CBD, pre-ABS materials).

From an economic point of view the balancing of costs and benefits of a certificate system seems to be the major challenge. Put simply, the transaction costs should not outweigh the potential benefits. The costs of documenting resources and implementing a regime to monitor resource flows need to be carefully evaluated, especially as the vast majority of resources being collected will never become the subject of research for commercialization purposes. Placing onerous requirements for certificates at the point of collection could then prove counterproductive both for science and for providers of resources who could find themselves with large administrative costs.

Our dilemma is that while some collection activities are carried out for the express purpose of commercially oriented research, in which cases certification of compliance with ABS regulations would be relatively simple, there are many cases where material initially collected for basic research is later requested by third parties for use in commercially oriented research. If certificates are only required for commercial research, then such users will need a mechanism to either apply ex post facto for a certificate or find that their costs of demonstrating rights to use resources may be prohibitively high at the end of the commercialization process.

If on the other hand certification at source is required for all collection activities, there is a danger that the costs of maintaining such a system may fall disproportionately on scientific users and provider countries. The result could be the virtual subsidization of the private sector through provision of a scheme to ensure legal certainty for use of genetic resources funded by non-commercial users and providers. The challenge therefore is to find the optimum balance of rights, responsibilities and costs between certification at source and the responsibility to demonstrate rights to use resources.

One proposal suggested that a certificate could accompany genetic resources like a passport through their entire history from collection to use, but the obligation to produce a certificate would only arise only at specific trigger points, such as for transboundary movements, patent and product approval authorities as well as the international depository system within the Budapest Treaty. Participants noted that in order to

determine the viability of any system it will be important to consider where possible the use of existing infrastructure, human resources and existing checkpoints,

Some participants highlighted the existence of significant practicalities that need to be considered reflecting the reality of biodiversity research that have important implications for determining the feasibility, practicality and the cost of either a “passport” concept or others. Examination of these issues will require careful mapping out of how research and commercialization processes actually occur, with full and active participation of the scientific and private sectors, as well as administrative bodies, resource providers and other stakeholders.

The workshop highlighted the importance of a bottom up approach to governance. In the current context of the crisis of the system of multilateral governance it is important to have stakeholders more involved. The commitment of industry associations and research institutions to the building of a system of certificates of origin is seen as a key element in reaching acceptability. Indeed, for efficient and legitimate governance of a system of certificates of origin one has to look beyond the law, in direction of the network of institutions on which the implementation will depend. Institutions such as national focal points, traditional knowledge registries as well as experimental contractual and licensing schemes as those suggested by the creative commons are examples of steps in that direction.

From the legal perspective there are many questions regarding the regulatory framework which have to be answered. For instance, what can be certified? Will it be the gene, sample, species, or batch which is certified, or should the certificate be of a defined collection activity or of all the collections made under a specific bioprospecting agreement? Who can issue a certificate? Will it be a national authority, and if so will there be the political will to designate a single authority or will there be multiple authorities granting certificates? Who can certify rights to use traditional knowledge? When would obligations to provide a certificate terminate? How would compliance be enforced? Will disclosure of origin requirements in patent or product approval procedures be a sufficient enforcement and control instrument to enforce a certificate system? The status of pre-CBD collections for the purposes of any certificate system is another complicated matter, which has to be resolved.

Pilot studies (country- and sector-based) should be promoted to assess the feasibility of certificate of origin systems in countries with different infrastructure and evaluate further commercial practices and systems including those of intermediaries and end users of genetic resources. However, concern was expressed that we cannot postpone the development and implementation of ABS tools, but should go ahead in the modeling of a certificate system to test for tractability, recognizing that there are many practical and cost implications still to be understood. Development of any certification system is therefore likely to be an ongoing process allowing for review and modification in order to respond to the needs of both providers and users.

#### **4. Certificates of origin and disclosure of origin**

Disclosure of origin requirements are being adopted into law both in developing and developed countries to attempt to include the concerns of the evolving access and benefit sharing regime. A variety of measures have to date been employed with a view to restore the balance between public and private law, and rebalance patent law to meet social as well as commercial ends. Certificates of origin were originally proposed as a means to support a disclosure of origin regime, by providing evidence of a right to use

resources for specified scientific or commercial purposes. Certificates it was suggested during the roundtable would help to simplify the role of patent authorities in determining questions regarding compliance with disclosure requirements relating to the origin/source/legal provenance of resources in any IPR application procedure. Existence of a certification scheme would not prejudice rights to provide the source or origin or legal right to use resources by other evidence, such as ABS contracts, scientific collection permits allowing for commercial use, etc.

There is a need to distinguish between disclosure of origin requirements in intellectual property law and any system for proof of origin and most importantly of the right to use resources and of the equitable sharing of benefits.

Certificates of origin might perhaps be integrated into the existing system of requirements for disclosure of information in the patent system. In such a case proof of origin or right to use resources could come from a certificate issued by the competent authority of the country providing the resources.

According to the experts and countries promoting disclosure requirements such as Belgium, Switzerland and Norway, such disclosure of origin requirements are compatible with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in a system where

- disclosure of origin is only a formal requirement for patent application (and not a substantive criteria for patentability, which determines the eligibility of the invention such as novelty),
- the disclosure obligation only holds if the origin is known (so no requirement that the patentee has to do further research on the origin),
- and where the sanctioning mechanisms lie primarily outside the patent system (for example a system of fines for commercialization on basis of non certified genetic resources or financial advantages for the certified ones)

Sanctions outside the patent system for non-compliance with disclosure requirements could include criminal and civil sanctions. By placing sanctions outside the patent system penalties can be imposed without paralyzing research and development activities. In some cases sanctions might require the transfer of rights over a patent to an aggrieved party, in particular an indigenous or local community whose knowledge had been appropriated. Developing countries such as the Andean community have developed more rigorous requirements on disclosure with sanctions which fall within the patent system. The Swiss proposal for amendment of the PLT and for incorporation of disclosure requirements into Swiss law also allows for a sanction within the patent system by enabling an application to be denied. These systems have not yet been tested in courts of law.

As many commercial uses of genetic resources are non-IPR related any system must consider a range of regulatory and non-regulatory procedures for ensuring benefit-sharing in product development and commercialization. If certificates are required for patent application procedures there is a question over what should happen with pre-CBD collections and pre-certificate resources. Proposals for a comprehensive certification regime covering both pre and post CBD material could help to resolve this dilemma. However, the status of collections, and the legal right to provide material for commercial use would require an extensive research into contractual rights pertaining to material collected pre-CBD or pre-certificate, or a multilateral agreement on the status of all such collections.

## **5. Certificates of origin and international trade rules**

Voluntary certificates do not raise any conflicts with international trade rules. The case of mandatory certificates is different and a number of key issues need to be considered. For example what is the subject matter of transboundary movement of genetic resources or products including genetic resources? It may be very complex if obligations extend to products which incorporate genetic resources. Another important issue relates to where compliance is being required, i.e. in the provider or recipient/user country. If it is in the user country it is more complicated and may violate WTO rules, however, there is need for care not to artificially construct a link to WTO and Process and Production Method (PPM) regulations. If there is national legislation in the provider country then requiring compliance with such legislation in the user country is less problematic. In the absence of national legislation in provider countries there is a need for an international system.

Building an international consensus for a certificate regime is important for ensuring it does not become the subject of attacks under WTO. WTO members could adopt an authoritative declaration that a certificate system was held to fall within the ambit of GATT Article XX (The General Agreement on Tariffs and Trade). It is not necessary to consider WTO as an opponent of the CBD. Any system should be designed with a view to functionality and practicality without unnecessary impact on trade. A multilateral regime is probably the most appropriate to overcome potential concerns with regard to WTO and to cover for countries which do not have relevant national legislation.

## **6. Traditional knowledge and certificates of origin**

Concerns were raised regarding the lack of clear recognition of the rights of indigenous peoples over their traditional knowledge and the lack of necessary mechanisms to ensure that access to traditional knowledge conforms to customary law and practices of indigenous and local communities.

A system of certificates of origin could serve as an interim measure to help protect rights over traditional knowledge, in particular where associated with a system requiring the disclosure of origin of traditional knowledge and of prior informed consent for its use as a condition for processing patent and other IPR applications. The manner for ensuring that certificates of origin for resources associated with traditional knowledge had been approved by relevant indigenous and local communities is a question requiring further consideration. Any proposals for establishment of a certificate system which involves traditional knowledge will need to be developed with full participation of indigenous peoples and local communities.

## **7. Conclusions**

A certificate of origin scheme offers opportunities for creating economic incentives for the conservation of biological diversity by increasing the value of the resource. It has the potential to support the CBD's objectives and to facilitate the exchange of genetic resources by tracking flows, providing evidence of legal title to use resources, simplifying and harmonizing existing ABS procedures and promoting compliance with ABS law and policy. The apparent simplicity of certification masks a potential for complexity and further bureaucratic, monitoring, compliance and other cost implications for both users and providers, if not carefully thought through. It also carries with it the possibility of creating highly charged inter-sectoral conflicts within provider countries, where rationalization of procedures brings with the potential for loss of power and income.



Clear objectives of a certificate system have to be identified and formulated to establish the basis for an effective system. Objectives have to be linked to the conservation objectives of the CBD and address trust, transparency, traceability, and tractability.

A certificate system has to be cost-effective. Increased and expected benefits need to outweigh transaction costs arising out of the system's implementation. The use of existing infrastructure, checkpoints and human resources as well as the avoidance of increased bureaucracy and administrative complexity should guide the development of any system. What is required is a simple and flexible scheme which can address the nature of genetic resources in the innovation process and can be used by different stakeholders for different purposes, e.g. in material transfer agreements, in patent applications or in the process of product approval for commercialization. Any system should be designed without unnecessary impacts on trade to avoid any conflicts with the WTO.

A certificate of origin scheme will need to consider and balance the heterogeneity of users and providers of genetic resources by addressing the interests of the research community, the business community, local and indigenous communities and provider countries. The approach has to be developed with full participation of all stakeholders. Only then it can protect the interests of resource providers, in particular with regard to traditional knowledge, without being restrictive and preventing desired flows of genetic resources.

A certificate system will need to meet these challenges if it is to provide a viable mechanism to effectively support the ABS objectives of the CBD and advance the development of an effective international ABS regime.

# The implementation of access and benefit sharing (ABS) regimes for genetic resources

## A minimalist look from the other side of the mirror

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### 1. Abstract

The central problem of effective implementation of the provisions of the CBD regarding ABS is a relatively straight forward one: conserving genetic resources is costly and those using them should contribute to both their conservation and enhancement of their value. Implementation of this apparently uncontroversial goal, however, has been complex. Shortly after the ratification of the CBD, several countries adapted their legislation to implement the Convention's provisions regarding access to genetic resources and their number, although still limited, has been growing over the years. The degree of specificity of these regulations has varied enormously, from those that are mere reiteration of the basic CBD provisions to fully fleshed regulations with detailed processes and requirements.

Two aspects are particularly noteworthy in this implementation process. First, most legislations tend to be based on a linear conceptualization of the process from access-utilization-benefit sharing that has little relevance in real applications. There is little or no reference to practical implementation problems such as the status of ex-situ collections, of pre-existing mechanisms of exchange of genetic resources, nor means to address the diversity of ways in which genetic resources are used in different industrial sectors. The above in addition to problems associated with the uncertainty of success in these industries and the fact that multiple genetic resources may contribute in complex ways to a single invention/product. This oversimplification implies that legal utilization and benefit sharing obligations can only happen for fully vertically integrated projects which start from the point of collection and which could foresee commercial utilization of such resources.

The second aspect is that only those countries that saw themselves as *net* beneficiaries from such a system decided to pass implementing legislation, namely, those that perceive themselves as *net* providers of genetic resources. These two developments have resulted in an inviable and ineffective way to implement the CBD's third objective. It is often the case that genetic resources are being utilized *prior* to obtaining legal access, mostly through non-commercial scientific research, thereby escaping the ABS provisions and, once the research and development process has concluded and genetic resources have been studied, collected and redeployed in new uses, there are little incentives to adhere to ABS principles. There are many reasons for this lack of interest:

- Utilization often occurs in countries other than the country of origin with no clear obligations for *users* of genetic resources to comply with ABS provisions and share benefits

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- It is difficult to trace back the origin of genetic resources due to lack of coordination in recordkeeping and documentation practices (different actors record different things)
- Increasing complexities in contractual arrangements in the R&D chain make it difficult to perform due diligence with regard to ABS obligations
- Little awareness of ABS obligations in both academic and industrial community
- Once information has been derived from genetic resources value of new access is zero (Arrows' information paradox)
- Biotechnological products tend to use genetic resources in the process of development or indirectly, by exploiting information derived from them, making it difficult to establish a link between genetic resource-end products

Therefore, both the link of utilization to access and the lack of measures in *net* users of genetic resources have created a situation in which those utilizing genetic resources have had incentives not to comply with ABS principles. This perverse situation will be worsened as more *net provider* countries pass legislation under the principle that access cannot be separated from utilization. At the same time, countries with higher proportion of *users* than *providers* under their jurisdiction perceive themselves as *net* losers of any effective system and face a strong lobby from their users not to change their legislation. The result is the critical failure of the ABS system. The source of the basic failure stems from one basic fact: utilization is not being regulated, except when it is directly linked to access. In other words, the central and most direct requirement of CBD is being ignored: the requirement to share benefits from utilization in a just and fair manner whenever and wherever genetic resources were utilized.

There is no impediment for countries to pass legislation obligating their *users*, regardless of the point of access, to comply with the CBD. In fact, this is already being called for in the Bonn Guidelines. Implementation of so called *user measures* remains a central piece of the International Regime for ABS. We need to start implementation of ABS provisions exactly at the opposite end of what is current practice: deal with utilization first and move back to access. This approach is taken up in the next section.

## **2. A minimalist International Regime?**

Imagine you are the representative of a government and are asked to prepare a proposal to implement the third objective of the Convention. Imagine for a moment that your county only has users of genetic resources. The most likely thing you would do is to identify your main *obligations* that emerge from the CBD.

Basic *user* obligations:

- a) Benefits arising out of the *utilization of genetic resources* must be shared in a fair and equitable manner, including (1) by appropriate access to genetic resources, (2) by appropriate transfer of technologies and, (3) by appropriate funding (Article 1)
- b) Endeavor to carry out scientific research based on genetic resources provided by other Contracting Parties with the full *participation* of, and where possible in, such Contracting Parties. (Article 15(6))

- c) Take legislative, administrative or policy measures 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....where necessary through the financial mechanism. (Article 15(7))
- d) Provide and/or facilitate *access for and transfer to* other Contracting Parties of *technologies* that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not use significant damage to the environment... where necessary, in accordance with the financial mechanism. The above under fair and most favorable terms, in the case of technology subject to patents, transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. (Article 16 (1-2))

From these obligations, it is clear that nothing prevents the creation of regulations aimed at sharing benefits, including technologies and results from research, as well as the creation of incentives for carrying out research in countries providing genetic resources as a separate body of requirements from those of access. This is the system that is lacking and is needed. By targeting on the utilization end, the regime would be vastly more efficient, since only those resources for which there are some actual benefits to be shared would be regulated, while the remaining genetic resources could be regulated through the existing permitting systems for wild collections with minor amendments to ensure sharing of results of research. In essence, the proposed system would have the following components:

1. Internationally agreed:
  - a) Operational definitions of what constitutes *utilization*
  - b) Certificate *codes, databases* for access permits and minimum *checkpoints* as well as documentation standards
  - c) *Mandatory standard benefit sharing provisions* for genetic resources of complex origin (mandatory) or those of unknown origin but covered by CBD
  - d) *Voluntary standard benefit sharing provisions* for genetic resources not covered by CBD (e.g. *ex situ* pre-CBD collections)
  - e) Operation rules for use of the financial mechanism (for those resources without specific origin)
2. Nationally implemented:
  - a) Checkpoints for genetic resources
  - b) Incentives for compliance by individual users
  - c) Linkage of existing permitting systems to the certificate
  - d) Simplification of access permits by the use of default conditions such as “no *utilization* allowed without mutually agreed terms for benefit sharing”

Note that, under this system, a user of a genetic resource of known origin would have to negotiate the terms for the sharing of benefits with the Party providing such resources or else adhere to the Mandatory standard benefit sharing provisions. This, however, would only happen when and only for cases where successful genetic resources are found, thereby minimizing the administrative burden at the moment of access.

To further simplify the administrative costs, the means by which a private agent would prove that benefit sharing agreements are in place would be through the presentation of a consistent and valid Certificate *code* at the checkpoint. The Certificate record in the database would indicate if a benefit sharing agreement is in place. It is here that the idea of an internationally recognized Certificate of origin/source/legal provenance finds its rationale as a mechanism to facilitate verification of compliance with ABS provisions. Careful design of the checkpoint is necessary to ensure that by the time that *results* have been derived or *benefits from utilization* have been realized, the relevant contracting Party has been identified and terms for the sharing of the benefits have been negotiated.

The Certificate would therefore constitute the minimum piece of information, ideally a *code*, that must be maintained by those accessing genetic resources and that can be passed along to subsequent users to assist in the identification of the relevant Contracting Party providing such resources. To the extent that products *utilized* genetic resources as part of their process of research and development in a sufficiently substantive way so as to trigger the benefit sharing obligation, they must be able to trace back the relevant certificate or certificates of origin.

Finally, the system would allow for compliance with the *facilitation* obligations by eliminating the need for complex requirements at the point of access.

Furthermore, by constructing a system in which the utilization of genetic resources of unidentifiable or complex origin, as well as the simplified voluntary adherence mechanisms, allows to give greater transparency to the transactions, minimize loopholes in the regime and result in greater benefits being captured.

### **3. Conclusions**

There is a need to review the current model for implementing ABS provisions within the CBD and concentrate regulation at the utilization end, rather than at the access point. In fact, access conditions should be facilitated, while the loopholes through which *utilization* of genetic resources can occur without sharing benefits must be closed.

In the development of such a system, the Certificate of origin/source/legal provenance can further contribute to the transparency and reduced costs of the system. Overall, this would result in a truly minimalist regime.

### **4. Concluding statement/ recommendations to the Group of Technical Experts**

In the light of the preceding discussion, the following are recommendations for the work of the Group of Experts:

- Develop working operational goals for the overall International Regime to assist in assessing different Certificate proposals

- Consider several alternative designs of the Certificate, but always contrasting their desirability in terms of their contribution to the operational goals defined above
- Assessment of desirability and costs must be done in relative terms, i.e. it is no use saying that certificates are costly or not, but if they are *more* or *less* costly than other alternatives.
- Consider the Certificate in the context of complementary *packages* of policies, the Certificate won't resolve all problems.
- Be mindful of the implications of emerging new technologies

## II. Basic legal and technical information concerning certificates of origin/source/legal provenance

### Certificates of origin/source/legal provenance: different concepts and legal issues

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#### 1. Abstract

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 labour contents of the product, in order to be able to identify the country of origin.

The concept of certificates of origin was introduced into the ABS debate in the 1990s by Brendan Tobin and others to be used as evidence of Prior Informed Consent (PIC) for the purposes of disclosure of origin in patent applications. It first came up in the ABS negotiation process in 1999. COP-7 decided in 2004 to further examine the ‘internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge’ as an element of the negotiation of an international regime on ABS (Decision VII/19).

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) but which were acquired in accordance with the CBD (Art. 15.3 CBD). However, the term ‘certificate of origin’ is used quite often to imply that ABS requirements such as prior informed consent have been fulfilled. As opposed to that a ‘certificate of geographical origin’ is explicitly restricted to indicating where the genetic resource came from.

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. A certificate of source would track the genetic resource only as far as the place where the user obtained it, which may be a collection or depository and not necessarily the country of origin. This concept is found in different laws (e.g. Indian patent law). 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. In favour of introducing a certificate of source it has been brought forward that the term “source” best reflects the multitude of entities that might be involved in access and benefit sharing, and especially the fact that there are “primary” and “secondary” sources.

A 'certificate of legal provenance' (CLP) has been introduced in a couple of countries (e.g. Costa Rica and Mexico) to designate documentation providing evidence that the laws of the country of origin have been complied with. The 'certificate of legal provenance' does not refer to the supplier of the material but to the fact that the current owner obtained the material legally.

The discussion of the different uses that could be made of a certificate of legal provenance (CLP) has moved from a 'tracking system' to a simpler 'registration or market system'. The former intended to require a CLP for the every step in the commercialisation process, from the first export of the genetic resource to the patent application. It also intended to cover to all transboundary movements of genetic resources. However, there is a consensus now that e.g. border controls are unfeasible for genetic resources. Thus, the CITES permit, which is needed at the passing of borders, is not a comparable system. Instead, a registration system, which allows verifying that the resource was acquired respecting the existing ABS laws of a country, could be introduced. It was proposed that the certificate could take the form of a number or code that could then be checked against a central clearinghouse.

A registration system would still be relevant at a number of "checkpoints". These include the disclosure of origin when patenting an invention that is based on GR but could also comprise R&D funding, food and drug administration applications, and other commercialisation procedures. Already, disclosure requirements are being adopted into law in developing and developed countries.

In this context one has to keep in mind that most people agree that the goal of an international ABS regime cannot be to deter users from scientific and commercial research. Thus, the costs of acquiring a CLP have to be taken into account. This is also true for the costs of issuing a CLP since in many instances it will be difficult to recover the costs from the users. Finally, any system has to be acceptable for scientific and especially taxonomic research.

There are a number of legal issues that relate to international trade law. Voluntary certification schemes do not pose problems under international trade law. Mandatory certificates for genetic resources on the other hand potentially could when they are necessary for the import or export of products. Thus, a registration scheme that does not apply to the import or export of products would also be preferable from the perspective of international law. Even if the certificate is used for import/export controls, however, it has to be kept in mind that a system of certificates would be adopted under the auspices of the CBD, a multilateral environmental agreement which has been ratified by 188 countries world-wide. It is generally stressed that international trade agreements and multilateral environmental agreements shall be mutually supportive. It is therefore rather unlikely that a system of certificates would be challenged before the WTO. Patent law will be the focus later on of a presentation by Richard Tarasovsky from Chatham House. This presentation therefore limits itself to saying that it is possible (and has been done) to include disclosure requirements into national patent law in a way that they do not conflict with international rules.

So it could seem that introducing certificates of legal provenance are rather straightforward. However, CLPs still pose more questions than answers; these should also be considered by the Technical Group of Experts:



## **2. Concluding statement/ recommendations to the Group of Technical Experts**

A system of certificates can only work effectively if all countries – user as well as provider countries – adopt the necessary legislative measures, which seems rather improbable. What is the justification of a system that has loopholes?

Tomme Young has pointed out that the full meaning and coverage of the term ‘genetic resources’ under the CBD is unclear, especially in regard to the differentiation between biological and genetic resources. It should be clarified what kind of material and especially uses are understood by the term GR.

How should the system be designed in order to minimise bureaucracy and high costs for both users of resources and provider countries?

How will a system of CLPs deal with pre-CBD resources? How will post-CBD resources be identified?

While the discussions on the certificate of legal origin become more concrete, many actors remain rather sceptical about the concept. However, one has to keep in mind that a certificate of legal provenance could not only place a burden on (economic) actors. It could also enable them to prove that they have accessed a resource legally.

## Integration of a certificate into the international legal context

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This presentation focuses on a key question which will underlie both the design of the certificate and the manner in which it can be adopted. That question is as follows:

*How will the Certificate function within the International Regime, and what added value is expected from the Certificate?*

Up to now, the discussions of the Certificate have primarily focused on the contents of the certificate and the pathway by which it will be filed. The underlying question of value addition – whether and how the Certificate will fill an as-yet-unfilled niche in the regime, or improve and ineffective niche.

The basic practical fact underlying this presentation is that passing a law is a first step, but the implementation of the law is not automatic when a law is passed. This is even more true where the “law” is an international instrument under which countries commit to adopt and require some legal provisions.<sup>15</sup> The determination of the role of the Certificate in the regime will be important as a determinant of the manner in which countries will use it, and also the incentives (i) for countries to adopt it and (ii) for users to use it.

Consequently, although the verbal presentation will be organised in a slightly different way, it will address essentially three working questions –

- What purpose is the certificate intended to address?
- How does the existing ABS system address this purpose, if it does?
- As a practical matter, how will the certificate concept promote the above purpose? (and if there is an existing mechanism addressing this purpose, what is the value addition of the certificate?)

### **1. Outcome focus: What purpose is the certificate intended to address?**

In general, answers to the “purpose” question have been relatively ambiguous, and have only been discussed after the certificate proposals were well under way. This approach of creating the tool and then deciding how to use it is, at best, unusual. To date, the following seem to be the main purposes which have been suggested (by any party or author) as the underlying reason to create a certificate:

- To streamline and facilitate ABS permit process for compliant users
- To provide official verification of a users' right to use genetic resources under ABS regime;
- To provide official verification of a users' payment of benefits under ABS regime;

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<sup>15</sup> For example, Article 15.7 of the CBD calls upon countries to “adopt legal, administrative and other measures... with the aim of sharing in a fair and equitable way. The benefits arising from the commercial and other utilization of genetic resources....” To date, no country in Europe has reported adopting any law or other instrument requiring user companies to share benefits, or providing any other kind of measures toward the aim of benefit-sharing. A few (fewer than 5) countries have enabled voluntary patent-application disclosure of information on the source of genetic resources used in the applicant’s innovation.

- To provide verification that user engages in "best practices" for ABS compliance (independent of source country decision);
- To facilitate non-commercial researchers' ability to obtain and remove samples;
- To increase source / origin countries' awareness of non-compliant users;
- To enable monitoring of *compliant* users after they obtain genetic resources;
- To enable monitoring of *non-compliant* users after they obtain genetic resources;
- To facilitate tracking of subsequent transactions involving genetic resources
- To improve legal/judicial enforceability of ABS rights
- To identify products of non-compliant users of involving genetic resources
- To provide the Source/Origin country with information on compliant user's progress on agreed milestones
- To assists source/origin countries to identify benefits that should be shared
- To enable international (system-wide) analysis/review of the ABS regime;
- To standardise international terminology
- To encourage compliance with ABS and/or ABS contract

Obviously, the certificate cannot serve all of these purposes. It will be necessary to determine the actual purpose/use of the certificate in order to design the certificate itself in accordance with those purposes. For example, many of the above purposes can only apply if the certificate is mandatory and formally adopted as a legal requirement by all parties. Up to now, however, most certificate discussions (including especially the “patent disclosure” concept) lead to controversies which can only be resolved by agreeing that the certificate or disclosure would be “voluntary.”

In addition, as noted below, it is not clear for many of these purposes exactly how a certificate would assist. This suggests that selection of particular purposes of the certificate will be necessary in order to determine whether it will be “worth the effort” to invest the time necessary to develop and implement the certificate.

## **2. Current Status: [How does/Does] the existing ABS system address this purpose?**

One of the most important questions in separately adopting any component of a legal regime is the nature of existing law. Of course, the answer to this question depends first on the purpose of the certificate. Any legally effective document can be considered a “certificate.”

However, it is notable that many of the purposes listed above are currently served by the “ABS Agreements” and other licensing systems already in use by most of the source countries that have ABS procedures in place. To a great extent, certificate proposals are addressed to *compliant* users – that is, to users who already are obtaining relevant ABS permissions. In such cases, the requirement of another document will not significantly change the current costs for compliant users, and may in fact increase those costs of compliance.

Often, the certificate is offered as a means of cutting costs, however, at most, they are mechanisms for shifting cost, because certificate systems are not “cost free.” Various proposed purposes for the certificate depend on more than a certificate – they depend on, *inter alia* –

- governmental attention at some level within user countries;
- intergovernmental communication protocols;
- processing/record-keeping/validation of certificates

### **3. Added value: How would a certificate promote the above purpose?**

Of the three questions, the “mechanism” question is the least addressed. Much attention has been diverted to the fascinating legal questions relating to patent disclosures. Here, however, the question is “*Can the law of patent be adjusted to enable a disclosure of origin requirement?*” But a far more important initial question has not been asked – “

*What value will patent disclosure (or other proposed certificate mechanisms) have as a means of increasing or improving compliance with ABS?”*

The answer to this question again depends on (1) the purpose of the certificate and (2) the nature of existing mechanisms *and the reasons that they are not effective.*

### **4. Synthesis**

On the basis of this information, it is then appropriate to consider a series of possible ways to utilise a certificate, and to practically examine the question of how these mechanisms will function to promote ABS compliance.

In addition to patent disclosure, the following possible mechanisms have been suggested:

- Creation of an internationally accessible database of GR-in-use (including research)
- Creation of an internationally accessible record of (“access” and “post-access”) GR transactions
- Other (non-patent) “disclosure of origin”

Adding to these options, the author suggests considering the following. The filing of a valid certificate could be used enable the user –

- To qualify for incentive benefits (e.g., tax deductions) in user's own country;
- To qualify for incentives (permissions, priorities, etc.) in source and other countries;
- To provide evidence of compliance in ABS-related cases (and claims?);
- To qualify for government assistance in the event of ABS case or complaint.

In addition, it is possible for the certificate (if designed appropriately) to become a component of key “social-responsibility” certification systems, such as FairTrade, BioTrade, etc.

The creation of an effective certificate is not normally a first step in regime development, but a response to primary decisions. The certificate system can usually add value only when it is “designed for use.” However, the current process may add value to the regime negotiations in other ways.

## 5. Concluding statement/ recommendations to the Group of Technical Experts

1. Consider this meeting as a first step only. That means that its goal should be to decide the primary questions first. Specifically:
  - Agree to use (and explain directly) the CBD definitions of “origin”; and “source”. Similarly, some agreement should be made on the meaning of “legal provenance” and “compliance”.
  - Decide on specific objectives to be addressed by the system in which the certificate will be a tool.
  - Decide what specific mechanism will be used
  - Consider whether a certificate will be needed/valuable for that mechanism

After these questions are asked, one should design the mechanism, and decide the precise role of the certificate, before discussing contents and tracing systems, etc.

2. A financial analysis of the certificate process requires not only estimating costs, but also comparing them to estimated/expected benefits.
  - Even a very costly system may be valuable if it provides a worthwhile benefit, but
  - a cheap system will be too costly if it does not.
3. The certificate is a tool of the regime. You have to decide what task you will use this tool for, before deciding what kind of tool to create.
4. Virtually all of the open questions of the international negotiations must be decided before a certificate can be designed. This suggests that the goal of the TEG is an *initial examination* rather than a final drafting process.

It is wasteful of time and effort to design a certificate before these basic issues can be decided. The question of what the certificate will “prove” and how can only be answered when we know how these primary questions will be decided.

# Certificates of origin: economic impacts and implications

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## 1. Abstract

The commercial value of genetic resources has immensely increased in the last decades and since the adoption of the Convention on Biological Diversity (CBD) it has been agreed that the benefits arising out of their utilization have to be shared with the ones who conserve and provide resources. Until now no efficient instrument has been implemented which can guarantee this objective.

For many years certificates of origin are discussed as instruments in facilitating the continuous flow of genetic resources for commercial and not-for-profit uses while protecting the rights of the owners of genetic resources and associated traditional knowledge and ensuring a fair and equitable benefit sharing. But until today there is still no clear understanding about a certificate of origin scheme, and especially about its rationale, need and objectives; the desirable characteristics and features; and the practicality, feasibility and costs at national and international levels.

By applying economics of information and trade to the case of certificates of origin interesting findings are made with regard to the analysis of the economic rationale of a certificate of origin scheme and its economic impacts. The market for genetic resources is characterized by under-consumption due information deficiencies regarding the quality of the demanded material. Quality consists of different elements as origin, biological traits, but also CBD compliance through prior informed consent (PIC). Users cannot differentiate whether the provided genetic resources comprise these elements. They estimate a value of which existence they can be sure. This value is usually underestimated. Users are only willing to pay the price for the low quality material. As a consequence, high quality genetic resources are marginalized in the market (adverse selection).

Certificates of origin, which indicate the origin of the obtained resources and provide a legal title to the users who obtains the material, can close the information gap. As labels they can inform consumers about the quality characteristics of the product and enable users to identify the appropriate value of the resource. Users are willing to pay a higher price for those labelled resources. Without certificates users depend on own utilization experience or own third party judgement to assess the resources' quality. By providing additional passport data of the provided material the value and the price users are willing to pay would be even higher. Additionally, the problem of adverse selection is addressed and the amount of low quality genetic resources in the market decreases.

But often provider countries lack human and technology capacities to collect and transfer these data. Therefore it is important to enable provider countries through capacity-building training, knowledge and technology transfer to collect and transfer data in an appropriate format. This would benefit both providers and users.

A certificate scheme has effects on the trade of genetic resources. If certificates of origin are instruments of a mandatory certificate scheme and used as an import/export permit supply of genetic resources will

negatively affected due to higher costs. The costs depend on existing frameworks and procedure and how they correspond with the introduction of a certificate scheme. However, if a certificate scheme helps to streamline ABS procedure in country without raising costs they might even have a positive effect. The demand is positively affected because certificates can reveal resources' real value. Besides, during exchange of material they can reduce search and information costs. However, research and development costs can immensely increase by implementation and enforcement.

When discussing about certificates of origin one has to keep in mind the heterogeneity of users. The public and private sector benefit by having an appropriate instruments to differentiate the quality of provided material and gaining certainty of legal title to genetic resources. These benefits are much higher for the private sector which uses the material for commercial purposes, because they can actually recoup the costs caused by the implementation and enforcement of a certificate scheme. Public sector users do not make profits by using the material, but due to their function they are involved in many more international transfers.

A certificate scheme has not necessarily to be mandatory. It stipulates an incentive to participate. A mandatory system comprehensively monitors all flows of genetic material, but the price would be relatively high. All users would be enforced to implement such the system regardless their individual costs and benefits. A voluntary system already institutes adequate incentives for participation. If users can decide about their participation it is ensured that benefits of the system outweigh the costs. However, many provider countries claim a mandatory system.

The case of Japanese users shows that certificates of origin are critically judged among users of both the private and the public sector, which also supports the argument of a voluntary regime. The documentation of samples the two formats paper and electronic are probably the most common form of documentation of used material and therefore the most preferred ones. Certificates of source are considered as least critical. All proposed checkpoints are positively evaluated and an international registry is preferred to the national registry.

A future certificate of origin scheme has the potential to address information problems in the market of genetic resources. However, when implementing such a system existing infrastructure and attitudes have to be taken into account. Only then such a system will be effective regarding practicality, feasibility and costs.

## **2. Concluding statement/ recommendations to the Group of Technical Experts**

- Market of genetic resources is characterized by under-consumption due to information deficiencies about quality of genetic resources
- Certificate is an effective instrument by providing information (compliance plus passport data) and disclosing the real value
- A certificate can fill the information gap and decrease the amount of biopirated material in the market
- The trade effect of a certificate will be increased demand which outweighs the decreased supply due to higher costs

- Existing infrastructure of documentation has to be considered
- Capacity building in provider countries is needed and essential, providers need to be supported
- Heterogeneity of users has to be taken into account when designing the certificate
- A mandatory system monitors comprehensively, however a voluntary system already institutes incentive and ensures that benefits outweighs the costs



# **Possible effects of a certificate on the Disclosure of Origin process in patent applications**

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## **1. Abstract**

First of all, I would like to thank the German Federal Ministry for Environment, the organizers, for inviting me to participate at this meeting.

The topic of my presentation is “Possible Effects of a Certificate on the Disclosure of Origin Process in Patent Applications”.

First, I would like to give an overview of the most significant issues regarding the requirement of the disclosure of origin of genetic resources in patent applications. I will identify the arguments for and against such mechanism; describe the current legislation on this issue, at the national and international level; explain the different approaches adopted by the countries that already implement a legislation on disclosure; evaluate the experiences of the implementation of this method; analyze the different international fora, where the adoption of the disclosure obligation is being addressed; present a list of practical issues that must be clarified; and elaborate on the intellectual property-related issues for international certificates of origin.

## **2. Introduction**

In the last years, there has been growing concern among biodiverse countries about misappropriation of genetic resources (GRs) that exist in their territories. In particular, these countries are concerned about intellectual property rights (IPR) being granted for inventions based on these resources and their subsequent commercial exploitation by foreign companies and scientists, without any benefits returning to them. This has led to requests to review the intellectual property system. The introduction of disclosure requirements (DRs) into patent law has been proposed as one important measure to help countries to maintain sovereign control over their resources. Proponents of this measure suggest that it will achieve this through increasing transparency within the patent system and by facilitating monitoring the use of their genetic resources. Opponents are not convinced about the feasibility of implementing such requirement and their effectiveness in preventing misappropriation of genetic resources.

Such requirement has already been introduced by a number of countries (developing as well as developed countries) and proposals are also being discussed for the introduction of international legislation on this issue. In fact, the disclosure requirement have become an important issue within international negotiations on trade and the environment, with ongoing debates within the Conference of the Parties to the Convention on Biological Diversity (CBD), World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).

### 3. What are the arguments for and against DRs?

The need to introduce a disclosure of origin obligation has been justified in several submissions made by developing countries and in the literature on the matter both:

a) within the patent system

- to improve examination
- to determine inventorship
- to prevent misuse of the IP system.

b) outside the patent system

- to ensure compliance with prior informed consent (PIC) requirements
- to promote effective benefit sharing (BS) arrangements.

Regarding the arguments within the patent system, DRs will guide the patent examiners in guaranteeing that all relevant prior art information is available to the patent examiners. Disclosure will also be relevant in helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under Article 27 paragraphs 2 and 3 of the TRIPS Agreement. Furthermore, disclosure would serve as part of a process to systematise available information of biological resources and traditional knowledge that will continuously build the prior art information available to patent examiners and the general public.

In addition to matters relating prior art, patentability and exclusions to patentability, the DRs will also be useful in cases relating to challenges to patent grants or disputes on inventorship or entitlement to a claimed invention as well as infringement cases. It has already been shown that patent challenges involve a great cost in terms of time and resources, and are not a suitable option for developing countries. Patent grant challenges, cases on inventorship or entitlement as well as infringement cases form an important component of processes that ensure patent quality.

Finally, the DRs are necessary to prevent misappropriation of commercial benefits that are improperly obtained as a consequence of applying for, owning or transferring intellectual property.

Regarding the arguments outside the patent system, the DRs may contribute to make the CBD principles effective, particularly in relation to the PIC and BS, where applicable. The role that this obligation may play in the context of the CBD has been widely recognized by the Conference of the Parties (COP).

The arguments against the regulation of DRs are following:

- disincentive to invest in R & D
- majority of patents do not involve use of genetic resources
- difficult to identify the origin of resources
- patent offices do not have the capacity to identify whether national ABS laws have been complied with
- determining equity of benefit sharing is beyond the remit of patent offices

- solution to the problem can be found under national law, by means such as:
  - collection permits;
  - contractual arrangements;
  - unfair competition rules;
  - civil/criminal penalties;
  - databases;
  - post-grant examination

Even though in the last years, the matter of DRs was heavily been discussed, it can be observed during the process of the national and international debates that there is some convergence of views and a more informed debate developed. For example, initially, many of those coming from within the patent and industry sector did not recognize any link between the IP system and ABS issues. Rather, the latter was regarded as being completely alien to IPRs, and so DRs were considered inappropriate to the patent system. While there is still debate as to whether ABS issues are best addressed through the IP system, there has been some acceptance of the links between these two areas, and a growing awareness of the need to address these issues within the IP system. On the opposite side, among the proponents of DRs there has been greater recognition of some of the problems which need to be addressed if more wide-ranging DRs are to be introduced, for example, the need for clarification of terminology and definitions.

#### **4. What is the current legislation?**

After the adoption of the CBD, developing countries were perhaps the first in making a link between the ABS issues and the IP system. So some countries (e.g. the Andean Community members (Bolivia, Colombia, Ecuador and Peru),<sup>16</sup> Brazil,<sup>17</sup> Costa Rica,<sup>18</sup> Egypt,<sup>19</sup> India,<sup>20</sup> and Venezuela (until May member of the Andean Community) have already implemented legislation on DRs at the national level. These countries are conscious that its effectiveness will be limited in the absence of an international rule that sets the terms of the obligation and the consequences of failure to comply with it. So they are in the last years actively pursuing, in different fora, the recognition of an obligation to disclose the origin of biological resources and the associated traditional knowledge (TK) claimed in patent applications.

The implementation of national legislation on DRs by European countries was prompted by the adoption of the EU Biotechnology Directive in 1998.<sup>21</sup> Under this Directive, disclosure of the geographical origin of biological material is encouraged. Recital 27 states that:

“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

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<sup>16</sup> Andean Decision 391 on Access to Genetic Resources from July 2, 1996 and Andean Decision 486 on Industrial Property from September 14, 2000.

<sup>17</sup> Provisional Measure No. 2.186-16 of August 23, 2001, Art. 31.

<sup>18</sup> Biodiversity Law from 1998, Law No. 7,788, Articles 77-85.

<sup>19</sup> Egyptian Law from 2002, Art. 13.

<sup>20</sup> Patent (Amendment) Act, 2002, Sections 8 and 18 and Biological Diversity Act from 2002, Art. 6 (1)

<sup>21</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July, 1998, on the legal protection of biotechnological inventions.

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”.

The inclusion of a reference to DRs in the Directive was first proposed by Denmark. It was the subject of some debate and negotiation between the European member states, and due to the reservations of a number of countries the paragraph on DRs was included in the Directive’s Preamble rather than in the main text. This means that it does not create a legally enforceable obligation, and indeed, when implementing the Directive, not all countries adopted legislation on this issue. Just five countries have done so to date (Belgium,<sup>22</sup> Denmark,<sup>23</sup> Germany,<sup>24</sup> Norway<sup>25</sup> and Sweden)<sup>26</sup>. Switzerland<sup>27</sup> has draft legislation, currently being considered by its parliament.

The decision of these countries to adopt DRs was influenced by a range of factors.<sup>28</sup> For example, the Danish Government was keen to implement such legislation because it had been proactive on this issue within Europe. Also significant was the fact that the national debates on disclosure were part of a wider consultation on implementing the EU Directive. The Directive was very controversial in some countries, mainly because it formalized the patenting of life-forms. So the introduction of DRs was, in part, a means of appeasing those opposed to it.

## 5. What are the different approaches adopted?

The particular approaches to DRs that were adopted by all these countries reflected the concerns and balance of interests within each of the countries. For this reason, and also because of differences in their legal framework, there is some variation in the legislation adopted.

The main differences that can be observed are the following:

### A) Regarding the consequences of non-disclosure

	Affect validity of patents	No affect validity of patents
Andean countries	X (affect the handling of the applications as well as the validity of the patents)	
Belgium	X (formal requirement; could in theory affect the processing of the patent application)	X (wrongful declaration could result in fine or payment of damages)
Brazil	X	
Costa Rica	X	
Denmark		X (criminal sanctions)
European Union		X
Germany		X
India	X (revocation if fraudulent; transfer to	X (criminal and administrative

<sup>22</sup> Belgium Patent Law from 1984 amended by Law 2005/11224, Art. 5.

<sup>23</sup> Danish Patent Act amended by the Act 412 31/5 2000 (consolidated Patent Act 926 22/9 2000).

<sup>24</sup> German Patent Law from December 16, 1980, Art. 34a, modified through the Law on the Implementation of the EU Directive on biotechnological inventions (Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen). This law came into force on February 28, 2005.

<sup>25</sup> Norwegian Patent Act from December 2003, in force since 1<sup>st</sup> February 2004. Norway had the option of implementing the Directive or not because it is in the European Economic Area (EEA) rather than being a member of the EU.

<sup>26</sup> Sweden Patent Regulations (SFS 2004:162) in force since May 1, 2004.

<sup>27</sup> Draft Law submitted to the Parliament on November 23, 2005. Switzerland had the option of implementing the Directive or not because it is in the European Economic Area (EEA) rather than being a member of the EU.

<sup>28</sup> See , Disclosure of Origin in IPR Applications: Options and Perspectives of Users and Providers of Genetic Resources, IPDEV, Work Programme 8: Final Report, May 2006, 4.

	rightful owner)	penalties)
Norway		X (criminal sanctions)
Switzerland	X (failure to comply would result in patent rejection)	X (wrongful declaration could result in fine up to 100,000 Swiss Francs)
Sweden		X (no sanctions)

In developing countries, the non-compliance with the DRs can affect the validity of the patents. So, the handling of a patent application as well as the validity of a granted patent can be affected.

Such strict requirements were not adopted by any of the European countries, due to concerns that this could create legal uncertainty, a critical issue for the industry. In addition, concerns were expressed that substantive requirements would be in conflict with TRIPs. For this reason, Norway and Denmark took the route of criminal sanctions. Here, penalties could be imposed under their penal codes, since these include an obligation to provide correct information to a public authority. This would allow for the imposition of a fine or a prison sentence.

In Sweden the approach taken in Norway and Denmark was not an option, because the Swedish civil code does not enable prosecution in the case of a false declaration being made within a patent application. Therefore, Sweden decided to introduce a voluntary requirement, with no sanctions for non-compliance.

Belgium introduced a simple formal requirement. Under this legislation, non-compliance could, in theory, result in a patent application not being processed, although this would seem an unlikely event given that the Patent Office does not check compliance. If a patent has been granted, then criminal sanctions could be sought through the courts for wrongful disclosure, and this could result in a fine or payment of damages. Switzerland has proposed a similar measure. Under its draft law, failure to comply would result in rejection of the patent application, while wrongful declaration could be prosecuted ex-officio, and the applicant would be liable to a fine of up to 100,000.00 Swiss Francs.

b) Regarding the scope of the obligation

	Genetic resources	Traditional Knowledge
Andean countries	X (included any derivatives of genetic resources)	X
Belgium	X (biological material)	
Brazil	X (genetic material)	X
Costa Rica	X (components of biodiversity)	X
Denmark	X (biological material)	
European Union	X (biological material)	
Germany	X (biological material)	
India	X (biological resource)	X
Norway	X (biological material)	
Switzerland	X	X
Sweden	X (biological material)	

In the Andean countries, disclosure is required for patent applications involving genetic resources and their associated traditional knowledge. In Brazil and Costa Rica the DR also encompasses the associated TK.

In the five European countries which have implemented legislation, disclosure is only required for applications involving genetic resources. This was because of concerns over the difficulties of defining

the concept of “traditional knowledge”, and so it was thought that such a requirement would not be workable. In Switzerland, its draft law requires disclosure for inventions based on either genetic resources or TK related to genetic resources. The considerations that disclosure of TK would be a useful measure to allow the providers of such knowledge to trace its use, and in particular, to facilitate searches for prior art, outweigh the difficulties to define the concept of TK.

c) Regarding the information that is to be disclosed

	DO	DS	Access Contract	PIC	BS
Andean countries			X	X	X
Belgium	X				
Brazil	X				
Costa Rica			X (certificate of origin)	X	
Denmark	X				
European Union	X				
Germany	X				
India	X	X	X (permission)		X
Norway	X	X		X	
Switzerland	X	X			
Sweden	X				

In the Andean countries, the Decision 486 (Common Industrial Property Regime) requires that applications for patents disclose the access contract and evidence of PIC for genetic resources or TK.

In Brazil, the Provisional Measure requires the disclosure of the origin of any genetic material or associated traditional knowledge.

In Costa Rica, patent applications must be accompanied by a certificate of origin.

Belgium, Denmark, Germany and Sweden – following the EU Directive – require disclosure of the geographical origin. Switzerland’s draft legislation uses slightly different terminology, requiring declaration of “source” rather than origin. The term “source”, as it is defined in the Swiss proposal, is a broader concept than that of origin and was employed in order to deal with those situations in which the origin was unknown. Thus, source is defined as the entity that is competent to grant access to the genetic resources, or to participate in the sharing of benefits arising from their utilisation. Applicants would be required to declare the “primary source” (in other words, the origin), which may be the country or community providing the genetic resources, or if this is unknown, to disclose the “secondary source”, for example a gene bank or a botanic garden.

Norway requires disclosure of the providing country and also of the country of origin, if this is different. Furthermore, information on whether PIC has been sought is also required (although not evidence of the PIC itself), if this is required by the providing country or country of origin. This information must be declared with respect to the providing country, but for the country of origin the option exists to state that it is known whether PIC is required.

None of the European countries introduced a DR for evidence of fair and equitable benefit sharing.

## **6. Experiences of implementation**

The legislation of all the developing countries had experienced some problems of implementation. In some countries, as in Brazil, the DR has not taken effect due to a lack of rules that implement this measure.

As already mentioned, in the Andean countries, the Decision 486 requires that applications for patents disclose the access contract and evidence of PIC for genetic resources or TK. Because of difficulties in implementing the Decision 391 (Common Regime on Access to Genetic Resources), the access system is very complex and unclear, and to date there has only been a very few access agreement granted (one case in Bolivia, another one in Colombia, no cases in Ecuador nor in Peru). The complexities of the system also resulted – as far as it is known - in (only) one case in which an applicant for a Colombian patent did not comply with the requirement to file an access agreement. Such an agreement had apparently not been obtained by the applicant because of the difficulties of doing so, although this was subsequently rectified through a provisional authorization being granted, allowing processing of the patent. A further problem in the Andean countries, is that DRs in the Decision 486 are included as a formal requirement. The Andean patent offices have days to examine if a patent application fulfils the formal requirements. At that time, it is difficult for a patent examiner to verify if the application involves a genetic resource or a TK from the Andean region. Finally, the DRs in the Andean countries only cover the cases where genetic resources or traditional knowledge comes from these countries.

In Costa Rica, there have also been no cases of disclosure. However, this is not because of implementation problems, but rather – as in the Andean countries - of the narrow applicability of the DR. Patent applications involving biodiversity or TK need to be accompanied by a certificate of origin, but this only applies if the resources or knowledge are from Costa Rica.

In the European countries, where DR have been implemented, these measures have had limited impact. This is in part because they have not been in place very long. Another reason is that in all these countries these requirements only refer to national patent applications. The Norwegian Patent Office estimated that about 20% of all patent applications that they receive are national.

Only the Norwegian patent office had data on the number of applications in which disclosure had been made. They had received three such applications, but only one of these is still active. In the other countries, they estimated that there had been few, if any, of such applications.

The impact of DRs on the work on the patent offices has also been minimal. This is explained because of the small number of applications that involved genetic resources and the fact that none of them check on whether disclosure should have been made, nor whether the information is correct.

## **7. What can be learnt from experiences of implementing DRs?**

The previous section highlighted that national DRs have had little impact, either on patent applications or on the work of patent offices. While this means that experiences of this legislation are limited, there are some lessons that can be learnt.

A first lesson that can be drawn from these experiences is that such legislation need to be carefully designed if it is to be effective, either for patent applications or patent officials. For example, in Brazil it

is uncertain how to enforce the DR legislation, so it is necessary further rules to clarify this. In the Andean countries, it is very difficult for the applicants to comply with the DRs because of the difficulties of complying with the country's access legislation.

A second lesson is the need to clarify a list of practical issues regarding DRs, such as:

- the concept of biological materials/genetic resources and associated traditional knowledge;
- the relationship between the claimed invention and the genetic material;
- the content of the obligation (e.g. to declare or prove the origin?);
- the extent of the obligation (what needs to be disclosed? Source or origin)
- the timing of the obligation;
- the sanctions for failure to comply;
- the role of patent offices (should they only file the information received or also check its veracity? Should they cooperate with other patent offices/institutions?);
- whether the requirement would apply to both pre- and post-CBD materials;

A third lesson is the narrow scope of the DRs. Mainly in developing countries, disclosure is only required for patent applications that use national or regional resources or associated traditional knowledge. If one of the objectives of DRs is to facilitate ABS or to prevent misappropriation of genetic resources, this undermines their effectiveness. Now, since in these countries disclosure obligations are linked with access contract and PIC for the genetic resources and today there are only some countries that already issued legislation on ABS, this can lead to the question of how to deal with resources and traditional knowledge that come from countries in which no access legislation has been implemented. One possible solution is to require disclosure of PIC only where the resources come from a country that has already implemented access legislation.

Another lesson is the fact that if DRs should enhance the transparency of the patent system, there is a lack of information regarding the patent applications in which disclosure had been made. This would make it difficult for a third party to search for any relevant applications in which disclosure has been made.

The final point to be highlighted is the limited impact of these measures, if they only exist at the national level.

## **8. How is the matter of disclosure handle in the International fora?**

With respect to the CBD, negotiations are underway on an international regime on access and benefit-sharing (ABS). Many countries consider that DRs should be an integral part of such a regime, in order to monitor the use of GRs or additionally, to enforce ABS requirements. Consequently, they have been one focus of debate within recent negotiations. The current draft text on the development of an international ABS regime includes extensive references to this measure – although the fact that these are all bracketed reflects the divergence of opinion on this issue.

In the WTO, DRs are being debated as part of the Doha round of trade negotiations. These negotiations are at a crucial phase, with the pressure on to conclude them by the end of 2006 to avoid a collapse of this



round of talks. DRs are on the agenda in discussions over the relationship between the TRIPs Agreement and the CBD. Developing countries are pushing for amendment of the TRIPs Agreement, which they regard as necessary to ensure mutual supportiveness of these agreements. However, a number of countries do not think that there is any conflict, and are opposed to dealing with issues linked to the CBD within this forum.

DRs are also being discussed in WIPO, where reform of the Patent Cooperation Treaty (PCT) has been proposed to allow for DRs in international patent applications, and they are being considered as part of the discussion over further international harmonization of the patent system, under the Draft Substantive Patent Law Treaty (SPLT). Debate on the issue of DRs within WIPO seems likely to increase in momentum with the opening of discussions on the establishment of a Development Agenda for this organization.

## **9. International certificates of origin and intellectual property-related issues**

Originally the term “certificates of origin” was coined to describe a proposal for use of patent applications procedures as a means for ensuring the existence of PIC for use of genetic resources and associated traditional knowledge.<sup>29</sup> The original concept was that the patent offices should require the disclosure of the origin of genetic resources and associated traditional knowledge as a condition for receiving applications for grant of patents. It was suggested that the establishment of a standardised certificate of origin (which would act as evidence of prior informed consent) would exempt patent examiners from the need to examine all of the documentation related to an ABS agreement in order to verify compliance with the CBD.

The term has since taken on a wider meaning which broadly encompasses tracking flows of genetic resources and documenting evidence for the right to use genetic resources.<sup>30</sup>

In the 8<sup>th</sup> Conference of Parties to the CBD (COP-8) in March 2006, a Group of Technical Experts (GTE) was established in order to investigate the following issues in relation to an international certificate system:

- Rationale, objectives and need of such mechanism
- Potential characteristics and features
- Distinction between options of certificate of origin/source/legal provenance
- Implementation challenges.

It will go beyond the scope of this presentation to analyse all of these issues. Even more, they are a subject for others presentations. So I will focus (only) on the potential role of certificates of origin might play in a system regarding the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights.

If certificates of origin were conceived as documents issued by entities competent to certify that the source of genetic resources and associated traditional knowledge has the authority to provide access and

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<sup>29</sup> Tobin, 1994

<sup>30</sup> Sarnoff/Correa, Analysis of Options for Implementing disclosure of Origin Requirements in Intellectual Property Applications, United Nations, 2006, p. 69 with further quotes.

specified conditions, and also to certify the existence of *ex ante* benefit-sharing requirements that are compliant with the CBD and with relevant laws and equitable principles of the country providing such resources or knowledge, they may provide relevant information regarding the types of disclosures of origin that may be required for intellectual property applications.

The value of the certificates of origin in this context will depend on the types of information contained in them and how they would be verified and tracked to ensure the integrity of their continuing application to the genetic resources and associated traditional knowledge that are relevant to the patent applications.<sup>31</sup>

Use of certificates of origin relating to intellectual property applications will raise the same considerations discussed above regarding disclosure of origin. But there are additional intellectual property law issues that might be raised by such certificates.

#### **10. Additional intellectual property law issues to be taken in consideration**

If certificates of origin may not only help to track flows of genetic resources and associated traditional knowledge, but also to provide a certification of access to the relevant genetic resources on specified conditions of use and *ex ante* benefit sharing, it is necessary, that certification authorities verify that the uses to which genetic resources and associated traditional knowledge have been established, conform to the authorized conditions.

Considerations should be given to the consequences of certification errors by competent authorities. For example, certificates of origin can fail to identify the country of origin or other persons involved, or can fail to name the correct source. Should these errors affect the validity of the intellectual property right? Or should the sanction from this error be outside the intellectual property system?

Considerations should also be given to the fraudulent acquisition of certificates by persons to whom they were issued. In that case, should the conduct/behaviour of the applicant have consequences on the validity of the intellectual property right? should the applicant lose the right to apply for the patent? Or it might be required to transfer ownership or any commercial benefits that have been or will be obtained? Also in this case, consequences might be imposed within or outside the intellectual property system, including administrative fines, criminal penalties, additional benefit-sharing obligations, among others.

Confusion may also result when different countries issue certificates of origin that are in conflict regarding claims of authority to use genetic resources or regarding the equity of the benefit sharing arrangements.

In order to guarantee traceability of the genetic resources (and of the derivative genetic material) it is necessary that the certificate of origin include information related to the intellectual property application or any granted rights. Without such information it is difficult to verify in further developments based on the genetic resource, if disclosure of certificates of origin are required. This information will also be useful in order to ensure integrity of authorized access and equitable benefit-sharing.

For the last purpose, the certificate of origin should, in addition, include information regarding uses for which intellectual property applications may not be sought (e.g. trade secrets). Although it must be admitted, that in this case it will be very difficult to determine what kind of information must be included.

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<sup>31</sup> UNU-IAS, 2003

How a certificate of origin will ensure equitable benefit sharing based on an arrangement made ex ante such benefit sharing, is not clear. In any case, the information related to intellectual property applications and rights related to the genetic resources is relevant, as the premise of such applications is the granting of exclusive rights that may subsequently result in commercial benefits.

Another issue to be resolve is whether to impose or not disclosure of the certificates of origin in order to meet disclosure of origin obligations. Such decision will depend on the comprehensiveness of the certificates of origin system and on the degree to which certificates of origin include the information required to be submitted by mandatory disclosure of origin obligations within the intellectual property system.

Finally, consideration should be given to whether and how the certificates of origin can be transferred. Similarly to the US-trademark law, certificates of origin may need to be transferred with the relevant genetic resources.

## **11. Final considerations**

Despite the merits of the proposal to establish an international certificate of origin, the development of this concept will take considerable time and it may divert attention and efforts away from that required to achieve concrete and more immediate results in relation to the disclosure of origin obligation. In addition, the lack of ABS legislation in many countries is problematic for such a measure, and also, that the points at which a certificate would be required would need to be clarified.

## **12. Concluding statement/ recommendations to the Group of Technical Experts**

Even if there remain differences between the various stakeholders on the issue of disclosure of origin requirements (DRs), the complexities and potential problems of DRs are widely recognised by both supporters and opponents of this mechanism.

Benefits could be derived from DRs (improve patent examinations and better assure the integrity of IP determinations; facilitate to correct actions where IP is improperly granted or where ABS violations have occurred), although care should be taken to minimize the administrative costs and burdens of implementation.

The use of international certificates of origin could assist in complying with DRs. However, the use of this mechanism raises substantive and procedural triggers. It is also necessary to specify the types and timing of evaluations of disclosed information, and the mandatory or facultative consequences of disclosure failures.

Like other types of certifications documents, there is a need to address certification standards, improper and false, misleading, or confusing uses, and transfers of ownership. Consideration must be given to whether to mandate or to facilitate use of certificates of origin in satisfying DRs. Moreover, to determine what entities are competent to issue certificates of origin may be complex.

In addition, the use of certificates of origin raises other issues regarding ex-ante verification of information by certifying entities, the consequences of errors of certification, ex-post tracking of certified information to assure the continuing validity, and misuse of certificates by persons to whom they are issued and by others.

# Legal nature and subject matter of certificates of origin for genetic resources and traditional knowledge

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## 1. Why certificates of origin?

While there is no clear agreement on the objectives of a system of certificate of origin/sources/legal provenance (hereafter “certificates”) this might not be too problematic as these objectives are not strongly conflicting.

1. Some peoples insist on the objective of *monitoring* the use of genetic resources (GR) and traditional knowledge (TK) and *enforcement* of ABS legislations and ABS contracts. Their hypothesis on the functioning of the ABS system is biopiracy: they believe that a lot of GR are accessed and used in violation of ABS legislations.
2. Other peoples insist on *facilitating access and use of GR*. They hope that certificates could bring legal certainty and reduce transaction costs. Their hypothesis is that the current ABS system hinders access and use of GR because it creates transaction costs and legal uncertainty
3. Some peoples believe that certificates will enable *transparency and traceability* which could increase trust among providers and users and help to calculate the value added at each step of the innovation chain including the value of raw GR and possibly TK.
4. Last, the issue of certificates is not without connection with efforts by scientists to *document* their *collections* and transfer of resources as well as scientific information about those resources.

## 2. What is the legal nature of certificates of origin?

There is much ambiguity on the nature of certificates of origin, different authors use the same term to designate different things with different legal nature. Sometimes within a single document, one can observe that the notion of certificate designate, consciously or not, refer to different legal notions.

1. Often a certificate is regarded as a *piece of evidence*: it proves that a users has obtained the prior inform consent of the country of origin and that he has complied with ABS legislation
2. Certificate seems sometimes to be a synonymous for a *permit* either for research, or for collecting, for exportation, for use or for a combination of all these permits
3. Some authors suggest that certificates could be a *market tool*: a voluntary certification scheme like those delivered by the Forest stewardship Council.
4. Sometimes the term certificate is used to designate *contracts*: in that case the certificate becomes a particular format for ABS contracts. Indeed, it is sometimes associated with shrink-wrap or click wrap licences (adhesion contract), standard contracts, and viral licences
5. In some limit cases certificates looks like another word for a *property right*. If the use or the patenting of a GR requires showing a certificate, it involves that the issuer of the certificate has

an exclusive right on the use of that resource and that the user must obtain a license. In addition, there is a reversal of the burden of proof. While you are usually presumed to own what you possess, here it would be presumed that you are not entitled to use those resources unless you can prove your right by showing a certificate.

6. In addition, it is sometimes envisaged that certificates could be *part of a documentation system for research purpose* common to all collections of resources and database of related information (or at least an interoperable system)
7. Last, some descriptions of a system of certificates suggest that it should include a *central register* (or a cadastre or a clearing house) that would contain information about the location of the resources (countries and collections) and rights to these resources.

As an additional remark, one should observe that if certificates are a form of contract (possibly with shrink wrap licence, standard contract and viral licences) and if the system of certificate includes a central register (or clearing house) we then move to a kind of multilateral system of ABS.

In order to progress in the discussion of certificate, it seems urgent to have a common understanding of the legal nature of certificate and according to this understanding; it may be useful to reconsider whether the word certificate is the most suitable.

More importantly, the legal nature of certificate depends heavily on the subject matter of certificates.

### **3. What is the subject matter of certificates of origin?**

In my opinion, this is the most important issue because it determines possibilities of tracking and therefore the feasibility of the different options (see legal nature) for a system of certificate. However, as far as I am aware, there is no study examining clearly the pros and cons of different possible subject matters. Rather, most papers on certificate ignore this question (implicitly referring to different subject matters in different paragraphs) therefore overlooking important problems of feasibility.

*A double choice* must be made in the determination of the subject matter for certificates.

1. the *first choice* is to decide whether the subject matter will be
  - a) *a group of objects without individual identification*: for instance all resources collected under a single contract
  - b) *an individual object*: for instance one individual plant, one individual micro-organism, one individual fungi, or any individual sample
  - c) *a category of object* (in other words a piece of genetic information): for instance: one species, one variety, one gene, one protein, etc. In that case all individuals of that species, variety, gene, etc would be covered by the certificate.
2. the *second choice* is to decide if the subject matter will be “high” or “low”. For instance if it is decided that the subject matter should be a category of objects, one has still to decide whether it will be a “high” category like a species or a “low” category as a gene. The same is true if the subject matter is an individual object. The “size” of the object is an important issue because it influences the possibility to track that object throughout the innovation chain (*Cf. infra*).

I must now examine the feasibility of the different options first at the departure point when the certificate is emitted and then taking into account that the resources will go through an innovation chain.

### **3.1. Feasibility of different subject matters at the emitting point**

One must distinguish situations where resources are readily identifiable from situations where they are not:

*Where resources are readily identifiable*, for instance in exchanges of material between two ex situ collections, a certificate can be linked to an individual object or to a specific category of objects (piece of info).

*Where resources are not readily identifiable*: for instance in wide scale collection, in particular random collection or collection of unknown resources (collecting resources *in situ*), it is impossible to link a certificate with an individual object nor a specific category of objects. Therefore, the certificate might only be linked to an action: a specific activity of collection (area and time defined).

### **3.2. Feasibility of different subject matters if one takes into account the chain of innovation**

If we consider creating a system of certificate, it is because resources are used in a chain of innovation that might end with a commercial product whose benefits might be share with resources providers. Therefore we must take into account two effects of the passage throughout the chain:

1. *Reproduction*: resources as living organism are likely to be reproduced/multiplied/copied a large number of times in the chain of innovation.
2. *Transformation*: resources will be transformed or combined with other materials through the chain of innovation

We can now better understand the feasibility of the different possible subject matters.

1. If the subject matter is an *individual object*: it is possible to identify it the cost will vary according to the size (it is easier to identify an individual plant than an individual micro-organism). However, the individual object will not be present in the entire chain because of reproduction and transformation.
2. *If the subject matter is a category of object* (piece of information). We must also take into account the distinction between “high” categories (a genus, a species, a variety) and “low” categories (a gene)
  - For “high” categories: it can be easily identifiable at any moment, reproduction is not an issue as progeny are part of the same category; but transformation is an issue
  - For “low” categories: it is more difficult to identify at any moment, reproduction is not an issue as copies of a gene are part of the same category, and transformation is not an issue because a gene present at the entrance of the innovation chain is likely to be present at the end of it.

Further research should be made upon the link between the different possible subject matters for certificates and the legal nature of certificates At first sight, it gives the following results:

If the subject matter is a group of object without individual identification, the following options seem feasible:

Piece of evidence	Yes	Evidence of contract <i>but indirect link</i> with final product of patented invention
Permit	Yes	
Market tool	Yes	Evidence of contract <i>but indirect link</i> with final product of patented invention
Contract	Yes	
Property right	?	The certificate can include a transfer of ownership of the individual objects
Documentation	No	
Central register	No	

If the subject matter is a category of objects the following options seem feasible

Piece of evidence	Yes	<i>More or less direct link</i> with final product or patented inventions according to the size of the object
Permit	Yes	
Market tool	Yes	
Contract	Yes	<i>More or less direct link</i> with final product or patented inventions according to the size of the object
Property right	Yes	If use or patenting of a category of object requires showing a CO => the issuer of CO has an exclusive right on the use of that category/ information (IPR) and the user must obtain a license + reversal of the burden of proof
Documentation	Yes	Easier for “big categories” (a species vs. a gene)
Central register	Yes	

If the subject matter is an individual object, the following options seem feasible

Piece of evidence	Yes	Evidence of contract <i>but indirect link</i> with final product of patented invention
Permit	Yes	
Market tool	Yes	Evidence of contract <i>but indirect link</i> with final product of patented invention
Contract	Yes	
Property right	Yes	
Documentation	?	Little sense (except may be for sanitary reason)
Central register	?	Little sense (except may be for large object, e.g.: cattle)

#### **4. Implications if Certificates are to Cover Traditional Knowledge**

To what extent can we transpose those observations to traditional knowledge (TK)?

First of all, one must recall some characteristics of TK. TK consists of knowledge and not physical objects which will have an important influence on the possibility to track its uses. In addition, most TK can be regarded as tacit knowledge that is know-how that is best communicated through personal communication. Tacit knowledge is opposed to codified knowledge, that is knowledge that has been “written” on a physical support and that can be accessed by reading that support. Not all TK corresponds to this definition of tacit knowledge but it can still be assimilated to tacit knowledge as linguistic and cultural barriers hinder access by other means than personal communication. This nature of TK greatly affects its use by scientists in the innovation chain. According to Laird and Ten Kate, 45% of GR users admit using TK but for 80% of them they only refer to TK that has been codified in academic publications and databases. As a reaction, some TK holders interested in “selling access” to their knowledge started to codify their own TK in databases.

This distinction between “tacit TK” (or *in situ* TK) and “codified TK” (or *ex situ* TK) is essential because it determines the feasibility and the nature of certificates of origin. For tacit TK, it is hardly possible to identify who holds what knowledge, what is the precise content of that knowledge, who are the right holders to that knowledge. By contrast for “codified TK”, it is possible to better identify knowledge holders, the content of the knowledge and the right holders.

As a result, *if the subject matter of a certificate on TK is “tacit TK”*, a certificate is unlikely to be more than a piece of evidence of a contract on some elements of TK with some holders whose rights are not clearly known and it will be hardly possible to identify a link between the accessed knowledge and a final product or a patented invention (except if it is acknowledged by the user but in that case there is no need of certificates). *If the subject matter of a certificate on TK is “codified TK”*, a certificate could be a piece of evidence of a contract with clearer object, rights and rights holders, it remains that it will be difficult to identify a link between the accessed knowledge and a final product or a patented invention.

In total, it is extremely difficult to track the use of knowledge. For codified knowledge, it is possible to identify copies of a support containing knowledge (which is controlled by copyright) and to identify copies of an invention (which is controlled by patent law) but it is nearly impossible to track the use of knowledge as such in the course of an innovation chain. For tacit knowledge, it is even more difficult if not completely impossible as one cannot identify clearly the knowledge whose use he should track.

In conclusion, I can hardly imagine a system of certificate applying to tacit TK. Some possibilities might exist for codified TK but still they will remain difficult and limited.

#### **5. Concluding statement/ recommendations to the Group of Technical Experts**

##### **5.1. Recommendation on certificates of origin on genetic resources**

An important issue is to determine *the subject matter of a certificate* because it determines possibilities of tracking and therefore the feasibility of the different options (see legal nature) for a system of certificate. However, as far as I am aware, there is no study examining clearly the pros and cons of different possible subject matters. Rather, most papers on certificate ignore this question (implicitly referring to different



subject matters in different paragraphs) therefore overlooking important problems of feasibility. In determining the subject matter, we must take into account three issues:

1. cost or easiness to track: it is easier to identify a plant than a gene
2. reproduction: resources as living organism are likely to be reproduced/multiplied/copied a large number of times in the chain of innovation
3. transformation: resources will be transformed or combined with other materials through the chain of innovation

## **5.2. Recommendation on certificates of origin on traditional knowledge**

It is extremely difficult to track the use of knowledge. For codified knowledge, it is possible to identify copies of a support containing knowledge (which is controlled by copyright) and to identify copies of an invention (which is controlled by patent law) but it is nearly impossible to track the use of knowledge as such in the course of an innovation chain. For tacit knowledge, it is even more difficult if not completely impossible as one cannot identify clearly the knowledge whose use he should track.

As most TK can be assimilated to tacit knowledge, *if the subject matter of a certificate on TK is “tacit TK”*, a certificate is unlikely to be more than a piece of evidence of a contract on some elements of TK with some holders whose rights are not clearly known and it will be hardly possible to identify a link between the accessed knowledge and a final product or a patented invention (except if it is acknowledged by the user but in that case there is no need of certificates). *If the subject matter of a certificate on TK is “codified TK” (TK that has been written in a support, e.g. a database)*, a certificate could be a piece of evidence of a contract with clearer object, rights and rights holders, it remains that it will be difficult to identify a link between the accessed knowledge and a final product or a patented invention.

In conclusion, I can hardly imagine a system of certificate applying to tacit TK. Some possibilities might exist for codified TK but still they will remain difficult and limited.

# Certification scheme and WTO agreements: Options to ensure consistency

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## 1. Abstract

This article aimed to contribute to this debate by investigating an option for a certification scheme that remained unexplored, which is the certification controlled by a state authority when genetic resources are imported and exported. We identified many advantages of such a scheme. Like every mandatory scheme, it would include in the system the users who are not familiar with the CBD objectives and even those who do not share them. Moreover, a certification scheme for transboundary movements of genetic resources can be implemented even if the consumer awareness is at a low level and if there is no precise international benefits sharing standards. It could also rely on existing checkpoints for control of transboundary movements and be integrated with other certification schemes. On the other hand, knowing the process of dematerialization permitted by new information technologies, it is unrealistic to assume that a certification scheme can monitor every transboundary movements of genetic resources. It is also unclear how this scheme will deal with intangible material such as traditional knowledge associate to genetic resources.

One of the most serious difficulties raised by a certification scheme for transboundary movements of genetic resources relies on its compatibility with WTO law. Minimal safeguard measures must be taken into account to minimize the risk of challenged. Among them, a country should wait for a multilateral decision before implementing its own certification scheme. For political reasons, a multilaterally negotiated MEA as never been challenged under the WTO even if some of them do have trade-related measures which appear far more restrictive than the proposed certificate of origin. We can also presume that a multilaterally negotiated solution would be more favorably contemplated by a WTO panel than any unilateral action. In addition, border procedures should not be unnecessary burdensome, a possibility that could easily bring some challenges under GATT Article XI or the TBT Agreement. In this way, an Internet-based certificate would be on the easiest procedure for importers. One of the important things regarding WTO rules is that the certificate must not be the least discriminatory possible. To avoid discrimination, the certificate system and the national laws implementing it would have to be designed on a "product" basis rather than on a "country" or "provider" basis. When designing the features of the said certificate and its related application laws, it would be important to keep in mind these details. It would be an unwise strategy to develop a certification scheme that may increase benefit sharing flows on the one hand, but that can lead to heavy trade sanctions on the other hand.

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<sup>32</sup> The article Sélim Louafi and Jean-Frédéric Morin, "Certificates of Origin for Genetic Resources and International Trade Law", IDDRI, Paris, November 2004, 16 pp. can be found [http://www.iddri.org/iddri/telecharge/biodiv/certif\\_origin\\_sl-jfm\\_04-11.pdf](http://www.iddri.org/iddri/telecharge/biodiv/certif_origin_sl-jfm_04-11.pdf)

### **III. Organisational aspects of a certificate system under a comparative perspective**

#### **The Standard Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture – lessons for a certificate?**

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##### **1. Introduction**

Under the Convention on Biological Diversity (CBD), it is being intensely debated how to improve implementation of the Convention's third objective, i.e. 'the fair and equitable sharing of the benefits arising out of the utilization of genetic resources' (Art. 1 CBD). In the present process of elaborating and negotiating an international regime on access and benefit-sharing (ABS), one potential instrument discussed is an internationally recognized certificate of origin, source or legal provenance. Roughly speaking and ignoring conceptual nuances,<sup>33</sup> the certificate's envisaged purpose is to support ABS implementation by documenting the origin, source, or legal provenance of a genetic resource and/or its associated traditional knowledge, thus making possible the resource's tracking.

The following paper analyses to what extent the ABS instrument developed under the International Treaty on Plant Genetic Resources for Food and Agriculture – the Standard Material Transfer Agreement (SMTA) – shares common features with the certificate, and whether it can potentially serve as a model.

For this purpose, the International Treaty on Plant Genetic Resources for Food and Agriculture<sup>34</sup> and its relation to the CBD will be outlined briefly. I will present the Treaty's system of access and benefit-sharing and especially the role of the SMTA in order to subsequently compare the SMTA to the concept of certificates of origin/ source/ legal provenance. I will argue that although the two documents are similar with regard to their (anticipated) form, they are intended to serve different functions. Hence, a certificate can be 'modeled' on the SMTA only to a limited extent. There are, however, some more indirect lessons to be learned from the SMTA when designing a system of certificates. Conclusions as to which insights exactly can be passed on will be built on an assessment of the SMTA.

##### **2. The International Treaty and the CBD**

###### **2.1. Negotiation history of the International Treaty**

The International Treaty developed from the 'International Undertaking on Plant Genetic Resources' had been adopted under the auspices of FAO in 1983. The Undertaking was the first, though non-binding

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<sup>33</sup> For such nuances, see Dross, Miriam/ Wolff, Franziska (2005): New Elements of the International Regime on Access and Benefit-Sharing of Genetic Resources – the Role of Certificates of Origin. BfN-Skripten 127. Bonn.

<sup>34</sup> In the following: 'International Treaty', 'ITPGRFA' or 'IT'.

agreement dealing with plant genetic resources for food and agriculture (PGRFA). It aimed at ensuring their conservation as well as providing unrestricted access to PGRFA as a 'heritage of mankind'. When the CBD was signed in 1992 and established national sovereignty over genetic resources, the Undertaking needed to be brought into harmony with the new Convention. Also, provisions were necessary with regard to matters left outstanding by the CBD, in particular with regard to access to *ex-situ* collections not acquired in accordance with the CBD (including the comprehensive gene banks of the Consultative Group on International Agricultural Research) and the question of farmers' rights. Based on the Resolution 3 of the CBD's Nairobi Final Act and on FAO Res. 7/93, the International Undertaking was revised and developed into the International Treaty. After eight years of negotiations, the Treaty was adopted at 3 November 2001 and entered into force on 29 June 2004. The Standard Material Transfer Agreement as the Treaty's ABS instrument was finally adopted at the 1<sup>st</sup> Session of the Treaty's Governing Body in June 2006. Presently, there are 106 Contracting Parties to the International Treaty, excluding, most notably, the US and Japan.

## 2.2. Relation between International Treaty and CBD

The International Treaty is in harmony with CBD, but it constitutes a stand-alone agreement under the auspices of FAO. With regard to the CBD, it is *lex posterior* and *lex specialis*: it entered into force later and covers only a part of the CBD's scope, namely plant genetic resources for food and agriculture.<sup>35</sup> Although the Treaty is based on the same basic principles (e.g. national sovereignty over biological resources) and objectives (conservation and sustainable use of biological diversity, fair and equitable sharing of benefit arising out of the use of genetic resources), it partly employs differing means to achieve these objectives. Above all, the Treaty's parties rejected the CBD's bilateral model of access and benefit-sharing where ABS is negotiated bilaterally between a country of origin providing a genetic resource and the entity requesting access to it. Rather, in the exercise of their sovereign rights over PGRFA, the parties adopted a multilateral system of facilitated access and benefit sharing for a selected list of PGRFA.

The rationale behind opting for a multilateral ABS system is the special nature of agricultural biodiversity. Unlike in the case of wild plants, we are dealing with man-made diversity and with material that has been improved by farming communities over hundreds of generations. The exchange and introduction of germplasm and consequently the breeding processes have been taking place in a transboundary fashion for centuries. As a result, some crops feature source material from over 50 countries.<sup>36</sup> It is hence often impossible to define a single 'country of origin'. The interdependence of countries on PGRFA induces a high density of exchanges. Visser et al. (2000)<sup>37</sup> show that under a bilateral ABS regime the related transaction costs of negotiating, tracking and monitoring would become excessively high. The importance of agricultural biodiversity for food security, however, makes it undesirable that the level of transaction costs leads to restrictions in the exchange. Against this backdrop, a multilateral ABS system was developed.

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<sup>35</sup> According to Art. 2 ITPGRFA, "plant genetic resources for food and agriculture" means any genetic material of plant origin of actual or potential value for food and agriculture. "Genetic material" means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.

<sup>36</sup> See Seiler, Achim (2003): Der Internationale Saatgutvertrag der FAO: Farmers Rights – geistige Eigentumsrechte – Zugang zu genetischen Ressourcen. In: Ch. Baumgartner/D. Mieth (Hg.): Patente am Leben? Marburg, S. 259.

<sup>37</sup> Visser, Bert/ Eaton, Derek/ Louwaars, Niels/ Engels, Jan (2000): Transaction costs of germplasm exchange under bilateral agreements. Global Forum on Agricultural Research, 21 – 23 May 2000, Dresden, Germany. Document No: GFAR/00/17-04-04.

However, not all plant genetic resources for food and agriculture are covered by the multilateral system; some remain under the CBD’s ABS regime (see Table 1). Above all, the multilateral system is restricted to a list of ca. 60 crops and forages specified in Annex I of the Treaty (Art. 11.1 IT).<sup>38</sup> These PGRFA then need to be under the management and control of Contracting Parties and in the public domain (Art. 11.2 IT),<sup>39</sup> or they need to be held by the CGIAR’s International Agricultural Research Centres or by other international institutions (Art. 11.5, 15.1(a), 15.5 IT). Finally, Annex-I crops fall under the multilateral system only to the extent that they are used for research, breeding and training for food and agriculture (Art. 12.3(a) IT).

Table 1: Delimitation of scope of ABS provisions with regard to PGRFA

Scope	CBD	International Treaty
I. General	Biological diversity	Plant Genetic Resources for Food and Agriculture (PGRFA)
II. With regard to Access and Benefit Sharing	Genetic resources provided by a Contracting Party that is a country of origin of such resources or has acquired the resources in accordance with the CBD (Art. 15.3 CBD).  This includes PGRFA other than those covered by Art. 10-13 and 15 of the International Treaty (e.g. non-Annex I crops, PGRFA for non-food/feed use)	PGRFA listed in Annex I of International Treaty to the extent that they are – under the management /control of Contracting Parties – in the public domain – or are held by IARCs and other int’l institutions – and are used for research, breeding and training for food and agriculture

Source: own.

Access to all other PGRFA and the sharing of benefits resulting from their utilization are covered by Art. 15 CBD. Most notably, this includes non-Annex I crops and PGRFA intended for non-food or non-feed use.

When discussing the relation between International Treaty and CBD, we should finally look at how the Treaty is dealt with in the ongoing CBD processes and especially in the elaboration and negotiation of an International ABS Regime. At COP-8, the parties determined that:

“3. [The international regime will not apply to the plant genetic resources [of those plant species] that are considered by [under annex 1 of] the International Treaty on PGRFA [or by the Commission of GRFA], [when those resources are used for the purpose of that Treaty]”

4. [The international regime is without prejudice to the FAO International Treaty on PGRFA...]”

5. [The international regime ensures mutual supportiveness and complementarity with relevant existing international instruments and processes] [and that they are supportive of and do not run counter to the objectives of the Convention]” (cf. Decision VIII/4, Annex on ‘Scope’)

Although the text (like all of Decision VIII/4) is still heavily bracketed, it transpires that parties do not (necessarily) intend the international regime – including the certificate of origin/ source/ legal provenance – to apply to crops contained in Annex-I of the Treaty, and possibly not even to PGRFA at all.

<sup>38</sup> The list includes most of the important food crops such as wheat, corn, rice, potatoes, millet, as well as many fruit, vegetables and fodder plants. Soy and tomatoes are among the most important food crops not included. Fruit and ornamental plants as other elements of ‘bred’ biodiversity are also not listed.

<sup>39</sup> This is not the case e.g. for material protected by Plant Breeders’ Rights or other Intellectual Property Rights, or for PGRFA under development by breeders and farmers.

Still, the Standard Material Transfer Agreement that implements the Treaty's ABS system may inspire the discussion on an internationally recognized certificate. In order to explain why this is so, we will take a closer look at this ABS system and the SMTA.

### **3. Access and Benefit-Sharing under the International Treaty**

#### **3.1. The general framework**

As was mentioned above, access and benefit-sharing under the International Treaty on Plant Genetic Resources is subject to a Multilateral System (MS). It covers the crops and forages listed in Annex I and under the conditions just described.

For those PGRFA, access is facilitated (Art. 12 IT). This means that access shall be accorded expeditiously, without the need to track individual accessions. Above all, it is free of charge or, when a fee is charged, it does not exceed the minimal costs involved. Neither Prior Informed Consent (PIC) nor Mutually Agreed Terms (MAT) are necessary.

The requirement to share benefits fairly and equitably (Art. 13 IT) extends both to non-monetary and to monetary benefits. Monetary benefit-sharing is mandatory when a product resulting from a genetic resource which was received from the multilateral system is commercialized and at the same time specific IPRs are applied to it (Art. 13.2(d)(ii) IT; see below). In other cases, monetary benefit-sharing remains voluntary.

This ABS system is implemented through two mechanisms. The first one is the Standard Material Transfer Agreement (SMTA), which serves as a template for the contracts to be used for concrete geneplasm transfers between providers and recipients. The SMTA operationalises the Treaty's ABS provisions. In addition, it sets out core definitions and specifies the level, form and manner of payment. The second mechanism is the Trust Account. It receives the means accruing from monetary benefit-sharing (as well as other resources that are part of the Treaty's funding strategy). The Trust Account funds shall flow primarily to farmers, especially in developing countries and in countries with economies in transition, who conserve and sustainable utilize PGRFA (Art. 13.3 IT). In this, the priority activity areas of the 'Global Plan of Action (GPA) for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture' are to be taken into account (Art. 13.2 IT). The GPA is an internationally agreed-on plan under the guidance of the Governing Body.

#### **3.2. The SMTA**

The SMTA is a model or 'template' for private contracts (i.e. Material Transfer Agreements/ MTAs). The parties to these contracts are the providers and recipients of material stemming from the multilateral system. In practice, the providers are above all gene banks, but also others (including entities that have initially received material from the multilateral system and then transfer it to third parties). Recipients typically include breeders, research institutions, NGOs, farmers or other private persons. The subject matter to be transferred under a MTA is a plant genetic resource for food and agriculture available under the multilateral system, plus the 'related information' (Art. 3 SMTA). The latter includes passport data and other associated non-confidential descriptive information (Art. 5(b) SMTA).

The details of access and benefit-sharing are regulated in the Articles 5 and 6 of the SMTA, which cover the rights and obligations of genetic resource providers and recipients.

**3.2.1. Access**

Table 2 summarizes the SMTA’s provisions on facilitated access. They are largely identical to provisions contained in the International Treaty: Facilitated access shall be provided if the material is used for the purposes of research, breeding, training for food and agriculture (Art. 6(a) SMTA). It shall be expeditious and free of charge, respectively not exceeding the minimum costs involved, and without the need to track<sup>40</sup> individual accessions (Art. 5(a)). Special provisions relate to access to PGRFA under development, which shall be at the discretion of their developer (Art. 5(c)), and to PGRFA protected by intellectual and other property rights, which shall be consistent with relevant national and international law (Art. 5(d)).

Table 2: Facilitated access as stipulated in the SMTA

Facilitated Access	Rights and obligations of:	
	Provider (Art. 5)	Recipient (Art. 6)
Only for purposes of research, breeding, training for food and agriculture		x
Expeditious, free of charge/ not exceeding minimal costs	x	
No tracking of individual accessions	x	
Special provisions on access to material under development and PGRFA protected by IPRs	x	
No IPRs which limit facilitated access to the PGRFA, or its genetic parts or components, “in the form received”		x
Third party transfers are subject to the conditions of SMTA		x
Notification obligations with regard to the MTAs entered into and to third party transfers	x	x

Source: own.

As regards the further use of the material, recipients shall not claim intellectual property or other rights that limit the facilitated access to it, or its genetic parts or components, ‘in the form received’ from the multilateral system (Art. 6.2). This language aimed to reconcile, without really clarifying, the conflict on whether or not it would be possible to receive patents on unaltered MS material. Identical wording was included into the SMTA. Crucial for the outreach of the multilateral system is Art. 6.4(a), according to which subsequent transfers to a third party of the material received are subject to the terms and conditions of the SMTA. The SMTA’s provisions that actually go beyond the International Treaty relate to notification obligations: The provider shall periodically inform the Governing Body about the MTAs entered into (Art. 5(e)), while the recipient is obliged to notify the Governing Body about any subsequent transfers they enter into (Art 6.4(b)).

**3.2.2. Benefit-Sharing**

The SMTA contains three options of monetary benefit-sharing: mandatory and voluntary benefit-sharing, and an alternative scheme that combines mandatory and voluntary benefit-sharing at a reduced rate. With regard to the mandatory option, the SMTA reiterates the Treaty’s stipulation that benefit-sharing is

<sup>40</sup> Actually, in the SMTA certain notification obligations were established to monitor compliance which come close to “tracking”, although the respective information needs to be provided only on a yearly basis.

mandatory when a recipient commercializes a product incorporating material from the multilateral system (MS), and when the product is not available without restriction to others for further research and breeding (Art. 6.7 SMTA). In addition, crucially, it delivers the definitions of what to understand by ‘commercialize’, ‘product’ and ‘available without restriction’. A ‘product’ hence means a ‘plant genetic resources for food and agriculture that incorporates the Material or any of its genetic parts or components [thereof] that are ready for commercialization, excluding commodities and other products used for food, feed and processing.’ During the SMTA’s negotiations, this product definition had gained acceptance over a competing, narrower option. According to the latter, not physical incorporation of MS material per se would have defined a product, but only incorporation of ‘an identifiable trait of value’.<sup>41</sup> ‘Commercialization’ is defined as the sale of a product for monetary consideration ‘on the open market’. It does not extend to selling PGRFA under development, i.e. intermediate breeding products such as elite lines. Mandatory monetary benefit-sharing is hence required when a variety is sold on the open seed market – provided the seed can be used ‘without restrictions’ for further research and breeding, be they legal, contractual or technological restrictions. This is generally understood to include patents,<sup>42</sup> trade secrets and genetic use restriction technologies.

Three aspects are salient in this approach: First, unlike in the CBD, not commercialisation itself triggers benefit-sharing, but only commercialisation that is linked to restrictions for further research and breeding. Second, there is no ‘checkpoint’ at which fulfilment of benefit-sharing obligations is controlled.<sup>43</sup> Third, once a product is on the market, further transactions with it or with derivatives of it are not subject to benefit-sharing (‘final product model’).

Table 3: Benefit-Sharing as stipulated in the SMTA

Benefit Sharing	Rights and obligations of:	
	Provider (Art. 5)	Recipient (Art. 6)
Monetary benefit-sharing: <ul style="list-style-type: none"> <li>a) mandatory, when recipient <i>commercializes a product</i> incorporating material from the Multilateral System, and the product is <i>not available without restriction</i> to others for further research and breeding (Art. 6.7) →cf. definitions (Art. 2) →Benefit-sharing rate: 1.1% of sales, minus 30% (= 0.77% net)</li> <li>b) voluntary, when product remains available without such restriction (Art. 6.8)</li> <li>c) alternative payment scheme if benefits are shared irrespective of whether mandatory or voluntary (Art. 6.11) → Benefit-sharing rate: 0.5% of sales</li> </ul>		x
Non-monetary benefit-sharing		x
Transfer of benefit-sharing obligations, if IPRs are assigned to a third party		x

Source: own.

In the case of mandatory monetary benefit-sharing, the standardized rate is 1.1 % of the gross income resulting from the products’ commercialization. This holds independent of the crop. From this rate, a

<sup>41</sup> This option was finally dropped as the difficulties were recognized to clearly establish whether an incorporated trait possessed commercial value. In the SMTA negotiations, agreement on the wider product definition was subsequently linked to a generally lower benefit-sharing rate.

<sup>42</sup> A debate actually takes place on whether specific kinds of patents would allow ‘unrestricted’ further research and breeding, e.g. patents in national legislations that contain a breeders’ exemption or a research exemption. Especially the latter, however, does not prevent restricting breeding when one accepts that as breeding is in most cases a commercial activity.

<sup>43</sup> See, however, the below description of notification obligations vis-à-vis the third party beneficiary.



lump sum is deducted which includes administrative costs, taxes, shipping costs etc., so that the net benefit-sharing rate amounts to 0.77% of gross sales.

Monetary benefit-sharing remains voluntary and follows no standardized procedure, when the product remains available without the restrictions in question (Art. 6.8 SMTA).

A third option is the alternative (optional) payment scheme contained in Art. 6.11 SMTA. It provides the opportunity to make payments at a discounted rate of 0.5% of a product's gross sales for a period of 10 years (renewable), and holds for all products belonging to the same crop. However, the reduced rate is independent of whether or not the product is available without restriction. This means that, in exchange for a simplified and cheaper procedure, the category of voluntary benefit-sharing is abolished in this scheme.

The SMTA reiterates the call to share non-monetary benefits. In addition to the mechanisms listed in the International Treaty,<sup>44</sup> recipients are encouraged to place a sample of a product that incorporates MS material into a collection that is part of the multilateral system, for research and breeding, once the product's intellectual property collection has expired or is abandoned (Art. 6.9).

A final aspect relevant to benefit-sharing is that recipients, who obtain IPRs on products developed from MS material and assign such IPRs to third parties, shall also transfer the benefit-sharing obligations to that third party (Art. 6.10).

### **3.2.3. Monitoring**

There is a limited possibility to monitor the MTAs' implementation. This function is performed by the Governing Body of the Treaty and by the so called 'third party beneficiary' (which is designed to be FAO<sup>45</sup>). It covers the following aspects:

- *MTAs*: providers periodically inform the Governing Body and the third party beneficiary about the MTAs entered into (Art. 5(e) SMTA);
- *Third party transfers*: providers periodically inform the Governing Body and the third party beneficiary about transfers of PGRFA received from the MS to third parties (Art. 6.4(b) SMTA), including transfers of PGRFA under development (Art. 6.5(c));
- *Compliance*: providers and recipients can be requested by the third party beneficiary to provide information, including samples, regarding their obligations (Art. 8.3)
- *Sales, benefit-sharing payment, IPRs*: recipients shall submit to the Governing Body an annual report setting forth a) the sales of products by the recipient, its affiliates, contractors, licencees and lessees; b) the amount of the payment due; c) information that allows for the identification of restrictions that triggered the benefit-sharing payment (Annex II, para. 3). This information can also be requested by the third party beneficiary (Art. 4.4).

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<sup>44</sup> Exchange of information, access to and transfer of technology, capacity-building.

<sup>45</sup> Cf. Resolution 2/2006 of the IT Governing Body.

### **3.2.4. Dispute settlement**

Dispute settlement typically is a means to ensure that parties to an agreement comply with this agreement. However, this important compliance function does not take effect when one of the parties is not substantially interested in the other party's compliance. This problematic was identified in the case of the SMTA: for the provider, it does not matter whether the recipient shares benefits, because these benefits accrue to the multilateral trust fund and not to the provider. It is hence questionable whether the provider will indeed bring action against a non-compliant recipient. In order to tackle this deficit, the third party beneficiary was introduced. It has the right, along with the parties to the MTA, to initiate dispute settlement procedures regarding the rights and obligations of both providers and recipients (Art. 8.3 SMTA). The dispute settlement procedure itself has three stages: amicable dispute settlement, mediation, and arbitration.

### **3.2.5. Procedure of signature/acceptance**

In order to take effect, the MTA either needs to be signed or to be accepted by a simple shrink-wrap or click-wrap procedure. In the 'shrink-wrap' procedure, a copy of the SMTA is included in the packaging of the material (seed), and the recipient's acceptance of the material constitutes acceptance of the terms and conditions of SMTA. In a 'click-wrap' procedure, the SMTA is concluded on the internet. The recipient accepts the terms and conditions of the SMTA by clicking on the appropriate icon on the website or in the electronic version of the SMTA.

### **3.3. SMTA implementation**

The MTAs are private contracts which are 'implemented' above all by the parties to the contract. However, measures of other actors are necessary for the SMTA's implementation.

Above all, parties to the IT are obliged to place Annex-I crops in the multilateral system and make the respective germplasm available under SMTA conditions (Art. 10.2, 12 IT). All other holders of Annex-I material, be they private entities within the jurisdiction of contracting parties or private or public holders in the jurisdiction of non-parties, are 'invited'<sup>46</sup> (Art. 11.2 IT) to do the same. Holders in the jurisdiction of non-parties are likely to be able to access MS material under SMTA conditions.<sup>47</sup> They will be obliged to use the SMTA in subsequent third party transfers. At international level, agreements have been signed between the Governing Body and CGIAR's IARCs according to which they make available PGRFA from Annex-I available in accordance with the SMTA (Art. 15.1 IT). Other relevant international institutions are 'invited' to enter into similar agreements (Art. 15.5 IT).

### **3.4. SMTA Review**

There are various clauses and agreements on SMTA aspects that are to be reviewed, once the SMTA has been in practice long enough for its assessment. Above all, at the third session of the Governing Body (2009), its implementation and operation will be reviewed, in particular the benefit-sharing provisions and

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<sup>46</sup> or 'urged' (see para 7 of Resolution 2/2006).

<sup>47</sup> Cf. <http://www.absfocalpoint.nl/frame150.htm>

the modalities of payment.<sup>48</sup> From the third session on, the levels of payment will be periodically reviewed.<sup>49</sup>

In addition, within five years from the Treaty's entry into force (i.e. 2009), the contracting parties may review whether the mandatory benefit-sharing payment shall apply also in cases where commercialized products are available without restriction to others for further research and breeding (Art. 13.2d(ii) IT). If the distinction between mandatory and voluntary benefit-sharing in the case of monetary benefits was thus be abolished, monetary benefit-sharing would be triggered like in the CBD.

As regards application of the SMTA, the parties shall decide at the Governing Body's third session whether access shall continue to be facilitated to private entities that have not trusted Annex-I crops to the multilateral system (Art. 11.4 IT). Without any specified deadline, they shall furthermore consider modalities of a strategy for voluntary benefit-sharing by the food processing industries profiting from PGRFA (Art. 13.6 IT).

#### 4. Comparison between the SMTA and Certificates of Origin/ Source/ Legal Provenance

Can a certificate of origin/ source/ legal provenance be modelled on the SMTA? It can, but only with regard to its form, not with regard to its function. The below table systematises the differences and analogies between the SMTA and the envisaged certificates.<sup>50</sup>

Table 4: Comparison between certificates and the SMTA

	Envisaged Certificate of O/S/LP (CBD)	SMTA (FAO International Treaty)
Form	Document that follows a genetic resource (not clarified till when) or registration system	Document that follows a genetic resource (till commercialisation)
	Describes origin/ source/ legal provenance of genetic resource and/ or associated TK	Describes source (Multilateral System) and at same time proves legal provenance
Function	Instrument to <i>support</i> implementation of (bilaterally negotiated) ABS	Instrument to <i>implement</i> (multilaterally standardised) ABS
Legal nature	Public certificate (issued by provider country authority)	Private contract (signed by provider and recipient)
	International or national (but internationally recognized)	International
Use	Checkpoints under discussion	No checkpoints

Source: own.

As regards form, the SMTA is a document that physically follows a genetic resource until its commercialisation. Likewise, the certificate by many advocates is intended to follow the resource, although it is not yet clarified up to what checkpoints; patent offices are one among several suggestions. Alternatively to having a certificate physically follow the material, there is the idea to attach to it 'virtual' identifiers which are entered in a registration system. In both cases, however, the idea is that the document/ identifier established a geographical or legal provenance. In the case of the SMTA, it is the multilateral system that is determined both as 'source'<sup>51</sup> of the genetic material and as its 'legal

<sup>48</sup> Para. (x)2, Resolution 2/2006.

<sup>49</sup> Para. (x)9, Resolution 2/2006, in accordance with Art. 13.2d(ii) IT.

<sup>50</sup> Since so far no specific type of certificate has been agreed on, this comparison can of course not be definitive.

<sup>51</sup> If available, the SMTA will also specify as passport data the provider country (in the case of gene bank material) and the country of collection (in the case of material collected in situ). However, this 'related information' (Art. 5(b) SMTA) on the physical source should not be confused with the legal source under the International Treaty.

provenance'. In the case of the certificate, both 'origin', 'source', and 'legal provenance' of the genetic resource, but possibly also of associated Traditional Knowledge, are discussed as options.

As was mentioned, the SMTA and certificate differ with regard to their function: while the SMTA is a tool to *implement* ABS, the certificate is designed to *support* implementation of ABS. The SMTA itself constitutes a (multilaterally standardized) access and benefit-sharing contract, whereas the certificate is a 'bookkeeping' tool that comes into play only after ABS has been negotiated (bilaterally and on a case-to-case basis). In its form as certificate of legal provenance, it proves that ABS has been complied with.<sup>52</sup> When such a certificate needs to be submitted at specific checkpoints, it ideally works as a means to uncover non-compliance with ABS.<sup>53</sup>

In accordance with functional discrepancies, the legal nature of the two documents differs, too. The SMTA is a private contract between a provider and a recipient. It is an internationally standardised document. The certificate is envisaged to be a public certificate to be issued by a provider country authority. It has not been decided yet whether there will be one international certificate or different national certificates, which will however be internationally recognized.

In the use of the SMTA, there are no 'checkpoints' where a party to the SMTA would need to 'submit' the document. On the other hand, there is a general agreement that a certificate needs to be linked to checkpoints; the disagreement only starts when it comes to the type of checkpoint – border controls, food and drug approval, R&D grants, patent offices etc.. This difference with regard to checkpoints is due to the diverging functions of the two documents.

## **5. Assessment of the SMTA and 'lessons' for the certificate**

It was shown that despite formal parallels, the SMTA and a certificate serve different purposes in different contexts – a bilateral ABS regime under the CBD, and a multilateral regime under the International Treaty. A certificate hence can only in a restricted sense be modelled on the SMTA. In a similar vein, a system of certificates should not apply to the material under the Treaty's Annex I: the SMTA already 'follows' the respective PGRFA, linking it directly to its 'source' – the multilateral system –, hence proving its legal provenance, and not least obliging its recipient to share benefits. If certificates were to be required for this material, too, it is unclear what such an extra document could add except transaction costs.

Despite this limited transferability of the concepts, policy-makers can learn from the SMTA for designing the certificate. In the following, I will attempt to briefly assess the ABS regime implemented through the SMTA<sup>54</sup>, focussing on aspects relevant for the certificate. Assessment criteria include technical functioning, transparency, legitimacy, efficiency and effectiveness.

As regards *technical functioning*, the SMTA provides easy access with its effortless click/shrink-wrap acceptance procedures and minimal documentation standards. Likewise, the benefit-sharing procedure is

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<sup>52</sup> This only holds as long as a country has implemented national ABS provisions.

<sup>53</sup> However, Tomme Young (in this volume) argues convincingly that, to a great extent, certificate proposals are addressed to compliant rather than to non-compliant users. Non-compliant users will conceal any links between their product and a (post-CBD) genetic resource accessed and will, if successful, not need to submit a certificate.

<sup>54</sup> In the assessment, overlap cannot be avoided completely between ABS aspects pertaining to the SMTA and to the International Treaty proper.

kept simple due to the final product model that underlies the SMTA. Both aspects are likely to foster technical functioning.

*Transparency* is advanced by the one-size-fits-all approach. On the other hand, the legal text is rather complex and is apt to fog things up.

Still, the SMTA as such provides legal certainty and predictability to providers and recipients, which is relevant for the document's *legitimacy*. Also, the third party beneficiary raises the enforceability and ultimately legitimacy of the ABS procedure.<sup>55</sup> The allocation of benefit sharing returns to farmers as stewards of agrobiodiversity likewise contributes to the SMTA's/ the Treaty's legitimacy as it balances breeding industry interests with farmer recognition. Even the rate of monetary benefit-sharing negotiated (1.1%) for the time being seems to be accepted as legitimate – at any rate, there was no loud outcry against it, neither by developing nor developed countries, industry nor civil society. On the other hand, there are aspects that impact negatively on the SMTA's/ the Treaty's legitimacy. For example, non-parties and private entities may profit from the multilateral system without contributing material to it, and it is not clearly settled whether or not patenting of unaltered MS material is prevented.<sup>56</sup> In terms of procedural legitimacy, it was certainly detrimental that during the whole process of negotiating the SMTA, civil society organisations – unlike industry representatives – were not admitted as observers.

As regards *efficiency*, the standardized benefit-sharing procedure that is organised through the SMTA reduces transaction costs vis-à-vis alternative approaches.

At this point of time it is not yet foreseeable how *effective* the SMTA will be, i.e. how conducive it will be to facilitating access and ensuring fair and equitable benefit-sharing. As regards access, it is expected that restrictions will be lifted which had built up in the past years. The view taken on benefit-sharing is commonly less optimistic. Firstly, the use of PGRFA from the multilateral system, and hence the flow of shared monetary benefits, will depend on how intensely users of genetic resources will utilize the system, and this again depends on their financial (or strategic) calculus. Secondly, whether or not a monetary benefit-sharing obligation arises at all depends on the interpretation of when an IPR actually restricts further research and breeding. Some actors advocate such a narrow interpretation<sup>57</sup> that it seems unlikely that the modest, let alone equitable sum of monetary benefit-sharing will accrue. In any case, considering the time lag between access and commercialisation connected to patents, 'quick wins' are not likely. As regards compliance, it is encouraging that the SMTA's/ Treaty's ABS regime allows for less evasion than the CBD's regime.<sup>58</sup> The third party beneficiary's right to initiate dispute settlement and to receive relevant information certainly increases the incentive of recipients to comply with their obligations. However, for this incentive to become real the third party beneficiary needs to fulfill its role (pro-) actively and needs to develop some clout. It remains to be seen whether the scope of its monitoring rights

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<sup>55</sup> This gain in legitimacy was noticeable during the negotiation process, after the African Group had first introduced the third party beneficiary concept.

<sup>56</sup> "It would be intolerable if (freeloading) companies or universities, benefiting from easy terms of access, were to come into the system to isolate valuable genes and then proceeded to use patents to make these genetic materials off limits to others. In this case, the system would actually serve to diminish the access to genetic materials." (Francois Meienberg, Access and Benefit-Sharing under the FAO Seed Treaty. EvB Paper, p. 2.  
Available at [http://www.evb.ch/cm\\_data/ABS\\_under\\_the\\_ITPGR\\_engl\\_2\\_\\_2\\_\\_2.pdf](http://www.evb.ch/cm_data/ABS_under_the_ITPGR_engl_2__2__2.pdf))

<sup>57</sup> See Footnote 42.

<sup>58</sup> For example, potential loopholes are avoided that emerge when distinguishing between pre/post CBD material, between genetic and biological resources, and between within/ beyond national jurisdictions.

and its capacity to exercise these rights will suffice to make this possible.<sup>59</sup> A final, positive aspect is that the SMTA with its various review options has a built-in potential for learning – and hence for increasing its future effectiveness as well as legitimacy.

Which of these lessons can be transferred to designing and negotiating a certificate? With regard to *technical functioning* it became clear that a standardized and international approach is simple and transparent. However, the question of technical functioning should be tackled only when the certificate's main purpose is agreed on. As regards *legitimacy*, a link between ABS and conservation/ sustainable use enhances the wider societal legitimacy – especially if the stewards of biodiversity directly profit from the shared benefits. In terms of procedural legitimacy, participation of civil society/ indigenous peoples is indispensable. As regards *efficiency* it is necessary that the costs of establishing and running a system of certificates do not eat up the gains in terms of improved benefit-sharing. In terms of *effectiveness* it seems likely that only a certificate design that will manage to increase compliance with ABS (e.g. through setting the respective incentives) will in the long run be accepted by users and providers alike. Built-in review options provide space for learning processes. Apart from such certificate-specific lessons, the example of the International Treaty and its SMTA shows in a general sense how access and benefit-sharing can also work through a multilateral regime.

## 6. Concluding remarks/ recommendations to the Group of Technical Experts

- A certificate has a different function than the SMTA
- A system of certificates should not apply to the material under the International Treaty's Annex I
- Nevertheless, there are 'indirect' lessons:
  - Technical functioning:
    - A *standardized* and *international* approach is simple and transparent.
    - The question of technical functioning is important, however, should be tackled only when the certificate's main purpose is agreed on.
  - Legitimacy:
    - A link between ABS and conservation/ sustainable use enhances the wider societal legitimacy; make the stewards of biodiversity benefit from ABS.
    - Participation of civil society/ indigenous peoples is indispensable.
  - Efficiency:
    - The costs of establishing and running a system of certificates should not eat up the gains in terms of improved benefit-sharing.
    - Effectiveness:

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<sup>59</sup> Especially with regard to the third party beneficiary's limited capacities, it might have been worth to ponder a role for non-governmental organisations (NGOs) in monitoring. Such a role is entrusted to NGOs for example in the context of monitoring implementation of the (voluntary) OECD Guidelines for Multinational Enterprises, where the complaint procedure allows NGOs to submit complaints concerning alleged breaches of the Guidelines to governments' National Contact Points.

- Only a certificate design that will manage to increase compliance with ABS (e.g. through setting the respective incentives) will in the long run be accepted by users and providers alike.
- Built-in review options provide space for learning processes.

# The permit and certificate system of CITES

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## 1. Abstract

In order to understand the permit and certificate system under the Convention on International Trade of Endangered Species of Wild Fauna and Flora (CITES), some basic concepts of this Multilateral Environmental Agreement (MEA) need to be clarified. These comprise the following: Parties / Non-Parties accepted in trade; Management Authorities (MA) and Scientific Authorities (SA); CITES protected specimen; the special procedures laid down for specimen of species included in the Convention Appendices I, II, III; standardized documents; monitoring of trade; and exceptions (i.e. derogations from documentation).

Likewise, it is crucial to be familiar with some definitions. “Trade” in CITES is understood as any transport (whether or not commercial) across national borders and introduction from the sea; “species” include species, subspecies or populations; and a “population” is any geographically or biologically separated group of specimen of a species.

CITES protected specimen can be any animal or plant, whether alive or dead, or any readily recognizable part or derivative of animal or plant species included in App. I and II (exemptions for App. III and plants). The term “readily recognizable parts and derivatives” shall be interpreted to include any specimen which appears from an accompanying document (the packaging, mark or label) or from any other circumstances, to be a part or a derivative of a CITES-protected species.

CITES documents include import permits, export permits, re-export certificates, pre-Convention certificates, certificates of captive breeding or artificial propagation, certificates of origin, phytosanitary certificates, labels for non-commercial exchange of scientific material, and finally permits and certificates issued under the simplified procedure for biological samples. The CITES Conference of Parties discussed for each case and adopted how CITES documents are structured, what information they must provide for and for what transaction they can be used. The current provisions in place on the use and concepts of such CITES documents are laid down in CITES Resolution Conf. 12.3 (Rev. CoP13) ‘Permits and Certificates’ ([www.cites.org/eng/res/12/12-03R13.shtml](http://www.cites.org/eng/res/12/12-03R13.shtml)). These documents will be elaborated below.

Standardised CITES permits must be issued in one of the working languages of CITES (E, F, S). They feature the full name and logo of the Convention, as well as the complete name and address of the issuing authority, name of the signatory and handwritten signature, an embossed seal or ink stamp, a security stamp (if used by the country). They also document the complete name and address of the importer and of the exporter, the date of issue and expiry date (mostly 6 months), the quantity allowed to trade (note that the unit must be clarified in each document: spec., kg, m<sup>3</sup>, l). In addition, the documents declare the space for export endorsement as made by customs or other designated officials, the country of export (MA of this country issues the export permit), the country of last re-export (MA issues re-export certificates, the number of the last certificate must be included in subsequent documents), the country of import (MA of this country issues the import permits, i.e. for App. I wild specimen), country of origin i.e. where the



specimen were taken from the wild or bred in captivity or artificially propagated (= country of export). The scientific name of the specimen (according to the nomenclature agreed by the Parties) is listed as well as the common name of the species and description of the specimens (to identify the specimen, this includes additional information as age, sex, date of birth, special marks such as colour, tags, rings, labels etc.). The CITES Appendix lists the respective species. Finally, the source of the specimen is specified (with source codes agreed by the Parties, i.e. W = wild, C= bred in captivity, A= artificially propagated, R= ranches) and the purpose of the trade (i.e. T= commercial, Z= zoo, S= scientific, M= medical/bio-medical research) is stated.

A CITES certificate of origin can be used only for export of specimens of species listed in Appendix III. They can be used only by countries which did not submit the species for inclusion in Appendix III. They must be issued by a designated Management Authority or by the competent authority if trade is from a State not a Party to the Convention. Parties do not accept certificates of origin unless they are issued by such authorities. A certificate of origin shall be valid for a period of not more than 12 months from the date on which it was granted.

Phytosanitary Documents can be used as CITES export document. They are restricted to Appendix II plants and Orchid hybrids, and can only be used by those countries which have notified the use of this document (Not. 1999/022 provides the present list of Parties which use this document). The phytosanitary certificate includes the scientific name of the species, its quantity, and a declaration that „the specimens have been artificially propagated according to Art. VII para 5 CITES“.

The exchange of scientific material in accordance with CITES Art. VII (6) can take place only between registered scientific institutions or persons which are notified to the Parties. It is restricted to non-commercial loans, donations or exchange, and may encompass live plants, herbar material as well as other preserved, dried embedded museum specimen. For this kind of exchange, simplified documents are used, so called labels.

The CITES simplified procedure for biological samples is also based on Resolution Conf. 12.3 (Rev.CoP13), chapter XII. In general, CITES Parties can use simplified procedures to issue permits and certificates in order to facilitate and expedite trade; where such trade will have either only a negligible or no impact, on the conservation of the species concerned. This is the case e.g. where biological samples of the type and size specified in Annex 4 of Res. Conf. 12.3 (Rev. CoP13) are urgently required; for the issuance of pre-Convention certificates; for the issuance of documents for animal specimen bred in captivity or for artificially propagated plant specimens or in any other cases, judged by a Management Authority which merits the use of a simplified procedure. Biological samples are ‚urgently required‘ when this is in the interest of an individual animal; in the interest of the conservation of the species concerned or other species listed in the Appendices; for judicial or law enforcement purposes; for the control of diseases transferable between species listed in the Appendices; or for diagnostic or identification purposes. In such cases, Parties need to maintain a register of persons / bodies that may benefit from simplified procedures, as well as the species that they may trade. They have to provide to registered persons / bodies partially completed permits and certificates that remain valid for a period of up to 6 months for export permits, 12 months for import permits or re-export certificates or three years for pre-Convention certificates and certificates of captive breeding or artificial propagation. Finally, they authorize the registered persons / bodies to enter specific information on the face of the CITES document

(completion of pre-issued documents). The CITES Management Authority has included in the pre-issued document a list of the boxes that the registered persons or bodies are authorized to complete for each shipment; any special conditions; and a place for the signature of the person who completed the document. The CITES Scientific Authorities develop generic non-detriment advice that would cover multiple shipments of such biological samples, taking into account the impacts of the collection of the specimens of species included in Appendix I or II to determine whether the export or import of biological samples would be detrimental to the survival of the species. The importing countries accept permits and certificates that were validated at the time the documents were granted, rather than at the time a shipment was exported or re-exported provided that the container bears a label, such as a customs label, that specifies ‘CITES Biological Samples’ and the CITES document number.

Following Dross/Wolff (2005: 96f),<sup>60</sup> the differences between CITES Certificates and the certificate concepts discussed under the CBD are summarised in the below table:

<b>CITES permit</b>	<b>CBD Certificate of origin/ source/ legal provenance</b>
<b>Object of regulation</b>	
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 ex-situ sources
Product is well described with the definition of the term ‘specimen’	“Product” might be unknown (coded samples)
<b>Goals</b>	
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
<b>Scope</b>	
Covers only one operation	May cover multiple operations
Role ends with the import into importing country	Applies to the flow / process of genetic resources use
The regulated action starts and ends with trade	Regulation of access implies a process, not just a movement
<b>Institutionalisation</b>	
A government agency decides on compliance with criteria for export / import (NDF, legal acquisition)	A government agency would decide on compliance with PIC and arrangements on benefit-sharing
Customs officers verify compliance	Other areas (i.e. patent officers might be involved as well)
Persons requesting the permit usually know the value of the specimen	Person requesting the certificate will probably not know the value of the specimen (uncertainty)

<sup>60</sup> Dross, Miriam/ Wolff, Franziska (2005): New Elements of the International Regime on Access and Benefit-Sharing of Genetic Resources – the Role of Certificates of Origin. BfN-Skripten 127. Bonn.

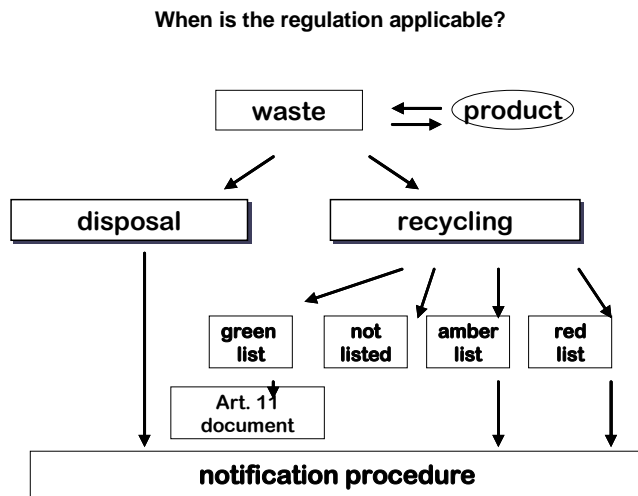
A problem that occurs when discussing the CITES system in relation to a Certificate of Origin/ Source/ Legal provenance is that identical terms used in CITES and CBD language have significantly different meanings. This includes “country of origin”, “source”/”country of source” and “derivatives”.

# Notification control mechanisms in the Basel Convention

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## 1. The Basel Convention

The Basel Convention is an international agreement for addressing the problems and challenges posed by hazardous waste and the disposal which establishes a system that controls the movement of hazardous waste. The rules and obligations of the Basel Convention are legally binding within the EU by dint of EU-Regulations on shipments of waste. The diagram below shows when the regulation is applicable.



Central provisions of the Basel Convention provide for that the import, export and transit of waste is allowed only if all states (authorities) concerned gave their consent in advance. Waste shipments to non-party states are in general inadmissible. The exporter or, alternatively, the state from which the wastes originate is responsible for (competent authority of dispatch) compliance with the Convention and is obliged to take back the waste in question, if necessary. This obligation applies in particular to illegal traffic of waste.

Within the EU, the legal basis for these provisions is the Waste Shipment Regulation (WSR No. 259/93, new No. 1013/2006) which integrates and improves the a. Basel Convention, b. OECD Council Decision [C(92)39; C(2001)107].<sup>61</sup> The Waste Shipment Regulation is supplemented by domestic law, in the case of Germany by the Act on the supervision and control of transfrontier shipments of waste.

The EC Waste Shipment Regulation aims at implementing the EU environmental policy principles of self-sufficiency, of proximity, the precautionary-principle, conditions for waste processing plants and the prohibition of shipment of waste to certain countries. EC Waste Shipment Regulation requirements

<sup>61</sup> The OECD-Council Decision is applicable in OECD-Countries for waste for recovery (implementation of OECD-Council Decision in national law). It provides for a waste classification into three lists (change of listing to conform with domestic legislation): Green - without supervision; Amber - requiring notification (permit); Red - requiring notification (permit).

depend on a. the route of the waste shipment (within a member-state, between member-states, exports from the EU, imports in the EU, transport through the EU) and b. the purpose of the shipment ((final) disposal, recovery).

Documents to be submitted with the notification include a notification- and movement form; the contract between the notifier (exporter) and consignee (importer) including the obligation to take the waste back; a liability insurance or transport licence of the transporters; a proof of deposit of financial guarantee; the description of the transport route; a declaration on waste-source and composition of waste; and the description of the waste treatment plant (treatment procedures, capacity, location, duration of permit).

The regulatory areas of the EC-WSR for import, transit and export of waste are summarized in the below tables.

<b>Regulatory areas of the EC-WSR for import and transit of waste</b>			
<b>Transfrontier shipment</b>	<b>Within the EU Art. 3 to 12</b>	<b>Import into the EU Art. 19 to 22</b>	<b>Through the EU Art. 23/24</b>
<b>waste for disposal</b>	permitted	prohibited with <u>exceptions*</u> <i>authorisation</i> Art. 19 to 20	permitted, <i>authorisation</i> Art. 23
<b>waste for recovery, Annex II, (Green List)</b>	<i>free movement*</i> Art. 11	permitted*) Art. 1 (3) Art. 11	permitted*) Art. 1(3) Art. 11
<b>waste for recovery, Annex III, (Amber List)</b>	permitted*)  <i>notification</i> Art. 6 to 9, 12	prohibited, with <u>exceptions*</u>  <i>notification*</i> Art. 21 to 22	permitted*) <u>for OECD:</u> <i>notification: Art. 24</i> <u>other states: authorisation</u> Art. 23
<b>waste for recovery, Annex IV, (Red List) or unlisted waste</b>	<i>permitted</i>  <i>authorisation</i> Art. 6 to 8, 10, 12	prohibited, with <u>exceptions*</u> <i>authorisation</i> Art. 21 to 22	permitted  <i>authorisation</i> Art. 23, 24
<p>*) Possible restrictions through stricter regulations or bans</p> <p>* <i>import from Basel parties and countries with which bi-lateral agreement is permitted</i></p> <p>* <i>import from OECD-MC, Basel parties and countries with bi-lateral agreement is permitted</i></p>			



# Tracking form

Companies involved  
Information on transport  
Information on waste

Acknowledgement of receipt

Certificate of final disposal

The image shows a complex form titled 'GRENZÜBERSCHREITENDE VERBINGUNG VON ABFÄLLEN' (Cross-border movement of waste) from the 'EUROPÄISCHE GEMEINSCHAFT (EG)'. It contains numerous fields for identifying the parties involved (1-4), the waste itself (5-8), and the transport details (9-11). It also includes sections for acknowledgment of receipt (12-14) and a final disposal certificate (15-16). The form is filled out with some information, such as the waste code '000000' and the date '1999-01-01'.

After authorization, the notification procedure includes the following steps: Three working days before the shipment is made the movement form has to be completed and copies have to be send to the competent authorities concerned. During transport a copy of the notification form, together with the stamp of authorization, the original movement form, and other relevant papers shall accompany each shipment. Within three working days following receipt of the waste, the importer shall send copies of the completed movement form (box 23/24) to the notifier and the competent authorities concerned. As soon as possible and not later than 180 days following the receipt of the waste, the importer shall, under his responsibility, send a certificate of disposal (box 25) to the notifier and the other competent authorities concerned.

## 2. Veterinary and zootechnical checks

Veterinary and zootechnical checks within the European Union are based on the Council Regulation 136/2004 procedures for veterinary checks at Community border inspection posts on products imported from third countries. Before the physical arrival of the consignment on Community territory the responsible person shall notify the arrival of the products to the veterinary staff of the border inspection post to which the products are to be submitted, using the Common Veterinary Entry Document (CVED). The veterinary checks shall be completed under the responsibility of the official veterinarian responsible for the border inspection post. The CVED shall be signed by that official veterinarian to give veterinary clearance to the consignment. The further control procedure remain under custom supervision.

# **The science commons project approach to facilitate the exchange of biological research material -Implications for an international system to track genetic resources, associated user conditions and traditional knowledge**

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## **1. Aim of this presentation**

In the following minutes I will provide you with a brief introduction to the science commons project approach to facilitate the exchange of biological research material.<sup>63</sup> The information presented to you is drawn from publicly available sources and personal communication that I had with John Wilbanks, the Executive Director of this project.

Why is the science commons project interesting to the international ABS negotiations in general and the discussions on an internationally recognised ABS certificate? - It is interesting because it provides fresh ideas on one of the key challenges in the ABS debate: how to technically enable the tracking of genetic resources and associated information (such as prior informed consent, user conditions established in material transfer agreements or on associated traditional knowledge) at very low cost. As we discussed yesterday, one expectation attached to the idea of an internationally recognised ABS certificate, is that it will allow for the "tracing" or "tracking" of genetic resources throughout the user chain.

In the second part of my presentation I will present some very preliminary thoughts on the potential implications of the science commons project for the establishment of an international system to track genetic resources, associated user conditions and traditional knowledge in the context of the international ABS negotiations.

## **2. The Science Commons Project and its Work on a Material Transfer Agreement for biological research materials**

What is the science commons project doing? Yesterday, in his presentation on an internationally recognised ABS certificate, Jose Carlos put on the screen a white box indicating the area of "free access", where, in his view, such certificate should not interfere.

This area of "free access" is in fact an area with many restrictions. Legal departments of universities and in the commercial sector invest a lot of time and money into negotiating access to interesting research material, in fighting third party claims based on conflicting intellectual property rights, or in seeking to clear legal risks before moving from the R&D phase to commercialisation.

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<sup>62</sup> Policy officer in the Environment Directorate-General of the European Commission. The views presented in this paper are personal and do not reflect official positions of the European Commission. Any inaccuracies in describing the science commons project fall under my personal responsibility.

<sup>63</sup> See <<http://sciencecommons.org/>> for general introduction to the science commons project, key motivations and further links to specific activities.



It is the main objective of the science commons project to reduce some legal and technical barriers to scientific collaboration and innovation and thereby speed up the process of and lower the costs for research and innovation.

As one part of its activities, the science commons project is currently finalising a standard Material Transfer Agreement for biological materials held in private and public collections. It is expected that this standard MTA will drastically lower transaction costs for researchers interested in obtaining specified biological material for their work. This hope is based on a number of interesting features:

*First*, science commons seeks to lower the time and energy spent on negotiations of MTAs by *standardising the possible choices providers and users can make*. This is nothing revolutionary. Interesting, however, is the process of how this was achieved.

To develop their standard MTA, science commons brought together a small group of lawyers familiar with MTA negotiations, to work through a large number of existing MTAs and to identify the few key issues that typically consume negotiating time. Only for these issues, providers and users are actually offered some choice in the form of a menu of standardised choices to pick from.

Restricting choices when concluding MTAs to a standardised set will not be ideal for cases in which biological material has been identified as commercially valuable. However, in the 99% normal cases, where there is, *ex ante*, high uncertainty if a specific material has any value at all to an ongoing research project, this approach will dramatically lower negotiating time and costs for both sides.

So in practice, a provider of biological material will select his/ her preferred combination(s) of licensing conditions and the potential user is faced with the choice to accept (one of) these conditions or to start costly and time-consuming negotiations.

The *second* innovative aspect is that MTAs concluded under this system not only exist in "human readable" form and as detailed legal text. They are also *automatically translated into an electronic, machine readable version* that can be communicated through electronic networks such as the world wide web. [NB:The system also allows for manually feeding in information on MTAs that have been "freely" negotiated.]

Linking real world samples of biological material and attached licensing conditions with the communicative abilities of the WWW opens a range of interesting options.

For instance, once information on biological material and potential user conditions is published on the internet (which only requires a PC, software and internet access and thus can be done from anywhere in the world at low cost) it can be picked up by specially programmed search engines that permanently crawl the web and update a virtual register of the internet-locations of biological materials and attached user conditions.

The fundamental approach of sharing information on samples and (potential) user conditions via the internet would thus dispense of the need to maintain a central registry of biological materials, their unique identifiers and potential licensing conditions.

Furthermore, it is feasible to automatically and electronically link the original entry by the original provider of biological material with subsequent entries on transactions that have taken place via this

system. Any further MTAs concluded regarding a specific biological material are automatically recorded in the licensing agreements that are electronically linked to specified samples of biological material.

The *third* innovative aspect is that science commons makes use of a new generation of internet language, the so called *semantic web*. Currently, information is put on the internet using HTML-text. HTML does not support the establishment of meaningful connections between different pieces of information found at different internet locations. This is, however, possible using semantic web language. As a result, it is, for example, possible to relate an entry on a specific research material to another entry on associated traditional knowledge or information on references to this research material in scientific journals. Such relations can then be extracted from the web through specific searches.

How would a working environment based on the science commons approach look like?

Potential users of biological research material would be able to retrieve from any point on the globe with internet-access comprehensive information on where a specified biological material can be obtained and under which licensing conditions.

After identifying the most favourable licensing agreement, a potential user would electronically accept the standardised contract and transfer the agreed amount of money to a "parking spot" (just like in case of E-Bay), while the provider arranges for shipment of the sample.

The transfer that has taken place is automatically recorded in the licensing agreement "attached" to the sample of biological material that is about to be shipped to the user.

If biological material is passed on from user-1 to user-2 and therefrom to users-3a and 3b, and user 3b discovers s.th. interesting, and plans to develop a product or claim a patent, he/ she can easily deduct from the licensing agreement "attached" to the biological material with whom to renegotiate the user conditions in case that the original licensing conditions were for non-commercial use only.

The original provider of biological research material would be in a position to search for the unique identifier of a specific research sample and he/ she would instantly obtain information on subsequent uses of this material and licensing conditions attached. This would allow, for instance, to check whether subsequent MTAs were concluded in accordance with the original licensing conditions granted to the first user in the chain.

### **3. Potential implications of the science commons project to the ABS negotiations**

There are some obvious implications of the science commons project to the international ABS negotiations, and specifically to efforts to establish an international system to track genetic resources, associated user conditions and traditional knowledge.

First, it is important to acknowledge that a *system to track biological research material and associated user conditions can be constructed in a way that many potential users of this system want to see it up and running as quickly as possible*. The science commons project is currently gathering a lot of support within the research community and by commercial users of biological material because it promises to hugely improve their working environment.

It would be a major step forward in the ABS debate if efforts to establish a system for tracking genetic resources and associated user conditions were perceived as an effort that would at the same time improve

the conditions for research and business to work on genetic resources found in situ and held in ex situ collections. Currently, much of the opposition to ABS in user communities stems from the perception, that an international ABS regime (however it might look like) will create additional costs and potentially uncertainties. It would change the character of the ABS debate if the benefits of participating in an ABS system would be seen to outweigh additional compliance costs that may be unavoidable.

While the use of latest technology along the lines of the science commons project might lower transaction costs for tracking genetic resources, this would, of course, only solve one challenge of ABS governance. Other challenges would remain, but some of them might become a slightly different flavour:

Going down this road would require the *development of one or more standard MTAs with lowest possible transaction costs*. The science commons approach to developing a standardised menu of choices for a MTA seems to provide valuable lessons that could be replicated in the ABS context, perhaps for different user sectors. However, the question needs to be raised to what extent parties to the CBD would actually need to negotiate suitable MTAs in a multilateral context. It might be much simpler and more elegant to agree to accept standard MTAs developed under the responsibility of groups of providers and users from different sectors.

Any tracking system, and this is not specific to tracking genetic resources needs to be supported by a *system that allows for the identification of the objects that shall be tracked*. Many such identification systems already exist for collections of genetic resources, mostly, because there is some value attached to it: Researchers are interested in the origin or research history of specific samples. Biotech companies are interested in unique identifiers since it allows them to capture royalties on their intellectual property rights in the user chain. The same interest of being able to identify subsequent uses, exists with countries or institutions that provide access to their genetic resources.

Clearly, the aim would not be to replace existing identification systems, but rather to develop a meta-codification system that links existing identifiers to a second and new layer of identification that would generate information that can directly be processed in electronic networks. Developing such identification system seems to be a technical, expert task.

Solving the challenge to link a specific genetic resource with information on one, more, or a series of MTAs is fine. However, what about PIC? Work would need to be done to ensure that providers would have access to such a system and are trained to use it. This raises the issue of capacity building.

Challenges to integrate "associated traditional knowledge" into any tracking system have already been discussed this morning. The system developed by the science commons project does not offer any concrete solutions to *protecting* traditional knowledge. However, it could be useful for ensuring that users in the genetic resources value chain can not excuse themselves for not having been aware of TK associated to specific genetic resources.

At last, being able to track genetic resources obviously does *not solve the challenge of ensuring that users of genetic resources comply with ABS requirements* flowing from prior informed consent and set out in material transfer agreements. In this context, an internationally recognised ABS certificate might have a role to play as would other measures, such as disclosure requirements, that would provide incentives to users of genetic resources to ascertain themselves that the resources they are using for their work or for commercialisation have been obtained in conformity with PIC and MAT.

#### **4. Concluding statement/ recommendations to the Group of Technical Experts**

Some general observations on the discussion during the Vilm Workshop<sup>64</sup>

##### 1) On the functions of a certificate

One function accorded to a certificate is to provide legal credibility to the claim documented in the certificate. In civil law, certificates are widely used to substantiate a claim, to provide it with legal credibility, to authenticate a statement.

A certificate of origin or source would thus not only provide factual information on the origin or source of a genetic resource, but this factual information would be certified, ie provided with some legal credibility. It seems important to clearly identify the value added such additional legal credibility could bring to, for instance, procedures requiring disclosure of origin or source of genetic resources.

As regards a certificate of legal provenance or compliance, certification would cover more than factual information, it would serve to prove that access legislation in the country of origin or source of a genetic resource has been complied with. Such certificate might be issued after a rather complex access process, depending on the particularities of national access legislation in the country from which a genetic resource has been obtained. It seems that in this case, a certificate might be useful for both users and providers of genetic resources, as it would authenticate a claim (eg, genetic resource obtained in conformity with national access legislation of the country of origin or source) that is very difficult to substantiate in other jurisdictions and with a time-lag of months or years between the access and the need to provide evidence of conformity with access legislation of the country of origin or source from which a genetic resource was originally obtained.

A second function frequently associated with an internationally recognised ABS certificate is the function of tracking or tracing genetic resources throughout the user chain.

It is difficult to see how a certificate could help with the tracking or tracing of a genetic resource, since, in general, an "ABS certificate" and its corresponding genetic resource would not be physically attached to each other. By its nature, a certificate does not address the key challenge of any tracking system, ie to link a specific physical material to the information about its origin, source, licensing conditions, associated traditional knowledge etc.. Establishing such link requires some type of infrastructure. This could be a physical infrastructure, such as check points at borders where customs officials screen imported goods (eg, CITES permit system) or it could be an electronic infrastructure, such as the science commons approach for tracking biological research material addressed in my presentation. Clearly, the choice of infrastructure needs to correspond to the type of physical material and associated information that needs to be tracked. - An ABS certificate might be a useful to authenticate a certain type of information about a specific genetic resource. However, it is not and should not be confused with tools to link information about a genetic resource to the physical resource itself.

##### 2) On the scope of a certificate

Will a certificate apply to only one specific GR? to all GR collected from one organism? to all GR collected at a specific site? to all GR collected with one research permit? These questions highlight that a

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<sup>64</sup> These comments are made in a personal capacity and do not reflect official positions of the European Commission.

certificate and its potential scope need to be considered vis a vis specific access practices. If there is no technical capacity to screen and catalogue GR at the point of collection/ within the country of origin, it might be difficult if not impossible for authorities of this country to issue a certificate at all.

Also, it seems important to be mindful of the scope of ABS certificates vis a vis the scope of Material Transfer Agreements. Unless there is a clear case that MTAs do not provide sufficient legal certainty to providers and/ or users of genetic resources, overlaps between the scope of application of MTAs and of an internationally recognised ABS certificate should be avoided.

### 3) On the WTO relevance of an internationally recognised ABS certificate

Some commentators have raised WTO concerns about an internationally recognised ABS certificate. Upon closer reflection, these concerns appear unfounded.

First, it is important to be precise about the point of departure of such analysis. WTO concerns voiced often make reference to an "ABS certification scheme" (akin to the Forest Stewardship Council but as a mandatory measure), whereas discussions on an internationally recognised ABS certificate in the CBD negotiations focus on providing legal credibility to a specific, much more focussed claim (origin or source of GR, legal provenance of GR). The CBD discussions on an ABS certificate bear no resemblance to discussions on, for example, a certification scheme for wood products derived from forests managed according to specified minimum environmental and social standards.

Secondly, WTO concerns about an "ABS certification scheme" ignore one fundamental difference between certification systems such as, for instance, the Forest Stewardship Council and what is being discussed under the term "internationally recognised ABS certificate":

Certification schemes for forest products, marine products, clothing etc. aim to push exporting countries/operators upstream in the production chain, to ratchet up their standards of performance (eg implementing higher environmental standards, prohibiting child labour). It is consumers in importing countries (in case of voluntary certification) or governments of importing countries (in case of certification as precondition for placing products on the market) that exert pressure on exporting countries to comply with specified environmental and/ or social standards.

An "internationally recognised ABS certificate", in contrast, would aim to support provider countries to implement their own domestic legislation more effectively. An internationally recognised ABS certificate would expand the reach of domestic legislation of provider countries beyond their national jurisdiction with a view to ensuring that users of genetic resources in user countries (ie "importing countries") have complied with access legislation of provider countries (ie "exporting countries"). It would thus seek to prevent the use of illegally obtained genetic resources in the markets of user countries ("ie importing countries") and do so in the interest of provider countries (ie "exporting countries").

It is important to appreciate this different perspective, since WTO law seeks to control importing countries to ensure that these do not discriminate against or unduly restrict market access of products/ services from other countries. From a WTO perspective, "certification schemes" for forest products etc. are therefore often regarded with scepticism. WTO law, however, does not impose restrictions on importing country measures adopted and enforced in the interest of exporting countries (if such measures are of non-discriminatory nature, of course).

Thirdly, even if one were to ignore these fundamental differences, it is important to highlight that CBD parties are looking into the feasibility etc of an internationally recognised ABS certificate. We are talking about national measures based on international standards established through multilateral cooperation in the framework of an international agreement with almost universal membership. It is worth to highlight that the WTO's Appellate Body has repeatedly stressed that international cooperation efforts are regarded as the most appropriate way to achieving mutual supportiveness between international trade law and other spheres of public international law. Should any WTO concerns arise regarding an "internationally recognised ABS certificate", it would be positively considered in the interpretation of WTO law that such instrument would constitute the consensual outcome of negotiations between the currently 189 parties to the CBD.

To conclude: academic commentators that identify a range of WTO concerns relating to an ABS certificate often start from the scenario that some user countries will unilaterally implement a demanding ABS certification scheme against provider countries that seek to flood the markets of user countries with "non-certified" genetic resources. Such scenarios (and respective considerations on their WTO (in)compatibility) bear no resemblance to discussions on an internationally recognised ABS certificate in the CBD framework.

Many thanks for your kind attention.

## **IV. Implementation challenges of an International Certificate in European Countries**

### **Survey: Users of genetic resources in Germany. Results according to an internationally recognized certificate of origin/source/legal provenance**

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#### **1. Abstract**

In the international discussions on the development of an international regime it is obvious that the role of users of genetic resources becomes more and more important. The survey on users of genetic resources in Germany was conducted in order to provide insights on the structure, the level of awareness and participation, the experiences and the positions of the actual and potential users of genetic resources.

The German user survey shows that users of genetic resources in Germany are very heterogeneous. They cover many different sectors (e.g. agriculture, health, horticulture) and they differ in size and research activities (e.g. only research or research and development). Therefore, their level of information and awareness, their willingness to participate and their perspectives and concerns vary by sectors but they are important determinants which should be considered for the design and implementation of strategies for an international regime.

The share of commercial users among the respondents is quite high. More than 40 percent of the identified users use genetic resources for the development of marketable products and 11 percent use them for the development of intermediate products. The rest of respondents uses genetic resources for research purposes or collection, conservation and distribution activities (as for example ex-situ collections). About 50 percent of all users have already developed products by using genetic resources, and/or applied for patents and/or plant protection rights. The role of intermediaries is very important of the acquisition. The main source of genetic material for users are providers from the country of origin and providers outside of the country of origin. Users still experience many difficulties to obtain resources. The main stated problems are difficulties in finding contact persons, uncertain regulations, and image problems.

In general, the level of awareness is quite low. Users are poorly informed about CBD and ABS regulations. The fact that many CBD member countries have their own authorities (National Focal Point and National Competent Authority) which serve as contact partners in questions of ABS is widely unknown, as well as the existence of the Clearing House Mechanisms (CHMs) for information exchange. Large companies are not necessarily better informed than small companies. However, ex-situ collections, universities and other research institutions are most familiar with the CBD. Users are aware of the

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<sup>65</sup> In collaboration with Karin Holm-Müller and Sabine Täuber, Universität Bonn

information deficiencies: half of the users who are familiar with the CBD don't feel to be sufficiently informed.

The participation of users in the CBD process is also very low, especially in the private sector. Only some public institutions, organized in sector initiatives, have developed policies and codes of conducts with governmental support. Nevertheless, users strongly support measures which address and alleviate the problem of information and uncertainty and do not restrict their activities. The actual level of participation and the willingness to participate differs by sectors and should be taken into account while aiming at a stronger user integration. Some sectors are already more involved in initiatives or more willing to participate than other.

In some sectors (e.g. plant breeding) associations play an important role regarding information dissemination and participation in the political processes. In these sectors policy makers should especially involve these groups. The respondents appear to be very open to CBD issues and the possible results of the CBD process. Suggestions of the users are more decentralized information strategies (e.g. integration of many local contact points), increased involvement of associations as well as sector initiatives to increase the commitment to the CBD regulations.

The future concerns regarding user measures and an international ABS regime seem to be small. Users positively judge the user measures which are under discussion on the international level. They consider instruments in form of services as more useful than measures interfering in and regulating their activities, but all measures are supported by a majority of the respondents. Certificates of origin are the most unknown instrument. However, it is positively evaluated by the pharmaceutical and horticultural sector as well as by research institutions and ex-situ collections whereas the plant breeding sector assessed it quite negatively.

From the above results it can be concluded that for the development of any instruments as the certificates of origin it is necessary to consider that the user sectors are very heterogeneous. Especially, the different levels of awareness, participation and positions have to be regarded. Besides, not only users have to play a more important role and assume responsibility also the role of intermediaries has highly increased and needs to be taken into account when developing a certificate of origin scheme. However, even if a international regimes will put more emphasis on the users the problems on the provider side when trying to implement ABS regulations will remain and policymakers have to continue to support provider countries in their efforts.

Until now the user participation in the CBD process is very low, especially in the private sector. Awareness raising and a higher participation of users are conditions for a higher willingness to support an international regime. Users most likely support the implementation of measures which address problems of information and uncertainty. Since some user groups have already successfully implemented measures which contribute to the compliance with the CBD further sector initiatives should be supported.



## **2. Concluding statement/ recommendations to the Group of Technical Experts**

- A certificate scheme should be flexible in its use because it needs to consider that the user sectors are very heterogeneous
- The awareness of the users has to be raised to enable an efficient implementation of a certificate scheme
- The role of intermediaries has to be taken into account
- User governments should support sector initiatives which voluntarily implement documentation and monitoring systems
- Certificates alone cannot solve the problem; providers countries should be supported regarding the implementation of ABS regulations

# Genetic Resources: Legal aspects of access and benefit sharing - Czech Republic

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## 1. Abstract

Surveys on genetic resources of the Czech Republic were done within the UNEP/GEF Project *Assessment of Capacity-building Needs: Access to Genetic Resources and Benefit-sharing, Conservation and Sustainable Use of Biodiversity Important for Agriculture, Forestry and Research – Czech Republic* (Sub-programme: Biodiversity Enabling Activities), implemented since August 2004 to December 2005. Surveys and analysis were focused to the following main areas: Agricultural and garden crops, Farm animals, Forest tree species, Botanic Gardens, Zoological Gardens and Fungi. Access to genetic resources and sharing of their benefits (ABS) were analysed with respect to international activities and national capacities. Results confirm that valuable genetic resources exist in the Czech Republic, both *in situ* and *ex situ*. Nevertheless outcomes reveal differences between individual observed groups as to character of genetic resources conserved, species and intraspecies variability and number of conserved plant and/or animals or fungi, institutional and legislation status, technical conditions, safety of conservation, evaluation and documentation, regeneration measures, skilled staff and funds available, as well as awareness of genetic resources importance. Analysis of the Bonn Guidelines implementation in the Czech Republic show certain differences in studied groups with respect to general measures adopted, role and responsibility of users and providers, participation of stakeholders, measures taken in ABS implementation and other measures. Common problems and measures needed to improve the current situation were summarized, strategy and further required measures were proposed. These proposals include measures such as systematic inventory and monitoring, enhanced effectiveness and management, including health status control, evaluation and regeneration of genetic resources in collections, as well as amendment of national legislation, development of research projects at national, regional and international levels, stabilization of corresponding financial resources or promoted information, education and public awareness.

Legal aspects of access to genetic resources and benefit sharing were subject of a special case study (published in Tošovská E., 2006: Biodiversity Conservation, Patent Protection and Damage Liability and Redress. Ministry of the Environment, Prague, 66 pp., in Czech, English Summary). The analysis was made with respect to three existing levels: international context, European activities – EC Directives, national legislation and participation in international and regional organizations. The main international organizations, in which activities the Czech Republic participated in the given sphere, represent: UNEP (CBD, CR 1993), FAO (ITPGRFA, CR 2004), WTO (CR 1996, mainly TRIPS commitments), International Union on Protection of New Plant Varieties (CR1993, UPOV commitments), WIPO (Intergovernmental Committee on Intellectual Property and genetic Resources, traditional Knowledge and Folklore). National legislation related to access to genetic resources covers besides wild species

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<sup>66</sup> In collaboration with Eva Tošovská, Economic Institute, Academy of Sciences of the Czech Republic

conservation and their habitat protection mainly plant varieties, farm animals and forest reproductive material – at present 8 basic Acts adopted between 1992 – 2006 (amendment). Main example of practical implementation represents National Programme on Conservation and Use of Genetic Resources of the Czech Republic (under the auspices of the Ministry of Agriculture), consisting of 3 sub-programmes (Plants and Microorganisms Important for Food and Agriculture; Forest Woody Species; Farm Animals, Bees, Fishes and Game in Farms). The analysis has shown that the Czech legislation in force does not represent any impediment in access to genetic resources and favours especially the access for breeding and research purposes.

## **2. Concluding statement/ recommendations to the Group of Technical Experts**

- Certificate – important document in increasing legal certainty and providing information
- Consider costs connected with the system, both at national and international levels
- Standardized system
- Use of existing infrastructure
- Avoid complicated system (not paper, but electronic documents – use of identifiers)
- Establishment of central register at national, international levels (who charged)
- Establishment of checkpoints (who charged)
- National legislation important

# **Belgian Federal Survey: Public infrastructures and ABS regulations for innovation in the life science research: access, conservation and use of biological diversity in the general interest**

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## **1. Introduction**

In order to consolidate the Belgian ABS national and international policy, and to know the exact situation regarding ABS provision and genetic resources users in Belgium, the DG Environment of the Federal Public Service Health, Food Chain Safety and Environment issued a notice of tender aiming at organizing a survey on the extent of knowledge and use of the CBD provision on access and benefit-sharing by Belgian users of genetic resources. The full title of this notice of tender is « *Marché relatif à l'analyse du degré de connaissance et de prise en compte par les acteurs belges des dispositions de la Convention sur la Diversité Biologique en matière d'accès aux ressources génétiques et de partage juste et équitable des avantages résultant de leur utilisation.* »

In November 2005, the realisation of this survey was attributed to the Research Unit on Biodiversity of the Centre for Philosophy of Law of the Catholic University of Louvain (specialised in ABS issues). The study started in January 2006 and should end in June of the same year. In order to achieve this survey, information on the subject needs to be gathered from all Belgian potential actors in the exchange of genetic resources.

Within the scope of this study only those biological resources, whose origin is not the Belgian Kingdom, are of interest. They include resources which were taken from their natural habitat (in-situ) or from ex-situ collections and on-farm cultivation outside the natural habitat. In this survey, the term 'biological resources' covers the use of non human organisms or parts of organisms for fundamental research and research and development in the life science. That means organic material such as:

- Plant genetic resources (algae, bryophyte, vascular plants)
- Animal genetic resources
- Microbial organisms (fungi, mushrooms, yeast, etc.)
- Non autonomous fragments and parts of organisms (virus, plasmids, etc.)
- Bacteria
- Etc.

## **2. Methodology**

Two important constraints had to be taken into account in the choice of the methodology for this survey : (1) the unclear and moving boundaries of the statistical population of "concerned" actors (2) the difficulty of the subject matter which touches on complex issues of property rights on genetic resources and the traceability of the flow of the resources. The first difficulty is related to the evolution of the discussions

on the implementation of the convention on biological diversity. More and more “new” actors get involved in the debate, such as the scientific research communities and the culture collections, alongside the actors initially at the foreground of the debates, which are the commercial actors and the indigenous communities. To catch this dynamic nature of the convention it is important to adopt a broad approach to the statistical population, which implies to make some trade-offs with the requirement to circumscribe as precise as possible its characteristics and boundaries. The second difficulty is related to the legal uncertainty that characterizes the field of the exchange of genetic resources and the correlated regional and international controversies on different ways to interpret the position of the Convention and the Bonn guidelines on these matters.

For these reasons, we decided to adopt a step-wise qualitative approach. This approach is based on the recommendations of the VALSE project on survey methodology (Valuation for Sustainable Environments, financed by the EU, results published in *Ecological Economics*, Vol. 34/2) and aims at collecting information on the preferences of the different concerned actors on a qualitative basis (first step), in order to do a broader in depth survey amongst a representative randomized sample of the population (second step). We completed this methodology with a third step, where we confronted our results again with representative actors and academic experts (third step).

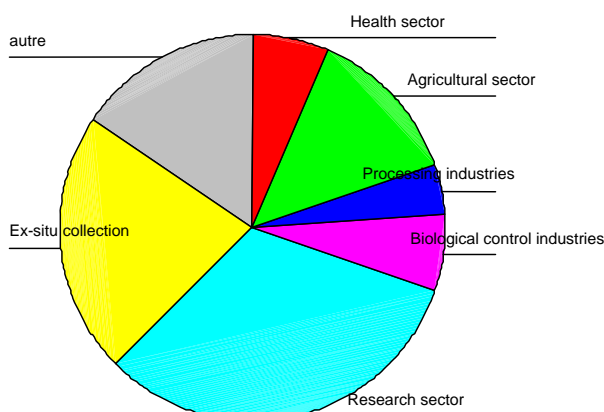
1. So we adopted the following sequence of work :
2. Identification of the actors : list of contact addresses of 1109 organisations active in the different sectors concerned by the exchange of genetic resources with foreign countries.
3. In depth interviews with 9 actors that are representative of the different sectors concerned by the ABS regulations.
4. Constitution of a random sample and conduction of in depth surveys in this random sample
5. Expert group meeting to compare the results with other surveys and to build consensus on the recommendations.

### **3. Synoptic presentation of the main results**

#### **3.1. The sample**

We conducted in depth surveys within a random sample of 400 organisations out of the main population of actors that we identified and received 57 full surveys out of this random sample. The response rate was fairly uniform along the different main sectors that compose the initial population of 1109 organisations, so that we can consider that this sample is sufficiently representative to indicate the overall tendency of the actors involved in the exchange of genetic resources, except for the biotechnology sector who was not taken up in the randomized sample and a slight overrepresentation of ex-situ collection and the research sector (for a definition of the different sectors, cf. question A.2. of the survey).

Figure 1. Overview of the surveyed sectors



### 3.2. Main results

The survey addressed three main questions :

1. The degree of knowledge by the Belgian actors of the Convention on Biological Diversity
2. The degree of adoption of the ABS dispositions contained in article 15 of the Convention and in the Bonn Guidelines on ABS
3. An overview of the institutional models and practices of exchange of material, in order to provide input to the ongoing negotiations on the implementation of the Bonn Guidelines.

The main two results are:

- First, that the Convention is well-known amongst the collection sector and the research sector and this both for public and private actors. In the other more applied sectors of the sample, which includes more private than public actors, the convention is poorly known. This overall picture tends to conclude that the convention is best known amongst actors involved in upstream research and innovation (fundamental research, applied research with a broad set of applications, etc.) and the least amongst actors involved in downstream research and innovation (market development, commercial activities), both amongst public and private actors.
- Second, that the implementation of the ABS dispositions is strong on the Prior Informed Consent for Access, but nearly inexistent on the level of the dispositions on Benefit Sharing. Moreover, the main tool for establishing prior informed consent is through research partnerships with provider countries.

In the below figures we represent these results alongside the 3 main questions addressed in the survey. We indicate in brackets the survey questions that provided significant answers on the relevant topics.

Table 1. Degree of knowledge of the ABS dispositions of the CBD

ABS dispositions of the CBD	Legal measures and treaties	Voluntary and market initiatives	Administrative measures
General knowledge of the CBD	Very good knowledge in the sector of the ex-situ collections and moderate knowledge in the research sector (both public and private)		
Knowledge of the ABS dispositions (if known) (Bonn guidelines)	If known, good knowledge (C.2.1.)		If known, moderate knowledge (C.2.2. and C.2.3)
Opinion on the usefulness of ABS measures	Very useful (C3.3., C.3.5., C.3.6.)	Useful (C.3.4. et C.3.4.7.)	Useful (C.3.1., C.3.2.), except for C.3.8. (very useful)

Table 2. Adoption by the Belgian actors of the ABS dispositions of the CBD

Typology of the relevant use and decision rights	Regulation of access and use of the resources	Adoption by the Belgian Actors
Access and direct use (conservation, use as a tool in an experimental method, etc.)	Prior informed consent by the provider	Yes (D.7.2)
Access and non commercial use of derived applications of the resource	Prior informed consent by the provider	Yes (D.7.2)
Access and commercial use of derived applications of the resource	Prior informed consent by the provider and contractual agreement on the benefit sharing	No, few use of MTA (cf. D.7.11), few commercial cooperations (D.7.12., D.2.3. and D.5.3.)

Table 3. Institutional models and exchange practices of Belgian actors

Typology of the relevant use and decision rights	Institutional Models	Exchange of the resources (qualified as increasing since 1992, but with diminishing growth rate (B.4.))
Access and direct use (conservation, use as a tool in an experimental method, etc.)	Establishment of cooperation for research with the partners in the providers' country, informal contact with the usual partners in the providers country (D.9.)	Frequent (D.6.1.)
Access and non commercial use of derived applications of the resource	Establishment of cooperation for research with the partners in the providers' country, informal contact with the usual partners in the providers country (D.9.)	Frequent (D.6.2. and D.6.3.)
Access and commercial use of derived applications of the resource	No direct <i>upfront</i> payment, no royalties agreement (D.5. and D.2.)	Nearly no distribution to commercial partners

## **4. Recommendations**

The main recommendations of the study should of course follow of the full analysis of the research results that will be presented to the expert group and the feedback of the expert group on the experiences in the neighbouring countries and in different representative organisations.

As a preliminary set of results, we would like however to present hereunder two general sets of recommendations that we think follow out of the survey and could be the object of further debate at the meeting.

### **4.1. Documenting the flow of resources**

Documenting resources flow would address the following concern raised in this survey :

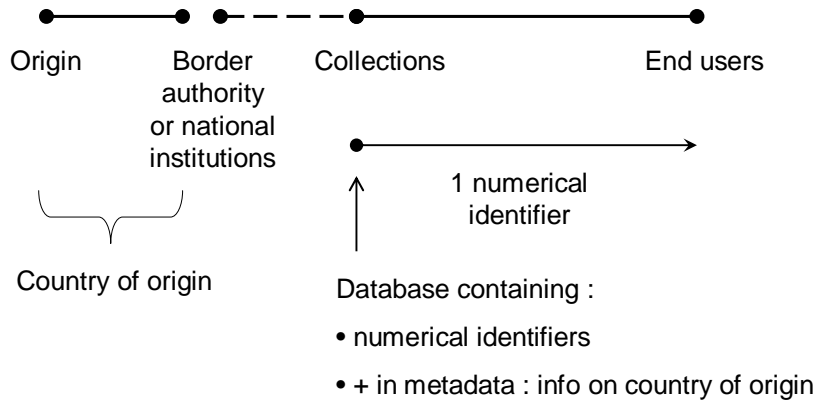
- Would enable compliance with ABS provisions :
  - Including the country of origin in the documentation would allow to identify the legal entity that is entitled to enforce appropriate ABS regulations for the collected material.
  - Documenting is compatible with a system of certificates of origin in the country of origin, but is also compatible with other internationally recognized mechanisms
- So this would help to
  - create legal certainty for the actors involved in downstream product development (both public and private), because they would be able to assess if benefit sharing would apply when accessing a resource form upstream actors (collections and researchers)
  - creating enhanced confidence between providers and end users of genetic material (the culture collections often being the intermediaries), by making the transactions more transparent

It is important to make a distinction between disclosure of source (often an ex situ collection of biological material) and the disclosure of origin (where it has been initially collected). As illustrated in figure 2, disclosure of source would allow a rigorous tracking system from the ex situ collection to the end user (company, research institution, etc.).



Figure 2. Documenting the resources flow

### Recomendation 4.1. : Documenting the flow of resources



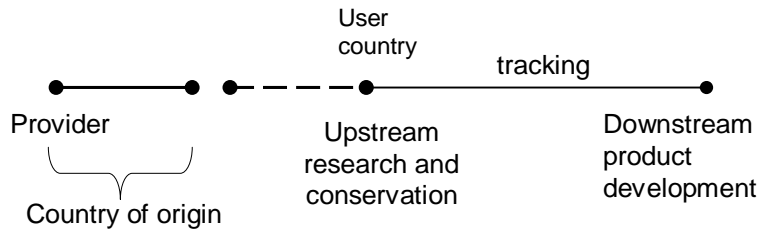
#### 4.2. Open access policy in user countries

One of the main difficulties implementing appropriate ABS regulation is the high transaction costs of the system. The main group of actors that would be disadvantaged if the transaction costs are too high are the researchers' communities who have only costs (more administration) and no direct advantage (they pursue their activities far from downstream product development). That's why it seems appropriate to complement the benefit sharing provisions (especially targeted to the downstream research), with provisions creating incentives for the actors that are upstream in the research and innovation process. This could be done (amongst others) by :

- developing a policy of free access and diffusion of biological material within public research institutions (universities, public culture collections, etc.) – as it is for example the case at the National Institutes of Health in the US – through measures specifying the public good nature of the resources and compulsory measures of sharing resources and information freely that apply for all upstream research.
- developing a two tiered system, where different, non-restrictive licensing policy apply for non-commercial and/or humanitarian oriented research, and a restrictive licensing policy applies for commercial use of the resources.

Figure 3. Open access policy in user countries

**Recommendation 4.2. : policy of free access and diffusion in upstream activities**



- institutional policies for sharing of data and resources
- non-restrictive license policies for upstream research activities

**5. Concluding statement/ recommendations to the Group of Technical Experts**

- Documenting the flow of resources including Certificates of Origin would help identify the legal entity entitled to enforce ABS regulations (= check points issue), and could help create economic incentives for complying with ABS regulations and promote conservation by increasing the value of genetic resources;
- Free access policy and diffusion of genetic resources within the research institutions by developing a two-tier system where different, a) non-restrictive licensing policy applies to non-commercial/ humanitarian research; and b) restrictive licensing policy to the commercial use of genetic resources;
- A Certificate of Origin scheme needs to consider and balance the heterogeneity of users and providers of genetic resources by addressing the interests of the research community, provider countries, business community etc.

# Non-paper on economic valuation of the use of genetic resources in France<sup>67</sup>

SARAH HERNANDEZ<sup>68</sup>

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## 1. Abstract

The purpose of this survey was to analyse the characteristics of some of the industries concerned by the use of genetic resources. The survey focused on understanding the distinctive markets, their industrial structure and organisation, in particular that related to research and development. The survey was aiming at seeing how the use of genetic resource intervened in the development of these sectors. Five industries have been analysed: pharmaceuticals, cosmetics, agriculture, forestry and agro-industry.

Methodologically, the survey used all secondary data information available, extracted some qualitative information from questionnaires given to some individual companies and analysed conjointly the information obtained through their respective business organisations. In particular, we should thank the GNIS (the national interprofessional association for seeds and plants), the LEEM (Pharmaceuticals industry association) and the Fédération des Industries de la Parfumerie (French Federation of Fragrance, Cosmetics and Toiletries) for their collaboration.

## 2. Pharmaceutical industry

The pharmaceuticals industry is one of the most dynamic sectors in the French economy. Its turnover was 38 billions euros in 2004, and around 40% of it, is derived from exports. In terms of shares in the global market, France is 4th position behind the United States, Japan and Germany.

This sector is not very concentrated because of a great diversity of products, techniques and markets. It devotes approximately 12% of its turnover in R & D. A greatest part of this sector is financed by private investments (99%) and the rest by public funds (around 0,5%). In 2002, the investment in research and development (R&D) for health and life sciences has been estimated at 3,7 billions euros and at around 6 billions euros in 2004 (private and public funds combined). Most of the R&D activities are externalized, in particular into countries with high added value in scientific research (the United States, Japan, GB, Germany). The part of R&D of the French subsidiary companies of foreign groups carry out 31% of the research in France. The French groups carry out 43,5% of their research abroad.

The organisational structure is characterized by multiples partnerships with small and medium-sized biotechnology companies, which play a driving part in the identification of active ingredients. The production, the distribution and marketing of the products derived from this research are taken in charge by the pharmaceuticals companies themselves.

This industry is largely dependent on the R & D. Considering the amount of money invested in getting a marketable product, the industry keeps on relying on patents and on its ability to maintain the productivity of its R&D.

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<sup>67</sup> This paper represents the final results of the survey but it is not necessarily the view of the French Government.

<sup>68</sup> Policy advisor in the Department of Economic Studies and Environmental Assessment of the French Ministry of Ecology and Sustainable Development.

It is quite difficult to define the share of pharmaceutical products elaborated on non-human genetic resource, but it is assumed to be largely inferior to that part based on human genetic resources. This industry is based on high technology that is evolving very fast. This renders a physical traceability of the genetic resource in the process of innovation difficult.

### **3. Seed Industry**

France is considered as the main contributor to the European agriculture. It represents around 20% of the total European agriculture production. The seed industries contributes up to 2,3% of French gross production. In 2002, seed industries invested around 8% of the turnover (312 millions euros) in R&D. The R&D sector employs around 21% of the total employment in agriculture.

Genetic resources are used by firms concerned by the obtention of new varieties, which represents 0,35% of the total seed industry. An important part of the R&D in this sector is financed partly by both the public research sector and private investments. This sector is mainly dependant on ex-situ collections. In that sense, France is the first provider of genetic resources.

Some companies have some bioprospecting activities in developing countries in order to obtain wild genetic resources. Seed industry's actors find it difficult to make a distinction between the initial genetic resource and the final new variety. The industry is characterized by a free access to any genetic resource and a clear rule of benefit –sharing compatible with the UPOV.

### **4. Fragrance and cosmetics**

This sector is little concerned by the use of genetic resource as it is defined in the CDB. Most of this industry is based on the use of biological material and products, which are exchanged according to trade rules principles. This sector is very sensitive to difficulties in getting access to primary products, due to the constraints imposed by some national legislations.

The sector has a heterogeneous industrial organisation. It deals with a lot of independent intermediaries for their raw biological material, and sometimes it is eventually difficult to ask for the legal provenance of the material they obtain.

The “natural” characteristic of the products is a major factor in sales. For this reason, this sector is dependant on reputation and image to gain markets.

### **5. Concluding statement/ recommendations to the Group of Technical Experts**

- Take into account the sectoral differences;
- Consider not to compromise the capability of innovation by introducing restrictions on patents system;
- Think in terms of transparency of transactions of genetic resources;

## V. Implementation challenges of an International Certificate for key users

### Academic research: Statement concerning an internationally recognized certificate of origin/source/legal provenance<sup>69</sup>

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Swiss Academy of Science

#### 1. Abstract

The following argumentation is based on the experience with the academic research community during the elaboration of the brochure “Access and Benefit Sharing – Good Practice for Academic Research” by the Swiss Academy of Science and the related campaign for information and capacity building. .

The rationale for the creation of an International Recognized Certificate of Origin/Source/Legal Provenance is assumed to be the legitimate utilisation of genetic resources (and TK). It is therefore focussed on access to, and transfer of the resources and on the sharing of benefits resulting of their use.

A survey over research carried out at Swiss academic institutes, and the collaboration with a variety of these institutes gave insights into types of research, research methods, and resources accessed; but also into the opinions and attitudes of the researchers. These results contribute to the evaluation of the concept of an International Recognized Certificate of Origin/Source/Legal Provenance from the point of view of academic research<sup>71</sup>. In particular they back the postulate for a specific approach for basic and applied research.

The results can be summarized as follows:

As to the types and methods of research:

- A considerable amount of the projects indicated are basic research (60%), one quarter taxonomic.
- None of the described projects aimed at the development of a commercial product<sup>72</sup>.
- Relevant steps with view to access and transfer of genetic resources are: the collection of samples, their transfer to a research institution in the provider country or abroad; or the transfer of samples for identification; the storage of samples.

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<sup>69</sup> The “Good Practice for Academic Research on Genetic Resources” is an ethical guideline for the implementation of the ABS-system by academic research, elaborated by the Swiss Academy of Sciences under a mandate of the Swiss Federal Office for the Environment.

<sup>70</sup> Dr. iur, Master in Applied Ethics, Consultant to the Swiss Academy of Science. The text represents the personal opinion of the author.

<sup>71</sup> Details are described in Biber-Klemm S. ABS and Research in Switzerland. The Development of a Tool for the Implementation of the Bonn Guidelines by Academic Research. Bundesamt für Naturschutz, Bonn, Treffpunkt Biologische Vielfalt 4, 2004.

<sup>72</sup> But there might of course exist such projects.

- Roughly two phases of research can be distinguished: basic and/or applied research on the one, and R&D for commercial purposes on the other hand.

As to the position of scientists<sup>73</sup>:

- Resources for research are rather scarce and acquisition is highly competitive.
- Researchers want to (and must) use these resources for their core business which is research.
- Additional bureaucratic burden means additional time and manpower (= economic resources) needed for the preparatory process.
- Research teams lack of the necessary administrative and legal capacities to go through complex access procedures.
- Financial requests of provider countries are difficult to fulfil.
- There is a great fear that ABS procedures prevent research necessary for conservation and sustainable use of biodiversity.

Accordingly scientists recommend:

- The countries to review their process for permits on research, collection, import and export of specimens to rationalize and streamline the ABS process;
- To ensure that rules and regulations are practicable.

There are several reasons to promote a specific instrument for academic basic and applied research<sup>74</sup>:

- There are many research projects and many resources implied; a simplified procedure might facilitate the task of the providing country.
- A great part of the research projects are to the advantage of the providing country.
- A great part of the research projects do not aim at producing marketable products.
- The benefits of academic research are not economic but consist rather in research partnership and sharing of the results.
- The benefits accrue *during* or *immediately after* the project and are therefore easier to control than the benefits resulting from industrial R&D.
- An elaborated system for tracking each resource (specimen) is bound to be too time consuming and expensive.
- Considered under the aspect of benefits and costs, such a system would primarily be at the expense of academic research.

## **2. Concluding statement/ recommendations to the Group of Technical Experts**

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<sup>73</sup> See also UNEP/CBD/COP/8/INF/46: Outcomes and Recommendations of the Meeting on „Biodiversity – The Megascience in Focus“ p. 12 and 13.

<sup>74</sup> I.e. research which does not a priori aim at resulting in a marketable product; this can also be the case in academic research.

The challenge is to bring the goals of providers and users in concordance. The overarching goal is doubtless to provide legal security – for the providers regarding the legitimate use made of the resources and the sharing of benefits; for the users the legitimacy of their access to and use of the resources.

There are two situations which present a certain risk for the interests of the providers:

- Academic research aiming at a marketable product is not declared as such.
- A specimen is accessible for third parties (e.g. in a research institute), or transferred to third parties, without information as to possible restrictions to use.

Given these reflections, the recommendation is to

thoroughly evaluate the option of a simple, formalised and generally recognized Material Transfer Agreement for basic research, which contains the mandatory condition, that for the transfer to third parties for R&D for commercial purpose, or the execution of such research in the same institution, the acquisition of the corresponding PIC from the owner of the resource is to be sought.

Besides such an MTA should contain the following elements: Particulars of the provider and user, details of genetic resources (or lot numbers), details of the approved use, or restrictions, details of the issuing authority.

The MTA is to be stored together with the other information on the sample and has to be transferred together with each exemplary of the sample.

In the course of academic research a great deal of genetic resources are acceded and investigated. Academics are an important stakeholder-group in the ABS system. Therefore it is further recommended to

assure the integration of academic researchers / the point of view of academic research into the process to elaborate a certificate of origin/source/legal provenance as well as in the negotiations regarding the International Regime on Access and Benefit Sharing.

# **The German Research Foundation (DFG) and its Committee on Biodiversity Research and Benefit-Sharing - brief statement on an internationally recognized certificate**

SUSANNE REYES-KNOCHE  
Deutsche Forschungsgemeinschaft / German Research Foundation

## **1. Abstract**

The presentation aims at contributing with some remarks concerning the issue of a certificate of origin/source/legal provenance from the perspective of academic research.<sup>75</sup>

Article 15 of the CBD provides for a legal framework to regulate the access to genetic resources. This legal framework was originally designed to give access to genetic resources for commercial purposes. Thus, the CBD does not make a distinction between the access procedure for (basic) research or for commercial purposes. Any kind of access to genetic resources has to go through the CBD access procedure. Some provisions of the Bonn Guidelines take special consideration to research activities. According to their Paragraph 16 special terms and conditions should be established to facilitate taxonomic research for non-commercial purposes. In the context of a prior informed consent system, Paragraph 34 states that specific needs of taxonomic and systematic research should be taken into consideration.

In spite of these provisions many national ABS regulations do not take this into account.

The impact of the CBD access procedure on scientific research related to biodiversity and its components, such as genetic resources, is growing, as countries implement CBD work programs, applying CBD decisions and guidelines often in a very heterogeneous way. Hence, new developments in the CBD process have the potential to make access to biological material for basic research increasingly difficult, since researchers have to pay attention to new requirements originally designed to regulate access to biological resources for commercial purposes.

Therefore, in the context of the negotiation of an internationally recognized certificate of origin/source/legal provenance the following issues should be carefully looked at:

- It is crucial to make a distinction concerning the access procedure for (basic) research or for mainly commercial purposes: this will have repercussions on the type of requirements to be fulfilled.
- It is also very important to use clear definitions and to agree on basic concepts (for example: access; utilization; genetic resources; benefit-sharing; derivatives, etc.)
- The large variety of users and their special needs and peculiarities have to be considered within the negotiations of the certificate.
- A possible approach could be a sector specific solution.

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<sup>75</sup> Beside the brief DFG's statement to the discussed topic, the views expressed are solely those of the author.



- The function, the content and the timing of the certificate have to be clarified. The certification system should allow a change in intent.
- Other alternatives, instruments or complementary measures have also to be taken into consideration in order to find the most adequate solution. Concerning academic research the review of the (national) research permit procedures could be a starting point.
- It is crucial to keep costs low: basic biological science lacks the necessary administrative and legal capacities to go through a complex access procedure (cit. Megascience in focus); funding budgets are not designed to cover these costs.

To achieve a fair, flexible and balanced solution the key stakeholders should all be present at the negotiation table. Therefore the scientific community should stay involved in the negotiation process in order to safeguard the special needs of non-commercial driven scientific research within the CBD framework.

## **2. Brief statement of the DFG to the issue of certificate of origin/source/legal provenance:**

- The German Research Foundation, DFG, supports the implementation of the main objectives of the CBD as stated in its article 1.
- Biodiversity-related basic research requires direct handling of biological resources and has specific characteristics, needs and working methods.
- Hence, if the adoption of an internationally recognized certificate of origin/source/legal provenance is considered, this certification system should include a specific research type of certificate taking into account:
  - the importance of scientific research for the conservation and better understanding of biodiversity,
  - the non-commercial driven motivation of pure scientific research activities,
  - the indispensability of a simplified certificate procedure for scientific institutions.

## **3. Concluding statement/ recommendations to the Group of Technical Experts**

Biodiversity-related basic research requires direct handling of biological resources and has specific characteristics, needs and working methods.

Hence, if the adoption of an internationally recognized certificate of origin/source/legal provenance is considered, this certification system should include a **specific research type of certificate** taking into account:

- the importance of scientific research for the conservation and better understanding of biodiversity,
- the non-commercial driven motivation of pure scientific research activities,
- the indispensability of a simplified certificate procedure for scientific institutions.

Therefore the scientific community should stay involved in the negotiation process in order to safeguard the special needs of non-commercial driven scientific research within the CBD framework.

# The pharmaceutical industry and access and benefit-sharing<sup>76</sup>

FLORIAN KERN

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## 1. Abstract

The CBS's ABS provisions and the Bonn guidelines do not constitute any legal obligations for users of genetic resources (GR) directly even though ultimately the implementation of ABS is thought to be relying on contractual agreements between users and providers. However, the voluntary Bonn guidelines contain certain provisions for the realisation of ABS by private actors using GR commercially.

So far it has been unclear to which extent these stipulations have been translated into action on the ground by private actors since most countries did not transpose international ABS provisions into national law. Out of the 188 parties to the CBD only about between 50 and 60 countries have passed some form of ABS legislation (Koester 2005; Young 2003) and almost all of these are provider countries. Even in countries where ABS legislation is in place the implementation of these laws and their enforcement proves to be difficult.

At the World Summit on Sustainable Development in 2002 world leaders called for negotiating an international regime on ABS. Amongst other issues, the necessity of a legally binding instrument is currently being argued. This paper aims to contribute to the discussions through answering the question 'To what extent are pharmaceutical companies voluntarily realising the ABS provisions of the CBD?'. As the pharmaceutical sector is one of the most prominent commercial users of GR, the behaviour of the world's 20 biggest pharmaceutical companies is analysed.

The approach draws on regime theory and the debate about global governance which acknowledges the potential of private actors in implementing sustainable development. The data is derived through an analysis of the instruments of corporate social responsibility (reporting, codes of conduct, management standards). Additional empirical data has been generated through a questionnaire survey among the companies as well as a thorough literature review.

The behaviour of pharmaceutical companies is measured against three criteria: The basic criterion is awareness of the company that biodiversity loss is an important environmental problem. The second criterion is to accept that the CBD and its ABS provisions concern the company and to transpose the imperative of those provisions in a corporate ABS policy. The final criterion is to put this corporate policy into action, thus to engage in concrete bioprospecting contracts which contain PIC, MAT and benefit sharing. Only if all three criteria were met, we talk of full realisation of ABS.

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<sup>76</sup> This abstract is based on work of Fabian Busch and Florian Kern in 2005: *Governing Biodiversity. The Realisation of Access and Benefit Sharing under the Convention on Biological Diversity*, [http://dspace.ruc.dk/bitstream/1800/1148/1/Busch\\_Kern+Governing+Biodiversity.pdf](http://dspace.ruc.dk/bitstream/1800/1148/1/Busch_Kern+Governing+Biodiversity.pdf)

The following two conclusions can be drawn from our work:

*Conclusion 1: In the realm of biodiversity governance, voluntary business measures based on corporate responsibility are inappropriate to safeguard access and benefit sharing.*

On a voluntary basis the pharmaceutical industry realises the ABS provisions of the CBD only to a very limited extent. The three out of the biggest 20 pharmaceutical companies which fully realise ABS, namely Bayer, GlaxoSmithKline and Novartis, only accounted for 11.5 % of the global pharmaceutical market in 2004. This number is an important and new revealing on the overall behaviour of the pharmaceutical sector with regard to ABS.

*Conclusion 2: An internationally binding protocol is required to enhance the implementation of ABS.*

Seemingly, after more than a decade, cases of benefit sharing remain more an exception than the rule. In order to enhance the implementation of ABS, an international regime is currently being negotiated, especially considering the use of certificates of origin/source/legal provenance. The nature of such a regime is unclear so far.

Our analysis shows that only very few companies voluntarily realise access and benefit sharing. Under unchanged legal status of the ABS provisions, it is unlikely that this number is going to increase significantly. Commercial users of biodiversity are located in countries which have not transferred the ABS provisions into national law. If a voluntary instrument (such as an internationally recognised certificate of some sort) is going to be added to the international ABS regime, user countries will presumably continue to be reluctant in implementing ABS. National legislation to ensure ABS is neither in their interest, nor has such attitude internationally been denounced to an extent that would have marked the tipping point of a 'norm cascade'. The idleness of user countries will not stimulate the large number of non-complying companies to realise ABS in the future.

In our opinion, the transfer of the ABS provisions into national law by all Parties to the Convention is deemed indispensable as a precondition for the realisation of ABS through commercial users of GR. A legally binding protocol as the outcome of the negotiations would ultimately further ABS as an international norm and pressure provider as well as user countries to enact concrete national legislation. National ABS legislation in both provider *and* user countries would complement each other. It has been argued that provider countries are not capable of taking adequate measures for the realization of ABS without the support of user countries. Hence, the introduction of national laws based on a common point of reference – the 'ABS protocol' – in *all* states is believed to significantly improve the enforcement and monitoring of ABS.

## **2. Concluding statement/ recommendations to the Group of Technical Experts**

1. An internationally recognised certificate for origin/source/legal provenance should be part of a legally binding ABS protocol based on the Bonn guidelines. The rationale for a multilateral certificate scheme would be twofold:
  - To increase the transposition of ABS principles into national law of all parties to the CBD
  - To provide a tool for ensuring compliance with ABS provisions by users of GR.

2. Beyond a multilateral system for certificates of origin/source/legal provenance the ABS protocol should include economic incentives to encourage compliance of users of GR as enforcement of legislation will be particularly difficult. Those economic instruments could be spelled out as part of the protocol but could have a voluntary character (such as emissions trading under the Kyoto protocol).
3. The protocol based on the Bonn guidelines should also clarify some of the definitions in the realm of ABS (such as GR), specify goals and thereby help streamline existing national ABS legislation. It should also contain a timetable for its implementation.

## **A pharmaceutical industry perspective**

IVAN HJERTMAN  
IP Interface AB

### **1. Abstract**

*The pharmaceutical industry supports the CBD and its objectives: to promote biodiversity, to promote its sustainable use, and to share the benefits of such use equitably between providers and users. Issues regarding access and benefit-sharing in regard to genetic resources, ABS, are high on the agenda for companies and their business associations. The creation of the Technical Experts Group, TEG, is welcomed. The industry will take an active part in the discussions on the work of this Group as well as in the discussions on an international ABS regime.*

The increasing realisation in the CBD that engagement of business and industry is crucial in the implementation process for the CBD is welcomed. This was expressly recognised at COP-8 in Curitiba. An example is that the private sector was assigned a seat in the TEG.

*The mandate for the TEG given by COP-8 is broad. It does not prescribe that a certificate system will be introduced. It requests the TEG “to explore and elaborate possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance...”, and to “analyse its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention”. Further, the TEG is requested to “consider the possible rationale, objectives and the need for an internationally recognized certificate of origin/source/legal provenance”, to “define the potential characteristics and features of different options...”, and to “identify associated implementation challenges, including the practicability, feasibility, costs and benefits of the different options..., and including ... compatibility with the Convention and other international agreements”.*

It is clear that the discussions on a certificate regime are linked with the discussions on an international ABS regime. It must be considered what role a certification scheme might play in an international ABS regime.

*A possible certification scheme for genetic resources, GRs, will affect not only the pharmaceutical sector. Other industry sectors which will be affected include the cosmetics, plant breeding, natural medicines, horticulture, industrial biotechnology, and the seeds sectors. The potential implications of a certification scheme are broad and include impact on science, trade, and trade policy. And this especially if what is generally termed “derivatives” are to be included in a certification scheme.*

*The significance of and need for careful consideration of the practical implications of any certification scheme cannot be overstated. Availability, ways of acquisition, and uses of GRs vary greatly. Sometimes GRs are uniquely available from certain countries only, sometimes GRs are widely available as staple commercial products. GRs may be acquired by traders, industries, academia, gene banks, etc. GRs may be used in production processes, where they may or may not be present in the final product. GRs are used in trade and in research. Should “derivatives” of GRs be included, then the scope of any scheme would*

increase dramatically, depending on what definition to be applied to that term. For example, would a product “directly based” on a GR include bread and wine?

*The definitions of terms used are very important.* Examples of critical terms are “country of origin”, “source”, “genetic material”, “genetic resource”, biological resource”, “derivative”, “legal provenance”. Any terminology should provide legal certainty, clarity/predictability, enforceability, clarity on possible retroactive effects, clarity on consequences for existing and future commercial activities, and clarity of impact on the public domain. Very different understandings of such terms have been suggested, as is clear e.g. from document UNEP/CBD/WG-ABS/4/7 dated December 5, 2005. Here, just as an example, there are 20 suggestions what to be understood by the term “derivative”.

*Significant issues* are the objective of a scheme, the scope of a scheme, the certification criteria, how a scheme will be applied, what the legal effects of a scheme will be, what the operational issues will be, what the costs will be, and the overall impact of a certification scheme. From a practical standpoint, these elements give rise to many questions. To name a few:

*Objectives:* What precisely is any scheme intended to achieve? What practical problems exist? How frequently do they arise? How will any scheme achieve those objectives and what other means are there for doing so? Evidence as to the need for any scheme is vital.

*Scope of a scheme:* To what materials will the scheme apply? Will it apply to all GRs? For example, will plants sold in nurseries or live herbs sold in supermarkets be within a scheme? Will human GRs be excluded? Will non-human GRs found in humans be excluded? For example, would a virus identified on a patient and used for developing a vaccine be excluded? Will only physical transfer be included? What about transfer of knowledge? E.g. knowledge derived from research involving GRs? What about traditional knowledge?

*Derivatives:* will derivatives fall within the scope of a scheme and, if so, how are they to be defined? For example, would a loaf of bread or a bottle of wine, each of which is clearly a derivative of a GR, be included?

*Transactions:* To what transactions will a scheme apply? Is it to apply, and if so how, to all transactions in which legal title or the physical possession of individual units of the GR/derivative changes? How apply to chains of transactions: will certification be needed for each form of the GR?

*What will be certified?* Countries of source or of origin? Compliance with national laws? Existence of use restrictions? Legal provenance?

*Who will certify?* Who will be responsible for certifying which transactions? The country of origin? User countries? Users themselves? An international institution? Could a possible single international certificate take into account all different national ABS laws and regulations, provided such are in place?

*Application of a scheme:* Will a scheme apply to GRs acquired before the CBD came into force? How will a scheme apply to GRs obtained from countries whose laws do not regulate access to GRs? Will a scheme apply to publications or other transfers of knowledge about GRs?

*Legal effects of a scheme:* What will the legal effect be of a certificate? What will the legal effect be of not having a certificate? What obligations will apply in a transaction chain as to possible need for a certificate?

*Operational issues of a scheme:* what will the form be of a certificate? A unique identifier held on a database? Physically annexed to a product or its packaging? Available in respect of each unit of a GR or any derivative covered by a scheme?

*Costs:* what will the financial costs of setting up and implementing a system be for individual countries and any relevant international institution? Who will pay?

*Overall impact of a scheme:* how will a certification scheme impact on trade and on use of GRs and derivatives? Will a scheme facilitate access to GRs? Will a scheme impose restrictions that run counter to the objectives of the CBD? What mechanisms should there be to monitor the effect of any scheme?

## **2. Concluding statement/ recommendations to the Group of Technical Experts**

- The setting up and implementation of national ABS regimes is key.
- The TEG should consider whether any international scheme is necessary or desirable before national ABS regimes have been implemented and tested in practice.



# **Botanic gardens and the International Plant Exchange Network (IPEN) - a brief statement on an internationally recognized certificate**

DR. ANDREAS GRÖGER  
Munich Botanic Garden

## **1. Botanic Gardens on the conflict line between North and South**

Concerning Art. 15 of the Convention on Biological Diversity, several mega-diverse countries submitted national laws which affect the management of Botanic Gardens severely. In spite of the Bonn Guidelines, most of these legislations do not differentiate between access for non-commercial and commercial purposes. As a consequence, Botanic Gardens are thrown onto the conflict line between North and South. Botanic Gardens depend absolutely on the access to plant genetic resources. Now not only the access to sources in the wild, but also the exchange of plants within the garden community is affected. To answer these challenges, Botanic Gardens started early to develop common policies in the field of Access and Benefit Sharing. Main objectives of these policies are to be perceived as partners in the implementation of the CBD and to strengthen the confidence of the countries of origin.

## **2. IPEN as a voluntary certification system**

In 1996, the Association of Botanic Gardens of German Speaking Countries started to develop common ABS policies. In these efforts, it received generous support of the Federal Agency for Nature Conservation. The policies should facilitate acquisition and exchange by common standards which are in accordance with the CBD. Transparency should guarantee that the origin of the plant genetic resource is traceable at any time of plant exchange. The International Plant Exchange Network (IPEN) was developed as a voluntary certification system, which covers the transfer of plant genetic resources within the Botanic Gardens community, exclusively for non-commercial purposes. Within IPEN, commercialisation is not possible.

To become registered IPEN member garden, the IPEN Code of Conduct has to be signed. It covers acquisition, maintenance and supply of living plant material by the gardens as well as benefit-sharing. A crucial point of the code is, that IPEN members are advised to treat all their plant material 'as if' acquired after the CBD came into effect, i. e. there is no distinction between pre- and post-CBD material. For exchanges with institutions that are not member of the IPEN network, the code provides a standardized Material Transfer Agreement. For the facilitated exchange between IPEN member gardens, a documentation system with the help of so-called IPEN-numbers is the core issue.

## **3. IPEN documentation system and IPEN material transfer agreement**

IPEN distinguishes between two types of documentation: a 'maximum documentation' and a 'minimum documentation'. The 'maximum documentation' covers all relevant information about an individual plant accession, such as taxonomic and collecting data, type of material, source, permits related to the acquisition and any conditions or terms of the country of origin. All these data are recorded on a documentation sheet by the first garden who introduces the plant material into IPEN. It is this garden who keeps the 'maximum documentation' sheet, and who tags an individual IPEN-number to the plant

material. This number is unchangeable and sticks to the material and all its descendants through all further exchanges. The IPEN-number represents the ‘minimum documentation’, which is sufficient for the exchange within IPEN. It allows to trace the origin of the material and to contact the first garden for further details on the material.

If the recipient is not member of IPEN, he will have to sign the IPEN Material Transfer agreement, which binds him to the same terms and conditions. In case of intended commercial use and other uses not covered by the IPEN Code of Conduct, the requesting institution has to look for a new Prior Informed Consent of the country of origin and has to negotiate bilateral agreements regarding Access and Benefit Sharing.

#### **4. Status report of IPEN**

IPEN started as an initiative in the German speaking countries. In 2001, IPEN was lifted on the European level by the EU Consortium of Botanic Gardens. One year later, it entered CBD negotiations during COP6 in The Hague. Although planned as an international tool, IPEN members are still limited to the European continent. Currently, IPEN counts 91 member gardens out of 12 European countries.

A survey of all member gardens is given on the IPEN website (<http://www.bgci.org/abs/ipen>), which is hosted by Botanic Gardens Conservation International, Kew. On this website all relevant documents are available as downloads, and all membership applications are collected. The panel of ‘IPEN National Nodes’ ensures, that applicants meet the IPEN criteria. This panel consists of contact persons, who represent national networks of botanic gardens and who promote IPEN in their country or region. Another panel is the ‘IPEN Task Force’. It is a small group of representatives, appointed by the IPEN National Node Network. Its main task is to develop and to update the IPEN instruments, and to attend the correspondent political processes.

#### **5. Concluding statement/ recommendations to the Group of Technical Experts**

IPEN presents a model system for a unique identifier, which responds to ABS provisions by providing increased transparency in the transfer of plant genetic resources. Referring to an Internationally Recognized Certificate, following recommendations are given to Technical Expert Group:

1. Sectoral codes already adopted by Botanic gardens and research institutions, should be included in any future certification system as an accepted method. The design of codes such as IPEN complies with ABS provisions and at the same time reflects the requirements of the correspondent sector. Feasibility and broad acceptance are the major precondition for any certification system.
2. Access modalities in provider countries should differentiate between commercial and non-commercial users of plant genetic resources, thereby clarifying responsibilities and benefit-sharing expectations.
3. Competent National Authorities should offer practicable administrative procedures, thus enhancing long-term partnerships between Botanic Gardens and research institutions in provider and recipient countries.

4. Botanic Gardens feature a strong potential as mediators and catalysers of the CBD. By the creation of a transparent documentation system, they want to be perceived as reliable trustees of plant genetic resources. These efforts should be acknowledged by governments of mega-diverse countries and in national policies. Confidence on both sides, of the provider as well as recipient countries, is the prerequisite for more long-term partnerships as a way to ensure collaborative research and benefit-sharing. Only a facilitated access to genetic resources as required in the CBD may generate benefits than can be shared.

# **ABS in case of microbial resources - MOSAICS Integrated Conveyance System**

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Belgian Co-Ordinated Collection of Micro-Organisms (BCCM)

## **1. Summary**

MOSAICS central objective is the development of an integrated conveyance system to manage the access and benefit sharing issues related to microbiological resources, in the context of the CBD and the enforcement of other relevant international rules.

The purpose of the project is to design procedures and documents that set the rules at the source or original provider and during transfers. MOSAICS looks for an effective uncomplicated 'lightweight' system to enable tracking of the biological resources from origin to the final user, through the use of Globally unique identifiers (GUIDs).

In the field of microbial genetic resources, strain labels are used as locally unique identifiers. These may consist of a culture collection acronym followed by a number, or may just be any name given to the strain by an individual researcher. At this given moment, there is no universal way to refer to all resources stored in the different culture collections or private collections, and thus no reliable way to detect if multiple digital resources present data on the same biological source.

Persistent unique identifiers for global use need to combine both the strain label and a persistent location were to retrieve the information.

An initiative in this context, StrainInfo.net, which is a cooperation pilot project between the Laboratory of Microbiology and the Department of Applied Mathematics, Biometrics and Process Control of the University of Ghent and the Information Network Centre of the Chinese Academy of Sciences in Beijing [7,8] operates through an Integrated Strain Database, a curated central repository that provides a complete and correct view on the synonymous labels assigned to biological specimen during their lifetime. The StrainInfo.net portal adds to the commonly used strain numbers a more persistent and dumb identifier; in order to incorporate it within a larger namespace that provides extended unicity.

Taking advantage of the StrainInfo.net project, which was available as an example within the framework of MOSAICS, a hypothetical model was build for assigning GUIDs to biological resources.

Preferentially, such an integrated database should be located at the World Data Centre for Micro organisms (WDCM; <http://www.wdcm.org>), which is the heart of the World Federation for Culture Collections (WFCC) and already retains an ID system for registrated culture collections and institutions.

In the framework of MOSAICS, we would recommend to microbial resource centres and microbial data providers or database owners to work towards registration at WDCM and assignment of persistent globally unique identifiers to their material items and data elements.

Unique identifiers do, by no means intend to replace the traditional labelling of strains, genes or other data elements, but allow incorporating them in a larger namespace that provides an extended unicity and interoperability.

Among the different models of identifier systems, Digital Object Identifiers (DOI's) seem to be the most appropriate system for tracking of microbial resources, with the strongest business plan and safest expectations for the future.

DOIs can be assigned to any identity, for use on digital networks. Information about a digital object may change over time, including where to find it, but its DOI will not change.

## **2. Context**

The world is changing; people are more interested in the environment, worried about climate change, loss of biodiversity and many other matters. Appreciation of this has led to increased concern about and regulations for biological resources. Authorities are now demanding that accession history of a particular specimen be documented to ensure that each and every specimen was legally acquired. Nations value their biodiversity and are granted legal rights to it by the Convention of Biological Diversity (CBD, <http://www.biodiv.org>).

The March 2003 CBD “Open-Ended Inter-Session meeting on the Multi-Year Program of Work for the Conference of the Parties up to 2010” requested in its conclusions to work further on the processes, modalities and scopes of implementation of access and benefit sharing (ABS), including the “Bonn guidelines”; and also to check their effectiveness. This was reaffirmed during the third meeting of the working group on ABS in Bangkok in February 2005.

To abide by the CBD rules of access and to enable benefit sharing, the key issue is tracking of the (micro) biological resources.

## **3. MOSAICS objective**

MOSAICS central objective is the development of an integrated conveyance system to manage the access and benefit sharing issues related to microbiological resources, in the context of the CBD, the drawing up of the “Bonn Guidelines”, and the enforcement of other relevant international rules. Such a system must have three features:

- provide reliable tools to evaluate the economic value of microbiological resources,
- utilise validated documents with standard provisions to enable tracking via an uncomplicated procedure,
- be widely used by microbiologists, working in culture collections, public or private research institutes, commercial companies, non profit organizations, etc.

In general, this integrated conveyance system must thus be compatible with the political framework, be easily applicable in most conditions, full the needs of both users and providers and be an attractive system enforceable without constraints.

#### 4. Tracking versus traceability

MOSAICC<sup>77</sup> has defined a procedure to implement the rules of access. It can be summarized as follows: register the source of the (micro) biological resource and trace it to its final destination.

The purpose of MOSAICS is to design standard documents that set the rules at the source or original provider and during transfers. These documents constitute the documenting part of the tracking system. In complement, MOSAICS looks for an effective uncomplicated ‘lightweight’ system to enable tracking of the biological resources from origin to the final use.

During the different transfers, the biological resources are subjected to very different environments. Only when the transfers are restricted to moves and/or exchanges between biological resources centres, which have a well-established quality management system and compatible legal systems, control and conveyance all along the way is possible and true traceability can be achieved. In all other cases, this total conveyance can not be guaranteed, since gaps in the quality control may occur, and the term TRACKING should be used, rather than traceability, referring to the follow up of the material from original provider to end user rather than registration of every single movement of the biological resource.

The MOSAICS project aspires to make recommendations on the use of unique identifiers to enable tracking of biological resources. These identifiers constitute the practical tool of the tracking system and should preferentially enable tracking through an electronic path, organised as a build in system, allowing *ex ante* and *ex post* conveyance.

#### 5. Unique Identifiers

Focusing on the need for tracking and interoperability, some examples are given below, which clearly illustrate the need for ‘unique identifiers’ in different life science fields. This need has today been resolved in many different ways, for the different applications:

1. The Entomological Collection Network<sup>78</sup> attempts to tie the data derived from a specimen to that particular specimen by using attached barcodes. According to them, barcodes, while still expensive, allow the identification of individual specimens and greatly reduce the cost of subsequent data handling.

The problem of prospective data capture has been solved by one collection: INBio; barcodes are attached as part of the labelling process, data on locality, time, collector, ... are captured when the print order for the label is generated (60-100 characters per label). The problem of retrospective data capture can be solved by using a similar approach. When researchers study previously collected specimens, they capture the specimen label data. Each specimen that is handled gets a unique number that links the specimen to an electronic data record.

2. Bar-coding of life ([www.barcodinglife.com](http://www.barcodinglife.com)) is a project that uses DNA sequences as genetic barcodes. A 648 base-pair section of the mitochondrial cytochrome oxidase I (COI) gene has been shown to provide species-level resolution in varied animal phyla. The COI database could

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<sup>77</sup> MOSAICC stands for “Micro-Organisms Sustainable use and Access regulation International Code of Conduct “. The MOSAICC Code of Conduct now available on internet ([www.belspo.be/bccm/mosaicc](http://www.belspo.be/bccm/mosaicc)) is the result of five successive drafts improved through dialogue between MOSAICC partners and other experts.

<sup>78</sup> Thompson, F.C. (1994). Bar Codes for Specimen Data Management. *Insect Collection News*, 9, 2-4.

serve as the basis for a global identification system, a tool for taxonomists and a cost-effective system with which non-specialists can assign unidentified specimens to known species.

The consortium for the barcode of life is an international initiative of natural history museums, herbaria, other biodiversity research organisations, government organisations and private companies.

The weakness of this approach however, lays in the choice of the sequenced gene. Allowing powerful discrimination within the animal Phyla, the COI system does not necessarily work for other groups. For Archeae and Bacteria for instance, the method is complicated by the fact that horizontal transfer of DNA has heavily impacted their genomes.

3. The International Plant Exchange Network (IPEN, <http://www.bgci.org.uk/abs/ipen>) is an exchange system for botanic gardens for non-commercial purposes according to the CBD. The objectives are to comply with the obligations of the CBD and system transparency to countries of origin. All plant material supplied by an IPEN member therefore needs to be accompanied by an IPEN number that remains connected with the material and its derivatives through all generations to come. With the aid of this number it is possible to track where and under which conditions the plant entered the network.
4. The World Data Centre for Micro organisms (WDCM, <http://www.wdcm.org>) assigns unique identifiers to the different registered culture collections.

Collection acronyms followed by a number, are used to refer to a certain strain and act as such as an identifier at the strain level. When strains are being exchanged between collections however, synonym acronyms may cause great confusion. This problem is resolved by WDCM, by assigning a unique identifier to the collections or institutes that provide the strains.

5. The Organisation for Economic Cooperation and Development (OECD, [www.oecd.org](http://www.oecd.org)) documented on the designation of unique identifiers for transgenic plants.<sup>79</sup> They describe the unique identifier as being a key attributed to a biotech product, which could unlock information from a range of databases, as well as a harmonised unique entry point enabling information management related to that product. So the unique identifier should facilitate the ability to cross reference information in different databases, and improve access to and management of information by regulators and other interested stakeholders.
6. DNA or protein sequence databases make use of accession numbers as the identifier for a given sequence.

## 6. Persistent Globally Unique Identifiers (GUID)

In the examples mentioned above however, the role of the identifiers is restricted in most of the cases to the assignment of a **LABEL** to the material or data involved. The identifiers are developed for well-defined purposes and for use within a small context, scope or application and are only locally unique.

Within a global context, it is not only harmonisation that is of major importance, but also the need for more persistent globally unique identifiers.

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<sup>79</sup> OECD Documents: (ENV/JM/MONO (2001)5; 2001 and ENV/JM/MONO (2002)7; 2004).

In comparison, on the web, simple uniform resource locators (URLs) have the role of just identifying the location of a given digital object. URLs have largely been used to identify and access web-based digital resources, but they are by no means reliable or persistent and therefore uniform resource identifiers (URIs), Persistent URLs (PURLS) and other systems are now used.

Persistent unique identifiers for global use need to combine both the label and the persistent location were to retrieve the information. Besides assigning an ID to a resource, also the resource, for which the information can change over time, must be assigned to the ID.

The publishing sector has progressed the use and management of persistent identifiers more than any other discipline: the need to unify in one scheme the document management, digital libraries, copyright registration, object based software and to enable core interoperability, integration of disparate sourced data and the ability to trace ownership to manage rights led to the launch of the DOI initiative (Digital Object Identifier, [www.doi.org](http://www.doi.org))<sup>80</sup>, which has been the first system for persistent and actionable identification and interoperable exchange of managed information in the digital environment (see further).

Following the DOI initiative, many other systems have been reinvented. One of them, the Life Science Identifier system (LSID, <http://lsid.sourceforge.net>)<sup>81</sup>, has been specifically adapted for life sciences. The LSID is a URN specification from the Interoperable Informatics Infrastructure (I3C), with members from life science Companies, academic labs and vendors as IBM, and the Object Managing group (OMG).

I3C (<http://www.i3c.com>) was launched in early 2001 at the request of the life science community, with the mission to coordinate disparate efforts around the world and to drive data and tool interoperability across the value chain towards the goal of accelerating basic research, drug discovery and development. This initiative however, seems to have disappeared again today. This proves that an appropriate business plan is as necessary as the technical tools to ensure permanent operation.

## **7. Persistent unique identifiers for microbial resources**

In the field of microbial genetic resources, strain labels are used as locally unique identifiers. These may consist of a culture collection acronym followed by a number, or may just be any name given to the strain by an individual researcher.

There is thus, at this given moment, no universal way to refer to all resources stored in the different culture collections or private collections, and thus no reliable way to detect if multiple digital resources present data on the same biological source.

Furthermore, taxonomic names or strain numbers have constituted the key link between different databases, however, in the absence of a single comprehensive database of organism names and synonym strain numbers, individual databases lack an easy means of linking information.

According to Garrity and Lyons<sup>82</sup>, a resolution system is required that can handle the complex relationships between biological names and the entities they denote. They believe that an implementation of the DOI system may provide the most robust and future-proof solution and they are developing a model for assigning DOIs to prokaryotic taxa as a test case. Though the definition of a taxon may change

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<sup>80</sup> Paskin, N. (2005). The DOI Handbook. Edition 4.2.0, International DOI Foundation, Inc.

<sup>81</sup> Life Science Identifiers RFP response, OMG Document lifesci/2003-12-02.

<sup>82</sup> Garrity, G.M., Lyons, C. (2003). Future-proofing Biological Nomenclature. *OMICS: a journal of Integrative Biology*, 7, 31-33.



and its nomenclature may be redefined, the DOI will persist; leaving a forward-pointing trail that can be used to reliably locate digital and physical resources. This is of course also extensible to the level of individual genes.

Another initiative in this context, *StrainInfo.net*, is a cooperation pilot project between the Laboratory of Microbiology and the Department of Applied Mathematics, Biometrics and Process Control of the University of Ghent and the Information Network Centre of the Chinese Academy of Sciences in Beijing.<sup>83 84</sup> The *StrainInfo.net* portal envisions the establishment of a technology platform that works towards the use of multi-perspective integrated information in a broadened context. At the heart of this portal lays an Integrated STRAIN database, a curated central repository that provides a complete and correct view on the synonymous labels assigned to biological specimen during their lifetime. This data repository is constructed automatically through the seamless integration of label equivalence information as it is disseminated through the online catalogues of CC and BRC's.

Almost all BRC's keep track of the history of their resources, from the point of deposit, back to the initial point of isolation. This linear information however, only gives a fragmented view on the complete trace the strains have followed. With the help of the *StrainInfo.net* portal acting as an information broker between all online catalogue entries of the BRCs that have a given strain in their holdings, it gets straightforward to manually extract all history information of a strain as it is fragmentarily recorded over all these data sources.

The *StrainInfo.net* portal adds to the commonly used strain numbers a more persistent and dumb identifier; in order to incorporate it within a larger namespace that provides extended unicity. As a result of incorporating the unique identifiers maintained by the *StrainInfo.net* portal within well-established global network identification infrastructures, the flexibility and interoperability of the identifier will no longer be related to its use to indicate biological resources but can possibly be linked to additional services that work completely independent of the *StrainInfo.net* system.

Very recently, the International Nucleotide Sequence Databases (EMBL, GenBank and DDBJ) decided to promote the inclusion of specimen identifiers in the sequence database. The identifier will be composed of the institution code and the specimen number; however the format has yet to be fixed. The database of institutions will be maintained by GenBank/NCBI, which will therefore rely on stable databases of the directory of institutions, as is the CCINFO database from WDCM.

## **8. Use of Persistent Unique Identifiers in the context of Access and Benefit Sharing**

In summary, we can state that in the post-genomic era, a larger and larger portion of the value of any software application will consist of its ability to interoperate with other programs so that it reasons across a wider range of results. This additional value must be provided in an uncomplicated 'lightweight' way.

In the framework of MOSAICS, we would recommend to microbial resource centres and microbial data providers or database owners to work towards the assignment of persistent globally unique identifiers to

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<sup>83</sup> Dawyndt, P., Vancanneyt, M., De Meyer, H. & Swings, J. (2005). Knowledge accumulation and resolution of data inconsistencies during the integration of microbial information sources. *IEEE Transactions on knowledge and data engineering*, vol. 17, 8, 1111-1126.

<sup>84</sup> Dawyndt, P., De Baets, B., Zhou, X., Ma, J. & Swings, J. (2005). *StrainInfo.net*: Holding a wealth of downstream information on microbial resources right in our hands. In preparation.

their material items and data elements. These identifiers are of major importance for the appropriate management of both resources and related information and form the key element, rather than certificates of origin, for the tracking of biological resources. This is a prerequisite for reliable access and benefit sharing issues.

Certificates of origin only describe the source of the material and do not allow as such tracking transfers or exchanges of material or related information. However, these certificates stay of course compatible and, more important, complementary with the identifier system. By assigning an identifier to these documents too, it will be possible to link them automatically to the corresponding material and data elements.

Unique identifiers do, by no means intend to replace the traditional labelling of strains, genes or other data elements, but allow incorporating them in a larger namespace that provides an extended unicity and interoperability.

In principle, different kinds of identifier systems can be used, although it would be preferential to retain only one system in order to achieve maximal harmonisation and global uniformity.

In practice, to take advantage of an identifier system requires 2 pieces of software: a client piece within an informatics application and a server piece associated with the actual data. Once database owners have a database in place, the information would be sent to an authority, which contains a list of all available data resources. An application that wants to access the data needs client software. The application makes a request to the authority, which returns a document that includes the location of the data and metadata that contain the practical information.

The recommendations made within this framework fit well with these made by the World Health Organisation (WHO, [www.who.org](http://www.who.org)) through the International Agency for Research on Cancer. They aim to work towards the defining of a persistent and unique identification and coding system for their medical data files.

However, as described extensively above, identifiers in the context of MOSAICS must be unique and must also be persistent to ensure their role in reliable tracking of the material for access and benefit sharing issues.

## **9. Digital Object Identifiers (DOI's) as the most appropriate system for tracking of microbial resources?**

DOIs can be assigned to any identity, for use on digital networks. Information about a digital object may change over time, including where to find it, but its DOI will not change. Using DOIs as identifiers makes IP in a networked environment much easier and more convenient and allows the construction of automated services and transactions. It provides a system for persistent and actionable identification and interoperable exchange of managed information on digital networks.<sup>85 86</sup>

The system is managed by the International DOI Foundation (IDF, founded in 1998), an open membership consortium including both commercial and non-commercial partners, and has recently been

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<sup>85</sup> Paskin, N. (2005). The DOI Handbook. Edition 4.2.0, International DOI Foundation, Inc

<sup>86</sup> Paskin, N. (1993). A 2003 Progress Report. D-Lib Magazine, 9.

accepted for standardisation by ISO. The IDF provides implementation through agreed standards of governance and scope, policy as well as a technical infrastructure and a social infrastructure; it is a central authority and maintenance agency [4, 9].

The DOI system was built using several existing standard-based components, notably the Handle resolution system and the indecs Data Dictionary, which have been brought together and further developed to provide a consistent system. The Handle system enables resolution to multiple associated data.<sup>87 88</sup>

The system consists of several components:

- a specified standard numbering syntax
- a resolution service
- a data model (metadata tools) allowing interoperability
- procedures for the implementation

Any existing numbering schemes and any existing metadata schemes can be used within the DOI system. E.g. 10.2245/LMG 3654.<sup>89 90</sup>

DOIs are widespread used now, with over 17 million DOI's assigned, from over 1000 naming authorities.

Examples of projects using DOI applications for scientific data are the German National Library of Science and Technology (TIB) and the Names for Life project.

Like domain name registration, DOI assignment requires a fee and agreement to follow the defined standard and rules. This makes the system managed. The model selected for a long- term position of the DOI organisation is a body that is not reliant on external sources, but is a self-funding system that can be supported in its perpetuity from its own resources (fee for participation, not for use of a DOI once issued).

Registration agencies hold a 'franchise' on the DOI. In exchange for a fee to the IDF, and a commitment to follow the ground rules of the DOI system, they are free to build their own offerings to a particular community (fee is based on number of DOI's assigned).<sup>91</sup>

Among the different models of identifier systems, the DOI system seems to be the one with the strongest business plan and safest expectations for the future.

## **10. A possible scenario, as recommended by MOSAICS**

Taking advantage of the StrainInfo.net project, which was available as a model for testing within the framework of MOSAICS, a hypothetical model was build for assigning GUIDs to biological resources.

Preferentially, such an integrated database should be located at the World Data Centre for Micro organisms (WDCM; <http://www.wdcm.org>). WDCM, which is the heart of the World Federation for

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<sup>87</sup> Paskin, N. (2005). The DOI Handbook. Edition 4.2.0, International DOI Foundation, Inc

<sup>88</sup> Paskin, N. (1993). A 2003 Progress Report. D-Lib Magazine, 9.

<sup>89</sup> Paskin, N. (2005). The DOI Handbook. Edition 4.2.0, International DOI Foundation, Inc

<sup>90</sup> Paskin, N. (1993). A 2003 Progress Report. D-Lib Magazine, 9.

<sup>91</sup> Paskin, N. (2005). Digital Object Identifiers for Scientific Data. Data Science Journal, 4, 1-8.

Culture Collections (WFCC) already retains an ID system for registered culture collections and institutions.

MOSAICS thus recommends that WDCM further develops the existing system of collection registration and makes it fit into a well established and funded global system, which can also function as a registration authority for GUIDs.

Also for biological resources (BR) other than microbial resources, a similar procedure would be recommended, such that most *ex situ* BR could be managed through one global system.

The participation of professional networks and federations must than be organized on a modular concept, allowing gradual connection of collections, institutions and scientists to a compatible permanent system, without making them interdependent.

At the level of microbial resources, MOSAICS suggests that the WFCC Board, including the WDCM Director, monitor the registration and GUID assignment and set up a program to improve the (tracking) system, helping culture collections to scope with the technical and administrative hurdles. Such a development, possible at the level of the WFCC, could serve as a model for other professional networks.

An appropriate management system has to be appointed, stipulating the role and responsibility of culture collections and individual researchers within this system, by deposit, transfer or exchange of microbial resources and information.

The WFCC should delegate representatives to foster proper communication in this debate.

MOSAICS suggests close collaboration with IUMS and IUBS to define a collaborative scenario between WFCC and the scientific community at large.

# Certificating biodiversity: practical issues for *ex situ* collections

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## 1. Summary

When discussing the development of an internationally-recognised certificate of origin/source/legal provenance, we must consider that a vast number of applications for access to genetic resources come from *ex situ* collections wishing to use biological material for non-commercial conservation or education related purposes, such as biodiversity inventories and ecological assessments and increasing taxonomic knowledge. Benefits generated by such institutions are almost always non-monetary and generally arise from the comparative use of a library of specimens (such as taxonomic tools, phylogenies, vegetation maps and conservation assessments) and from institution-level capacity-building activities (such as technology transfer, staff exchange, student supervision and training courses). Only very rarely are benefits attributable to individual specimens. These important general shareable benefits will decrease if access is further complicated, if administration and curation costs rise and if specimen exchange and use is limited.

Designers of a certificate system need to consider the complexity of non-commercial biodiversity research. There are large numbers of specimens involved – a single field trip may result in the collection of thousands of specimens. The taxonomic identity and number of specimens may be unknown at the time of collection and possibly for years afterwards, depending on the availability of specialist taxonomic expertise. Specimens may be variously collected in multiples (e.g. herbarium specimens or seeds distributed to several institutions), sampled (e.g. for pollen or DNA), loaned, multiplied (e.g. by propagation) or bred (to other specimens). Within a single institution a single specimen may be used in several ways and forms. Institutions have developed many different curation systems to deal with the different types of collections that they hold.

Current systems of access can be very complex, sometimes requiring separate permissions for research, collection and export. A system that simplified and coordinated these steps, resulting in a single permit recorded in a national database system and identified using a simple trackable code, could potentially ease the logistical difficulties of acquiring prior informed consent, and make the recording and tracking of PIC back to the *in situ* source providers simpler for providers and users alike. However timing of permission is crucial – collectors need assurance that permission has been granted before, not after, fieldwork takes place. Due to numbers and changes in form of specimens, it is not feasible to develop a system that requires one certificate per specimen, or one that requires generation of new certificates for samples, duplicates, progeny or information. Emphasis should be put on traceability back to *in situ* source providers - not tracking forwards from origin to all subsequent users, which would require the adoption of costly new systems for little or no benefit. One permit per Material Transfer Agreement or ‘fieldwork event’, involving one set of providers, resulting in one code to link to all specimens collected by that set of scientists in a given timeframe and place(s) under a given set of terms, could serve to record origin/source, PIC and MAT, and to facilitate benefit-sharing.

It is vital to consider the format of any new tracking tool, and to consider how it would work in existing systems. It would be most practical to develop a simple permit code that could travel with specimen data without necessitating the use of databases at all stages. Databasing requires considerable staff and infrastructure resources; barcoding costs are even greater. A paper-based system would be highly problematic for curation and exchange. The CITES model (paper permits for limited transboundary movements of a limited list of taxa endangered by trade, in readily-recognisable and enforceable forms) would be extremely impractical and costly to apply across all genetic resources. A focus on transboundary movement is not appropriate: provider country scientists exchange and use material too and a clear system would need to acknowledge such use. However it could be useful to consider a scheme for facilitating access for institutions with appropriate ABS policies and procedures in place, comparable to the CITES registered scientific institutions scheme, which has been invaluable to institutions needing to exchange material and unable to afford the considerable administrative and monetary costs of CITES permits, as well as to national authorities.

Finally, we should aim to develop constructive, positive mechanisms for recognising and recording institutional-level benefit-sharing (not on a permit or specimen basis) so that national authorities become better aware of its existence and value.

## **2. Concluding statement/ recommendations to the Group of Technical Experts**

- *Encourage coordinated national permit systems* – i.e. encourage simplification of current national permitting schemes, development of national permit databases that can be checked by national authorities or other providers, users and third parties, and development of permits that are broadly comparable internationally using some common key fields
- *Develop permit unique identifiers that can link back to national permit systems* – an alphanumeric code could travel with specimen data and be recorded in databases/ logbooks/ labels as appropriate; paper-based systems should be avoided
- *Permits should cover Material Transfer Agreements, or fieldwork events, NOT separate species/specimens/samples/genes* – i.e. one permit should cover all specimens collected within specified time range and place, by permitted scientists, with the prior informed consent and mutually agreed terms of the same providers
- *Avoid focus on transboundary transfers* – a system should be clear for both in-country and foreign scientists and promote collaboration and compliance
- *Facilitate range of low-impact scientific uses* and consider use of some common standard fields to clarify permitted range of uses
- Permits should clearly set out *when new prior informed consent is needed*
- *Use existing curatorial systems* as far as possible rather than imposing new tracking systems, to lower costs and increase compliance
- *Focus should be on traceability back to in situ source, not forwards to subsequent users* – i.e. no expectations that all genetic resources can be tracked from *in situ* source to all users

- *Consider a registration system for scientific institutions with appropriate ABS policies/record-keeping/procedures, and facilitate permits for them (facilitation as incentive for compliance, deregistration as penalty for non-compliance)*
- *Consider how to recognise and record institutional benefit-sharing at national level*

# Consequences of a certificate of origin for the seeds business

KEES NOOME  
Limagrain Advanta

## 1. Introduction

Much of the increase in food production in the last half century can be attributed to innovations achieved through plant breeding, drawing on existing resources.

In most crop species, a high to very high percentage of genetic resources has been freely exchanged over the ages and over all countries in the world. The resulting plant varieties are not based upon single accessions/origins, but on a screening of thousands of recombinations of genetic material. Most source genetic material that is used is public or privately owned; the Plant Breeders Rights' specifically enable free access of commercialized varieties for further breeding.

The concept of Certification as proposed in CBD context is intended to be some kind of a standard system of proof for correctly following Access and Benefit Sharing obligations with a Country of Origin of the genetic resources (biological resources/traditional knowledge).

It is not clear for what this certificate is intended; does it apply to genetic resources "in the form received", does it apply to the presence of components or even to derivations based upon (knowledge from) the material accessed? Does it cover biological products produced from Genetic resources/Traditional Knowledge?

Besides, it is not clear when this certificate will be applied; will this happen only at first commercialization/IP application or (also) further down the production chain and in trade? Will it be applied at transboundary shipments, or could it be a proof of ownership?

## 2. Issues relevant for the situation in seeds

### – *Scope of the Certificate*

As it is less than fifteen years after the CBD came into force, virtually none of the varieties commercialized are based on accessions with ABS obligations; they were developed from genetic material that was lawfully obtained before the CBD came into force. And virtually all of the new varieties developed since and to be commercialized are developed from public and private material that does not fall under the sovereign rights of countries as introduced by the CBD.

- Since the CBD came into force in 1994, access to in-situ and ex-situ genetic resources for commercial companies has reduced drastically and also exchange between gene banks etc. has slowed down. This is contrary to the objectives of the CBD, which intends to promote use of genetic resources.



– *Identity of the Certificate*

During the genetic recombination procedures the identity of the original accession is lost (the accession is never used “in the form received”). To maintain, the link with a certificate a formal “tracking system” during breeding and development will be needed, which will be a heavy burden on all research.

- *Identification of plant material* is necessary as a precondition for market introduction and plant breeders’ rights. This is done on the basis of DUS (Distinction, Uniformity, Stability) criteria of UPOV on a morphological description, which needs an evaluation period of two growing seasons. A standardized DNA characterization does not exist for most crops, for small crops there is no DNA method at all.

– *Identity of the material*

There is a very high degree of “genetic overlap” between accessions or even a complete duplication between different origins due to the extensive interchange that happened over the ages, which makes the value of a certificate questionable.

– *Volume of certificates*

The OECD scheme for certification of agricultural crops lists 37,000 plant varieties from 191 species; the number of seed productions produced and traded is a multiple of that. In the research phase many samples of crosses and trial varieties are shipped for local testing or seed multiplication. At a rough estimate this will be between 10 and 100 million samples shipped per year. If derivatives are also covered (farmer’s harvest) the volume expands even more.

- The FAO International Treaty recognizes above complications and has therefore created a structure that does not apply the Country of Origin concept nor ABS agreements based on individual accessions/recipients; individual certificates are therefore not applicable in PGRFA. There is only one Origin: the Multilateral System.

### **3. Considerations of feasibility**

#### *Effectiveness of a Certificate*

The rationale behind the certificate is that it will be a tool to stop bio piracy. However, it is only rare for plant breeding that access to genetic resources which are held by a Country of Origin is necessary. Moreover, it is shown in a report by the CBD (UNEP/CBD/WG-ABS/4/INF/6), which analysed claims of “misappropriation of genetic resources”, that many of the claims of bio piracy are disagreements arising out of uncertainties about ABS requirements. A certificate will not remedy this situation.

#### *Enforcement*

The patent office is not equipped to judge the correctness of certificates and even most Countries of Origin will not have the capacity to check up on correctness. Testing the certificates of living organisms (research samples and commercial trade) in the case of a customs check for a link between identity and certificate is hugely complicated and not comparable with a CITES approach of checking the rare shipment of a limited list of a complete species that fall under CITES.

It is to be expected that many countries will therefore favour an international institute that takes care of enforcement of correct application of certificates; it is extremely doubtful if such an organization can recover its cost in the case of seeds. A cost/benefit analysis is essential.

*Who pays?*

Since the certificate is intended to support the interests of the Country of Origin, it is clear that these should cover the costs of the system needed for it. To charge these costs to the recipients of the genetic resources would severely discourage any ABS agreement.

*Timing?*

Since the application of a Certificate will mainly be focused on commercial introduction after a development period that often is ten years or more, it seems sensible to focus in the coming ten years first on the creation and national implementation of the international Regime for ABS which determines the first moment that substantial access to genetic resources might possibly take place. Introducing and applying a Certificate can come much later.

*Pre-CBD material?*

Genetic resources have been used, exchanged and altered extensively in the past. It is essential to realize that those genetic resources that were obtained before the CBD went into force were obtained legally. Any certification scheme would therefore need clearly to exclude such materials and the materials derived from them. A practical way of distinguishing between such materials and genetic resources acquired after the CBD came into force would be needed. Solutions may also be needed for materials that were obtained between the CBD coming into force and the introduction of the certificate. There is also the problem of how to deal with materials obtained from countries that have not yet implemented access and benefit sharing rules, or even ratified the CBD.

*Existing Certificates of Origin?*

For example the Certificate of Origin (CO) – used since at least 1923 (1923 Geneva Convention) – is a document widely used in international trade to attest that goods are wholly obtained or produced in a particular country; these certificates apply to manufactured goods as well as to natural resources (coal, wheat). It is important that confusion is avoided.

#### **4. Conclusion**

Discussion of whether there should be a Certificate – and, if so, what it should be, how it should operate and its legal effects – must take account of reality: numerous and diverse uses and continuous intermingling of genetic resources in the past and at present. Any benefits of using a Certificate must be weighed against the practical impact of such a certificate on the real world use of genetic resources, the conservation of genetic resources and their sustainable use.

In the case of species for which there exist long standing plant breeding programs, the creation of a Certificate seems extremely complicated and therefore impractical; it seems not feasible since the origin of the material is usually not a Country of Origin. In view of the absence of functional ABS legislation a certificate has no benefits now and the system for enforcing a certificate based on living, intercrossing organisms will be very expensive.

Especially developing countries which strongly depend on breeding by public research and farmers should consider if a certificate will really help them. And will a certificate promote or hinder the objectives of the CBD?

#### **5. Concluding statement/ recommendations to the Group of Technical Experts**

- We need to specify which species are spread around the world versus the ones that are unique to a Country of Origin The first ones need a multilateral approach, the second ones can only have a bilateral approach.
- Introduction of a Certificate in parallel to the ABS regime will cause severe complications and delays to the Regime.
- Enforcement of ABS and Certificate is only possible if there is a system of characterisation and recognition of the genetic resources.
- The Regime will be too complicated for users.



*Programme*

**European Regional Meeting on an  
Internationally Recognized Certificate  
of Origin/Source/Legal Provenance**

Federal Agency for Nature Conservation,  
Isle of Vilm, Germany

24.10. – 29.10.2006



The goal of the expert meeting is to exchange information on topics out of the mandate of the upcoming Technical Expert Group on an Internationally Recognized Certificate (January 2007) among ABS experts and user sectors from European countries. The informal discussion will be based on different research studies of ABS Experts on an international certificate, contributions of different user sectors of genetic resources and other participants. Any information document/compilation of the CBD Secretariat for the Technical Expert Group will be taken into account (as far as already available before the meeting). The output of the meeting will be a report containing abstracts of all contributions of the experts as well as recommendations in the form of technical advice as a result of the workshop discussions.

- Programme

### **Tuesday, 24.10.2006**

Arrival of the participants

*18.30 Dinner*

21.00 Welcome and brief introduction to the meeting

(HORST, KORN, UTE FEIT, FEDERAL AGENCY FOR NATURE CONSERVATION)

### **Wednesday, 25.10.2006**

*8.00 Breakfast*

*Morning session*

9.00 **OPENING OF THE MEETING**

SIMONE IRSFELD, FEDERAL MINISTRY FOR ENVIRONMENT, NATURE AND NUCLEAR SAFETY  
MARINA VON WEISSENBERG, REPRESENTATIVE OF THE FINNISH PRESIDENCY

## **I. Background**

9.30 Overview of the outcomes of COP-8 concerning ABS  
(MATTHIAS BUCK, EU COMMISSION, DG ENVIRONMENT)

10.00 Overview of the different submissions by parties on an international certificate for the  
Technical Expert Group  
(VALERIE NORMAND, SECRETARIAT OF THE CBD)

*10.45 Coffee break*

11.15 Conclusions of the Paris Roundtable 2004 on Practicality, Feasibility and Cost of  
Certificates of Origin  
(CHRISTINE FRISON, CENTRE FOR INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW)

11.45 Suggestions for building a system of certificates of origin  
JOSE CARLOS FERNANDEZ UGALDE, INSTITUTO NACIONAL DE ECOLOGIA-SEMARNAT,  
MEXICO)

*12.30 Lunch*

*Afternoon session*

13.30 Guided tour around the Isle of Vilm

## **II. BASIC LEGAL AND TECHNICAL INFORMATIONS CONCERNING CERTIFICATES OF ORIGIN/ SOURCE/LEGAL PROVENANCE**

15.00 Certificates of origin/source/legal provenance: different concepts and legal issues  
(MIRIAM DROSS, INSTITUTE FOR APPLIED ECOLOGY)

*15.45 Coffee break*

16.15 Integration of a certificate into the international legal context  
(TOMME YOUNG, INTERNATIONAL RESEARCH INSTITUTE FOR SUSTAINABILITY)

16.45 Certificates of origin: economic impacts and implications  
(CARMEN RICHERZHAGEN, GERMAN DEVELOPMENT INSTITUT)

17.15 Possible Effects of Certificate on the Disclosure of Origin Process in Patent Applications  
(ANA MARIA PACON, UNIVERSITY OF PERU)

17.45 Implications if certificates are to cover traditional knowledge  
(NICOLAS BRAHY, UNIVERSITE CATHOLIQUE DE LOUVAIN, BELGIUM)

18.30 *Dinner*

*Evening programme (optional)*

21.00 Visit to the picture gallery and relaxing

**Thursday, 26.10.2006**

8.00 *Breakfast*

*Morning session*

9.00 Certificates of Origin for genetic Resources and International Law  
(JEAN FREDERIC MORIN, MCGILL UNIVERSITY, CANADA)

### **III. ORGANISATIONAL ASPECTS OF A CERTIFICATE SYSTEM UNDER A COMPARATIVE PERSPECTIVE**

9.45 The Standard Material Transfer Agreement under the International Plant genetic Resources Treaty  
(FRANZISKA WOLFF, INSTITUTE FOR APPLIED ECOLOGY)

10.30 *Coffee break*

11.00 Synergies between CITES and ABS certificate system  
(IRINA SPROTTE, FEDERAL AGENCY FOR NATURE CONSERVATION)



11.45 Notification control mechanisms in the Basel Convention  
(TILMAN BAEHR, PUBLIC AUTHORITY FOR DEVELOPMENT AND ENVIRONMENT HAMBURG)

12.30 *Lunch*

*Afternoon session*

14.00 The science-commons project on a standard MTA for the exchange of biological research material – some implications for an international system to track genetic resources, associated user conditions and traditional knowledge  
(MATTHIAS BUCK, EU COMMISSION, DG ENVIRONMENT)

14.30 *Coffee break*

#### **IV. IMPLEMENTATION CHALLENGES OF AN INTERNATIONAL CERTIFICATE IN EUROPEAN COUNTRIES**

15.00 German user survey: results according to an Internationally Recognized Certificate of origin/ source/legal provenance  
(CARMEN RICHERZHAGEN, GERMAN DEVELOPMENT INSTITUTE; KARIN HOLM-MÜLLER, UNIVERSITY OF BONN)

15.30 Legal Aspects of Genetic Resources Access and benefit Sharing – Czech Republic (relation with international regime)  
(MILENA ROUDNA, MINISTRY OF ENVIRONMENT, CZECH REPUBLIC)

16.00 Survey on the extent of knowledge and use of the CBD provision on Access and Benefit-Sharing by Belgian users of genetic resources  
(CHRISTINE FRISON, CLAIRE COLLIN, MINISTRY OF ENVIRONMENT, BELGIUM)

16.30 *Coffee break*

17.00 Results of the economic survey of the use of genetic resources in France  
(SARAH HERNANDEZ, MINISTRY OF ENVIRONMENT, FRANCE)

**V. IMPLEMENTATION CHALLENGES OF AN INTERNATIONAL CERTIFICATE FOR KEY USERS**

**ACADEMIC RESEARCH**

17.30 Good Practice for Academic Research on Genetic Resources -brief statement concerning  
an International Recognized Certificate  
(SUSETTE BIBER-KLEMM, SWISS ACADEMY OF SCIENCE)

18.00 The German Research Foundation and its Committee on Biodiversity Research - brief  
statement concerning an International Recognized Certificate  
(SUSANNE REYES-KNOCHE, GERMAN RESEARCH FOUNDATION)

18.30 *Dinner*

20.00 Klezmer Concert (jewish folklore) by „CHAVRIM”, a group of young musicians from  
the region  
(we ask for a contribution towards the expenses of 4,00 €)

**Friday, 27.10.2006**

8.00 *Breakfast*

*Morning session*

**PHARMACEUTICAL INDUSTRY**

9.00 The Pharmaceutical Industry and Access and Benefit-Sharing: An Empirical Analysis  
(FLORIAN KERN, SPRU, INTERNATIONAL RESEARCH INSTITUTE FOR SUSTAINABILITY)

- 9.45 Statement of the Pharmaceutical Industry in the discussions on an International Recognized Certificate  
(IVAN HJERTMAN, IP INTERFACE AB)

10.30 *Coffee break*

## **EX-SITU COLLECTIONS**

- 11.00 Botanic Gardens and the International Plant Exchange Network (IPEN) – brief statement concerning an International Recognized Certificate  
(ANDREAS GRÖGER, BOTANIC GARDEN OF MUNICH)
- 11.30 ABS in case of Microbial Resources – MOSAICS Integrated Conveyance System - brief statement concerning an International Recognized Certificate  
(PHILIPPE DESMETH, BCCM)
- 12.00 Certifying biodiversity: practical issues for ex-situ collections  
(KATE DAVIS, ROYAL BOTANIC GARDENS, KEW)

12.30 *Lunch*

*Afternoon session*

## **AGRICULTURAL , HORTICULTURAL SECTOR**

- 14.00 Consequences of the Certificate of origin/source/legal provenance for the seeds business  
(KEES NOOME, LIMAGRAIN ADVANTA)
- 14.45 Further Statements...  
(BIRTE LORENZEN, JÜRGEN GRUNEWALDT, CIOPORA; SABINE HOFFMANN-STOCKTER, FEDERAL MINISTRY FOR FOOD, AGRI-CULTURE AND CONSUMER SAFETY)

15.30 *Coffee break*

## **VI. Summary and way forward**

16.00 Summarizing relevant issues on the implementation of certificates of origin/source/legal provenance

Working Groups on selected topics according to participants' interests

17.30 Plenary: Final discussion of working groups outcomes

End of meeting

*18.30 Dinner*

Free time for a farewell party!

**Saturday, 28.10.2006**

*8.00 Breakfast*

*Departure or*

All-day excursion to the Historic City Centre of Stralsund (World Heritage Site) and the famous "Marine Museum", which is the most visited Natural History Museum and Aquarium in Germany

(optional)

*(If necessary overnight stay in Stralsund City, otherwise departure)*

*List of participants*

European Regional Meeting on an Internationally  
Recognized Certificate of Origin/Source/Legal Provenance

Federal Agency for Nature Conservation

**October 24-29, 2006, Isle of Vilm, Germany**

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