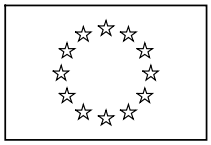

COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

The implementation by the EC of the "Bonn Guidelines" on access to genetic resources and benefit-sharing under the Convention on Biological Diversity

{SEC(2003) 1455}

List of abbreviations

ABS	Access and Benefit-Sharing
BCCM	Belgian Co-ordinated Collections of Micro-organisms
BCH	Biodiversity Clearing House
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CSR	Corporate Social Responsibility
COP	Conference of the Parties
EC	European Community
EC-CHM	European Community Biodiversity Clearing House Mechanism
ECCO	European Culture Collections Organisation
EMAS	Eco-Management and Audit Scheme
EU	European Union
FAO	Food and Agriculture Organisation
IGC	Inter-Governmental Committee
IT-PGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
MIRCEN	Microbial Resource Centre Network
MOSAICC	Micro-organisms Sustainable Use and Access Regulation International Code of Conduct
MS	Member State/s
NBSAPs	National Biodiversity Strategy and Action Plans
NGO	Non-governmental Organisation
PCT	Patent Co-operation Treaty
PIC	Prior Informed Consent

PLT	Patent Law Treaty
R&D	Research and Development
TRIPs	Trade Related Aspects of Intellectual Property Rights
TK	Traditional Knowledge
UNESCO	United Nations Educational Scientific and Cultural Organisation
UPOV	The International Union for the Protection of New Varieties of Plants
WFCC	World Federation for Culture Collections
WIPO	World Intellectual Property Organisation
WSSD	World Summit on Sustainable Development
WTO	World Trade Organisation

Executive summary

This Communication concerns the implementation by the European Community (EC) of the Bonn Guidelines on access to genetic resources and benefit-sharing which were adopted at the 6th Conference of the Parties of the Convention on Biological Diversity (CBD), in April 2002.

Genetic resources are of increasing importance for a growing number of economic sectors. Users of genetic resources are mostly located in the developed world while providers are often in developing countries.

Sharing fairly and equitably, between users and providers, the benefits arising from the use of genetic resources is one of the objectives of the CBD and the Bonn Guidelines are an important tool to achieve it.

The EC is committed to the implementation of the CBD provisions on access and benefit-sharing (ABS) and was an active negotiator of the Bonn Guidelines. The latter have the potential to contribute to the objective of sustainable development as they provide for the benefits arising from the utilization of genetic resources to be used to improve conservation and sustainable use of biodiversity.

The Communication addresses the wider international context of the debate on access and benefit-sharing which includes the recently adopted Food and Agriculture Organisation (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture, the work of the World Intellectual Property Organisation and the World Trade Organisation, the outcome of the World Summit on Sustainable Development and the Conventions under the International Union for the Protection of New Varieties of Plants.

An overview is provided of EC policy approach to and measures on ABS, including in the framework of the EC Biodiversity Strategy, in relation to the EC Directive on the legal protection of biotechnological inventions and the Regulation on community plant variety rights. EC stakeholders' action is also presented in particular with regard to institutional policies, codes of conduct and corporate policies.

After a brief description of the main features of the Bonn Guidelines, the paper introduces possible ways for the EC to implement them. The EC role as provider of genetic resources is presented as well as possible actions for the EC to foster users' measures which are in harmony with the Guidelines. Material transfer agreements and stakeholders' codes of conduct are singled out as key instruments for stakeholders to live up to their responsibilities as identified by the Bonn Guidelines.

The Communication presents measures which the Commission believes could raise users' awareness of their obligations under the CBD, including: the creation of a European network of ABS focal points; the establishment of a specific section on ABS on the EC Biodiversity Clearing House Mechanism, and the setting up of a register of stakeholders' groups on this clearing house. Moreover, the integration of the ABS issue into the EC process on Corporate Social Responsibility is also envisaged.

The Communication recalls existing requirements that can entail the disclosure of the origin of genetic resources and related traditional knowledge under EC law and European intellectual property law and recognises the possible role of such requirements in providing incentives for the respect of prior informed consent by the providers of genetic resources.

The Communication refers to the possible introduction of a self-standing disclosure requirement for patent applicants in the EC legal order. Such a requirement would be characterised as a 'self-standing obligation' whose non-respect will only have consequences outside the field of patent law. The Commission will also look into the feasibility of introducing a similar disclosure requirement in the context of plant variety rights. The Commission believes that the EC and its MS should also be ready to discuss, in the relevant international fora, the possibility of making this disclosure requirement a formal condition of patentability. In that case, the consequences of the non-respect of the requirement would fall both within and outside the field of patent law.

The Commission also considers that the EC and its MS should be open to further discuss the development, in the CBD framework, of a certificate of origin for genetic resources as evidence of prior informed consent, provided that this is not framed in a way which would prevent stakeholders from enjoying the flexibility needed in order to carry out their transactions.

The Communication highlights the possible role of arbitration and of ABS focal points to ease the addressing of infringements of ABS arrangements and the potential role of the EC Eco-Management and Audit Scheme as a voluntary certification scheme for organisations that comply with the Bonn Guidelines.

In relation to the possibility of fostering the implementation of the Bonn Guidelines in third countries, the Communication underlines the importance of the implementation of the relevant aspect of the EC Biodiversity Action Plan for Economic and Development Co-operation and of the EC Communication on Life Science and Biotechnology.

Finally, the role of the EC in international fora in order to further develop a transparent international regime on access and benefit-sharing is outlined.

1. INTRODUCTION

The issue: what does it mean?

The fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to them, is one of the three objectives of the Convention on Biological Diversity (CBD).

Genetic resources are usually classified under three broad categories: plant, animal and microbiological genetic resources. They are of fundamental importance for many areas of scientific research, in the field of agriculture (e.g. in plant breeding), and for an increasing number of industry sectors, including biotechnology, pharmaceutical, botanical medicine, horticulture and cosmetics. These industry sectors already make use of a wide range of genetic resources and some of them make considerable investments in bio-prospecting activities in order to discover possible new applications of genetic resources. These activities often take place in countries which hold the richest biodiversity on the planet (so called mega bio-diverse countries, mostly in Latin America, south-east Asia, Oceania and, to some extent, Africa).

The above mentioned CBD objective reflects the need felt by the negotiators of the Convention to ensure that companies and research institutes, located mostly in industrialised countries, are obliged to share the gains derived from the use of genetic resources.

Therefore, the issue of Access and Benefit Sharing (ABS) is seen as an issue of equity and fairness. In this respect, all Contracting Parties have accepted, in Article 15.7 of the CBD, to take measures aimed at sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Article 15.2 of the CBD encourages Parties to "create conditions to facilitate access to genetic resources for environmentally sound uses". This is important because without access there will be little or no benefits to share.

Europe is historically an important user of genetic resources in both research and product development. Europe is also a provider of such resources home to a rich biodiversity, including the Mediterranean hotspot, and to a large number of *ex situ* collections, including agricultural collections, microbial culture collections, zoos and botanic gardens. These collections have a high potential for conservation, as they often contain rare and endangered species and carry out propagation projects.

The level of demand for genetic resources within the EU across different industrial sectors is hard to estimate and shifts with time, e.g. in line with technological innovations. Nevertheless, the EU possesses substantial commercial R&D capacity and European entrepreneurial life sciences industry constitute an important sector of the European economy.

What has the CBD done for the implementation of its objective on ABS?

The CBD objective on ABS is enshrined in its Article 1. This provision only sets out general principles. A framework for the implementation of this objective is provided in Article 15 of the Convention which recognises the sovereign right of States over their natural resources and contains reference to the notions of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) to obtain access to genetic resources. In addition, Article 8(j) contains

provisions to encourage the equitable sharing of the benefits arising from the utilisation of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity, and Article 10(c) requires Parties to protect and encourage customary use of biological resources. Furthermore, Articles 16 to 19 put great emphasis on access to and transfer of technology, including biotechnology, on exchange of information and on technical and scientific co-operation as tools for the achievement of the objectives of the Convention.

Responding positively to developing countries' requests, the EU supported, in the fourth Conference of the Parties to the CBD (Bratislava, 1998) the launching of a negotiation process on the question of ABS to explore all options for access to genetic resources and benefit-sharing on mutually agreed terms. This process led to the adoption, in the Sixth Conference of the Parties (The Hague, 2002) of the "Bonn Guidelines" on access and benefit-sharing,[1] a set of detailed, voluntary provisions to help implementing Articles 1, 10(c) 15, 16 and 19 and, to some extent, 8 (j).

Why should the EC implement the Bonn Guidelines?

The European Community (EC) and its Member States (MS) are all Parties to the CBD and are under a legally binding commitment to implement articles 1 and 15 of the CBD, including Article 15.7. The Bonn Guidelines are a voluntary instrument. However, the Plan of Implementation of the World Summit on Sustainable Development (paragraph 44(n) calls for the promotion of their wide implementation as an input to assist Parties to the CBD when developing and drafting legislative, administrative and policy measures on access and benefit-sharing as well as contracts and other arrangements. Moreover, the Commission and the Member States have been very active in the negotiations leading to the adoption of the Guidelines and are at the origin of most of their provisions. Furthermore, as mentioned above, this is also an issue of equity: the EC should take action because it is fair to do so.

Ultimately, if the EC implements the Guidelines, it will enhance their credibility and the willingness of other countries, international institutions, companies and research institutes all over the world (and not only in the EC) to implement them. This, in turn, will facilitate the achievement of the objective of sustainable development as the Guidelines clarify that the benefits arising from the use of genetic resources should be used to improve conservation and sustainable use of biodiversity. The issue of ABS is potentially a win-win situation for trade and environment since benefits arising from the commercial use of genetic resources can be used to foster the protection of biodiversity and since the expectation of such benefits is an incentive for conservation.

This Communication will briefly present the international context on ABS after the World Summit on Sustainable Development (WSSD) held in August 2002 as well as existing measures on ABS at EC level. On this basis, concrete actions for the implementation of the Bonn Guidelines in the EC will be proposed and the approach for EC action at the international level will be suggested. The actions proposed here do not aim at an exhaustive implementation of all aspects of the Guidelines as the latter are to be used as a flexible tool which can be adapted to the needs of the different CBD Parties and stakeholders when they develop ABS-related measures and arrangements. The EC activities on the implementation of the Bonn Guidelines are to be seen as complementary to actions envisaged by the Member States that should obviously be in accordance with EC and international law.

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[1] See Annex for the full text of the Guidelines in English [SEC(2003) aaaa]

2. THE WIDER INTERNATIONAL CONTEXT

Are other international fora relevant to this issue?

The area of ABS is complex and in evolution as it ranges from science to environment and agriculture, from trade to intellectual property instruments. Some specific aspects of the issue of access and benefit-sharing are under discussion in international fora other than the CBD.

In 2001, the **FAO** concluded the negotiations of the **International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA)**. The latter is the outcome of a long process aimed at bringing a voluntary instrument pre-dating the CBD, the International Undertaking on Plant Genetic Resources for Food and Agriculture, "in harmony" with the CBD by creating a new binding instrument. This new Treaty provides for a multilateral system for facilitated access to genetic resources for food and agriculture and for a mechanism to share the benefits arising from the use of the genetic resources which are part of the system. This agreement addresses genetic resources for food and agriculture. The above multilateral system is limited to crops listed in Annex I of the Treaty.

The CBD, including the voluntary Bonn Guidelines, continues to apply to all biological resources, including those for food and agriculture which are not listed in the International Treaty. The International Treaty and the CBD are complementary and it is expected that their respective Parties will implement them in a mutually supportive way. The EC and its Member States signed the IT-PGRFA and are preparing its ratification. The Treaty will enter into force 90 days after the deposit of the 40th instrument of ratification.

In the **World Intellectual Property Organisation (WIPO)**, the Inter-governmental Committee (IGC) on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore discusses, *inter alia*, intellectual property issues that arise in the context of (i) access to genetic resources and benefit-sharing; and (ii) the protection of traditional knowledge (TK), whether or not associated with those resources. It is expected that this Committee will, in particular, identify means and ways to protect TK by resorting to intellectual property or other *sui generis* rights.

In the framework of the **World Trade Organisation (WTO)**, the Doha Ministerial Declaration, adopted in 2001, instructed the Trade-related Intellectual Property Rights (TRIPs) Council, in pursuing its work program, including under the review of Article 27.3(b), to examine the relationship between the **TRIPS Agreement** and the Convention on Biological Diversity, the protection of traditional knowledge and folklore. The debate has so far focused on the issue of disclosing the origin of genetic resources used as the basis for inventions when applying for patents on these inventions.[2]

The **WSSD** called on States, in paragraph 44(o) of the Plan of Implementation, to "negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources." The General Assembly of the United Nations invited the COP of the CBD, in paragraph 8 of Resolution A/Res/57/269, "to

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[2] In October 2002, the EC submitted a "Concept paper" to the TRIPs Council on, *inter alia*, the relationship between the TRIPs Agreement and the CBD. See 'Communication by the EC and its Member States to the TRIPs Council on the review of Article 27.3 (b) of the TRIPs Agreement, and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore'.

take appropriate steps in this regard." Following the deliberations of the CBD inter-sessional meeting on the Multi-year Programme of Work (March 2002), it is now foreseen that the second meeting of the Ad hoc Open-ended Working Group of the CBD, in December 2003, will address the issue of "an international regime on access to genetic resources and benefit-sharing". This issue will also be debated at the seventh meeting of the CBD Conference of the Parties (COP7), in February 2004, in Malaysia.

Two Conventions under the **International Union for the Protection of New Varieties of Plants (UPOV)** - the 1978 and 1991 UPOV Conventions - provide for the protection of new varieties of plants by an intellectual property right. They are therefore relevant in the context of the discussion on access to genetic resources and sharing the benefits deriving from their use.

Finally, it is also worth recalling the special role of the **Consultative Group on International Agricultural Research (CGIAR)** in relation to genetic resources for food and agriculture. The CGIAR is an informal association of public and private donors that supports an international network of 16 international agricultural research centres. The network holds the world's largest *ex situ* collection of plant genetic resources for food and agriculture and the EU is its main sponsor. These resources are placed in trust for the world community and are deployed for the benefit of developing countries. The Bonn Guidelines are relevant for the CGIAR centres to guide them in their role of users and suppliers of genetic resources, including in helping preventing misappropriations of the materials transferred.

3. EC LEGISLATIVE AND POLICY MEASURES ON ABS

As early as 1995, the European Commission funded a study on potential measures to implement CBD Articles 15 and 16 (access to and transfer of technology), the results of which were circulated at CBD COP3[3]. The EC approach to ABS has since evolved through negotiations within a variety of multilateral fora, as well as through a range of measures by the Community, Member States and individual stakeholder groups.

The EC has not introduced comprehensive legislation governing ABS and related traditional knowledge. However, a number of EC policy and legislative measures directly address the CBD provisions on ABS and the traditional knowledge, innovations and practices of local and indigenous peoples.[4]

With respect to policy, the **1998 European Community Biodiversity Strategy**[5] notes the need for the Community to promote appropriate multilateral frameworks for ABS, to encourage the development of voluntary guidelines for ABS and to support countries of origin of genetic resources in developing national strategies on bio-prospecting. The **2001 EC Biodiversity Action Plan for Economic and Development Cooperation**[6] refers, *inter alia*, to the need to support capacity-building in developing countries, so as to enable them to share the benefits from the utilisation of genetic resources. The parallel **EC Biodiversity Action Plan for Agriculture** highlights the need for compensation to local farmers who are the

3 Environmental Resources Management, Identification of Community Measures for the Implementation of Articles 15 and 16 of the Convention on Biological Diversity: Final Report, Part B. June 1996.

4 See EC Thematic Report on Access and Benefit-sharing (http://biodiversity-chm.eea.eu.int/), submitted to the CBD Secretariat in October 2002, for a full account of EC measures in this area.

5 COM (1998) 42.

6 COM (2001) 162 final.

ultimate providers of genetic material for research and breeding activities. Hence the need to provide them with access to the enhanced material and to share the benefits arising from the enhancement in a participatory manner.

In relation to legal provision, **Directive 98/44/EC on the legal protection of biotechnological inventions**[7] specifically takes into consideration ABS. Recital 27 to the Directive encourages patent applications to include information on the geographical origin of biological material. This provision supports compliance with national legislation in the source country of biological material and with contractual arrangements governing the acquisition and use of that material. Alongside Recital 27, Recital 55 of the Directive requires Member States to give particular weight, *inter alia*, to CBD Article 8j, 16.2 and 16.5 when introducing law, regulations and administrative procedures to implement the Directive. However, recitals, as such, do not create legally binding obligations for the Member States.

A number of other EC legislative and policy measures contribute to the implementation of the CBD's provisions on benefit-sharing. These include regulations and directives on **geographical indications,** which offer some potential for the protection of products related to TK, and on **Community plant variety rights**. With regard to the latter, Regulation 2100/94, as it is the case for Directive 98/44, contains a derogation whereby small farmers do not have to pay any remuneration to the right-holders for the use of seeds harvested on their own holdings while other farmers are required to pay an "equitable" remuneration. EC regulations on the **conservation and characterisation of plant genetic resources for food and agriculture** are also relevant as well as measures in support of **research and technology transfer**.

4. EC STAKEHOLDERS' ACTIONS ON ABS

The EC's existing array of measures should be considered alongside other stakeholder[8] initiatives to develop policies and codes of conduct, complementary of both the CBD and national ABS legislation.[9] Several MS and the European Commission have held or planned to hold wide stakeholder consultation with a view to discuss the possible use of the Bonn Guidelines.

Scientific research institutions and in particular networks of *ex situ* collections in the EC have pioneered **institutional policies and Codes of Conduct** on ABS, to facilitate the acquisition and exchange of genetic resources in accordance with applicable national and international law. Such policies and codes of conduct form part of a package of measures (for which the Bonn Guidelines provide a coherent framework) to assist in the development and implementation of ABS arrangements. They constitute an effective measure to increase user transparency, while providing sufficient flexibility to respond to the circumstances of specific

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7 OJ L 213/13.

8 The category of actual or potential stakeholders in relation to ABS is certainly very wide and open-ended. Major groups that can be identified include: several industrial sectors such as the pharmaceutical, botanical medicine, biotechnology, seeds and cosmetic industry; the horticultural sector; universities and research institutes; gene banks; botanical gardens; indigenous peoples; NGOs in the environment and development field; etc.

9 See EC Thematic Report on Access and Benefit-sharing (http://biodiversity-chm.eea.eu.int/), submitted to the CBD Secretariat in October 2002, for a fuller account of EC stakeholder measures in this area.

research sectors and users of genetic resources. Important initiatives have been taken by European botanic gardens,[10] microbial culture collections and germplasm collections.

Some European pharmaceutical and biotechnology companies have developed **corporate policies** on ABS though, with declining interest in some natural products research, these may be of less importance to corporate strategy in the future. Other sectors, including horticulture and botanical medicines, continue to exert significant demand for genetic resources but do not seem to have developed comprehensive corporate or sector-based policies on ABS.

As with institutional policies and codes of conduct for research institutions and *ex situ* collections, corporate policies form part of a package of measures (for which the Bonn Guidelines provide a coherent framework) to assist in the development and implementation of ABS arrangements. They constitute measures which can increase user transparency and good corporate citizenship. Corporate policies on ABS can also contribute to the development of companies' R&D strategy, by helping to identify likely partner countries, main suppliers and collaborators and the monetary and non-monetary cost of partnership.

The EC supports the implementation of institutional policies and codes of conduct on ABS by stakeholder groups, including for *ex situ* collections. Specifically, the Commission supported the development of the **Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)**[11] by the Belgian Co-ordinated Collections of Micro-organisms (BCCM), together with 16 other organisations from around the world.

MOSAICC aims at facilitating access to microbial resources and at helping partners to develop practical agreements when transferring microbial resources. It answers the need for easy transfer of microbial resources and the need to monitor such transfer. Access to microbial resources is a pre-requisite for the advancement of microbiology while monitoring is necessary to identify individuals or groups that are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the microbial resources.

One of the basic principles of MOSAICC is **to identify the *in situ* origin of microbial resources** via the appropriate procedure providing authorization for sampling. The World Federation for Culture Collections (WFCC), the European Culture Collections Organisation (ECCO) and the Microbial Resources Centres Network (UNESCO-MIRCEN) support MOSAICC's goal of putting in place practical and universal procedures to implement ABS arrangements in accordance with international and national laws.

The Commission will finance a follow-up of the MOSAICC project aimed at providing validated reliable methods for the value assessment of microbial resources. Such methods are necessary to put a socially, economically and environmentally sound 'price' on genetic resources and therefore facilitate benefit-sharing. The project also aims to develop validated model documents to enable traceability of microbial resources (origin, transfer and transport).

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10 Important examples include the "Principles on access to genetic resources and benefit-sharing for participating institutions", developed under the auspices of the Royal Botanic Gardens, Kew, involving 28 botanic gardens from 21 countries <www.rbgkew.org.uk/conservation>; and the International Plant Exchange Network (IPEN <www.biologie.uni-ulm.de/verband/cbd/list.html>) and its Code of Conduct for botanic gardens and similar collections governing the acquisition, maintenance and supply of living plant material.

11 http://www.belspo.be/bccm/mosaicc

Finally, the Commission has supported **policy research on ABS**, including on the commercial demand for access to genetic resources.[12]

5. THE BONN GUIDELINES

What do they say?

As mentioned above, the Bonn Guidelines may serve as inputs when developing and drafting legislative, administrative or policy measures as well as contracts and other arrangements for ABS. They are a voluntary instrument intended to gain support of users and providers of genetic resources and TK. They are flexible in order to be used across a wide range of sectors, users and national circumstances and are intended to be reviewed and revised as experience is gained in access and benefit-sharing. They have a wide scope of application covering all genetic resources and associated TK, innovations and practices covered by the CBD and the benefits arising from their use. The Guidelines are conceived as a complementary instrument vis-à-vis existing international instruments in related areas such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.

The Guidelines aim, *inter alia*, at contributing to the conservation and sustainable use of biological diversity, at providing Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable benefit-sharing; at providing guidance to Parties in the development of access and benefit-sharing regimes; at informing the practices and approaches of users and providers in access and benefit-sharing arrangements.

The Guidelines identify roles and responsibilities of different actors in the ABS area. They call for the designation of **national ABS focal points** which should be listed on the CBD Biodiversity Clearing House (BCH) and should provide information to applicants for access to genetic resources on procedures for obtaining Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) as well as on competent national authorities, indigenous and local communities and relevant stakeholders. In addition, **competent national authorities** may be nominated to grant access and provide advice on the ABS process under national legislation.

The Guidelines recognise that Parties and stakeholders can be both users and providers of genetic resources and identify **roles and responsibilities** for Parties which are countries of origin of genetic resources, for **users and providers** and for Parties with users of genetic resources under their jurisdictions.

Countries of origin, or other Parties which have acquired the genetic resources in accordance with the Convention, are mainly called upon to control the conformity of their national legal framework with the CBD, to report on access application to the BCH, to develop participatory mechanisms for stakeholders and indigenous and local communities while ensuring that environmental consequences of access activities are taken into account by stakeholders. **Providers** are urged to only supply genetic resources and/or TK when they are entitled to do so and to avoid arbitrary access restrictions.

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12 ten Kate, K. and Laird S.; *The Commercial Use of Biodiversity* (1999) Earthscan, London. This study was sponsored by the European Commission

A comprehensive list of measures to be taken by **users** and by **countries with users under their jurisdiction** is also provided. These measures will be dealt with in some detail in the following paragraphs as they are primarily addressed to users located in developed countries. However, as developing countries increasingly become themselves users of genetic resources, these measures are relevant to them too.

The Guidelines also contain provisions emphasising the importance of **involvement and participation of stakeholders** in the development and implementation of ABS arrangements and set out the different steps in the ABS process: the basic principles and elements for a **prior informed consent** system; the basic requirement for and an indicative list of **mutually agreed terms**; the possible types of **benefits** and mechanisms to share them. An Appendix to the Guidelines also suggests elements for **Material Transfer Agreements** of genetic resources and related TK.

6. HOW TO IMPLEMENT THE BONN GUIDELINES: EC ACTION CONCERNING PROVIDER AND COUNTRY OF ORIGIN MEASURES

The MS of the EC are providers of *in situ* genetic resources and also hold important *ex situ* collections. In both cases, *in situ* and *ex situ*, access to genetic resources is regulated by a wide range of national laws. These include specific legal frameworks for access to genetic resources; indirect regulation of access through laws on land ownership; laws regulating conditions to access and exploit State-owned land and natural resources; the law of contracts; etc.

Indigenous peoples are represented within the borders of the EC in a few regions. Also in this case the issue of their traditional knowledge is addressed at the national level.[13]

Under Article 15.5 of the CBD, Parties can choose if they want to subject access to their own genetic resources to their prior informed consent. The need for actions at EC level aimed at harmonising MS' legislation on access to genetic resources or concerning stakeholders participation is not apparent and will have to be further assessed also on the basis of the experience gained with the implementation of the Bonn Guidelines. In principle, national access laws and participatory mechanisms are best suited to adapt to local realities and stakeholders' needs. An action at EC level in this area could be justified by the need to remove obstacles to the internal market in relation to genetic resources. However, the presence of such obstacles is not apparent at the moment and, in any event, the provisions of the EC Treaty, in particular Articles 28 and 30, would apply, should such obstacles arise.

7. HOW TO IMPLEMENT THE BONN GUIDELINES: EC ACTION TO FOSTER USER MEASURES

The EC can play an important role in fostering the use of the Bonn Guidelines by a wide range of stakeholders who make use of genetic resources. In the process leading to the adoption of this Communication, the European Commission held a stakeholder consultation with major European stakeholders groups' representatives to discuss the implementation of the Bonn Guidelines. The meeting showed that the level of awareness of the CBD and of the Bonn Guidelines varies considerably from one stakeholder group to the other. While a

[13] For instance, for Sami people, indigenous of Northern Sweden and Finland.

number of botanical gardens, agricultural and culture collections have been proactive, even anticipating the work of the CBD, in revising their policies in accordance with Article 15 of the Convention, the biotechnology and pharmaceutical industries are at an earlier stage in the revision of their policies in this area.

Paragraph 16 b) of the Bonn Guidelines highlights, inter alia, the following four types of actions users should undertake:

1 seek PIC to access genetic resources by respecting, in particular, indigenous people customs and values;

2. respect terms and conditions under which genetic resources were acquired, including on change of use of the resources;

3. keep documentary evidence of PIC, origin and use of and benefits arising from the genetic resources and provide these materials to third parties to whom genetic resources are supplied;

4. ensure the fair and equitable sharing of the benefits in conformity with mutually agreed terms.

In principle, users' responsibilities are defined in the mutually agreed terms under contractual agreements. The Bonn Guidelines (paragraphs 42-50) identify basic requirements for mutually agreed terms and an indicative list of them. Appendix I contains "Suggested Elements for Material Transfer Agreements". A Material Transfer Agreement (MTA) is the document which is normally used to record the obtainment of PIC and to include all terms and conditions under which the genetic resources were acquired. Copies of MTAs can be easily transmitted to third parties to which the genetic resources are supplied. This would help the traceability of the genetic resources and contribute to ensuring the fair and equitable sharing of the benefits.

The EC and its Member States are actively involved in the process aimed at developing a standard MTA in the framework of the Multilateral System of the IT-PGRFA and are at the origin of the above mentioned Appendix I of the Bonn Guidelines. The Commission strongly recommends that stakeholders - including companies, universities and other research institutions - make full use of **Material Transfer Agreements** as a tool to live up to their responsibilities as identified in the Guidelines. The Commission also encourages the development of standardised MTAs for different uses in different sectors.

Furthermore, the Commission stresses the importance of the development of stakeholders' **codes of conduct**, based on the Bonn Guidelines, as a means to adjust the Guidelines to the needs of different sectors dealing with genetic resources and to make the actions indicated under 16 b) above become stakeholders' common practice. In developing such codes of conduct, it will be important to engage in an active dialogues with partners in countries of origin in order to identify practices which ensure the maximum transparency in the collection of genetic resources and in subsequent transactions.

Para 16 d) of the Guidelines invites Parties with users within their jurisdiction to support compliance by users with the requirements in paragraph 16 b) above by taking, inter alia, the following actions:

1. informing users of their obligations;

2. encouraging the disclosure of the country of origin of the genetic resources in intellectual property rights applications;

3. preventing the use of genetic resources obtained without PIC;

4. co-operating to address infringements of ABS agreements;

5. setting up voluntary certification schemes for organisations abiding by ABS rules;

6. discouraging unfair trade practices.

The actions already taken or envisaged by the Commission in relation to each of these 6 points are presented below.

7.1. Informing users of their obligations and discouraging unfair trade practices

As indicated above, the EC has already in the past taken some initiatives aimed at informing users of their obligations under the CBD and at facilitating their fulfilment. For instance, the Commission has supported policy research on ABS, including on the commercial demand for access to genetic resources.[14]

One of the objectives of the above-mentioned stakeholder meeting organised by the Commission and of the present Communication is also to raise stakeholders' awareness of their obligations under the CBD. However, the Commission considers that this can be pursued further by envisaging the following measures:

– *The establishment of a European network of ABS focal points and/or Competent National Authorities - building on existing networks - which could be connected,* inter alia*, through the EC Biodiversity Clearing House Mechanism (EC-CHM). To date, most MS have appointed an ABS focal point. The constitution of an effective network among them –without attempting to harmonise the content and structure of such focal points-would not only help those who may want to access genetic resources held in the EC but also contribute to identify relevant stakeholders at national level and raise their awareness about the Bonn Guidelines.*

– *The creation of a specific section of the EC Biodiversity Clearing House Mechanism devoted to the issue of ABS. Such a section could contain the text of the Bonn Guidelines together with an explanation of their relevance to different European stakeholders' profiles. The EC-CHM could become an important channel to inform stakeholders on their rights and obligations internationally, including in relation to other international instruments such as the IT-PGRFA; in the EC, and in the MS. To this end, appropriate links with,* inter alia*, the CBD and MS' Biodiversity Clearing Houses could be provided.*

– *Publicising the EC-CHM website widely and writing to all relevant stakeholders groups encouraging them to register on the EC-CHM and to provide copies of their own policies, codes of conduct, guidelines, principles, case studies, MTAs examples, etc., related to ABS. The listing in a register on the BCH of companies/institutions*

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[14] See ten Kate, K. and Laird S.; *The Commercial Use of Biodiversity* (1999) Earthscan, London. This study was funded by the European Commission

which are users of genetic resources and the presentation of their policies could prove beneficial for both users and providers. It would provide them with potential new markets for genetic resources. It could give providers a more accurate idea of the type and amount of benefits, including technology transfers, that can realistically be obtained from the use of different types of genetic resources. It is often difficult to predict beforehand the benefits which could arise from genetic resources. Therefore, explanations provided by users on the EC CHM could avoid creating unrealistic expectations which in turn could hinder access. The register could also enhance the profile of users since the registration of a fully-fledged ABS policy in compliance with the CBD would be evidence of a good sense of corporate social responsibility.

– *The integration of the ABS issue as an item to be tackled by the multi-stakeholder forum created by the Commission Communication on Corporate Social Responsibility (CSR)*[15] *and which will report on its work to the Commission in 2004. CSR is a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis. By following internationally agreed guiding principles and standards, of which the Bonn Guidelines are an example, and including them in their environmental reporting activities, multinational enterprises can contribute to ensure that international trade functions in a more sustainable way.*

The contribution of CSR to sustainable development, in particular in developing countries, is one of the issues which the CSR Communication invited the multi-stakeholder forum to address and agree guiding principles on. The multi-stakeholder forum identified three main ways to promote transparency and convergence of CSR practices and instruments: 1) the exchange of experience and good practice at EU level; 2) bringing together existing initiatives in different sectors seeking to establish a common EU approach, and 3) identifying areas where additional action is needed. All of these three actions would be beneficial in dealing with the ABS issue. The latter could be the subject of theme-based round tables to which relevant stakeholders, experts and representatives of developing countries should be invited. This would not only raise stakeholders' awareness of their CBD-related obligations but also contribute to discouraging practices which are not in conformity with the CBD and the Bonn Guidelines including unfair trade practices.

7.2. Encouraging the disclosure of the country of origin in intellectual property rights applications

As mentioned above, The **EC Directive 98/44/EC on the legal protection of biotechnological inventions** specifically takes into consideration ABS. Recital 27 to the Directive encourages patent applications to include information on the geographical origin of biological material. This provision supports compliance with national legislation in the source country of biological material and with contractual arrangements governing the acquisition and use of that material. However, this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

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15 COM(2002) 347 final.

7.3. Preventing the use of genetic resources obtained without PIC: the possible role of disclosure requirements and of a certificate of origin.

Article 15.5 of the CBD provides that access to genetic resources shall be subject to the PIC of the Contracting party providing such resources, unless otherwise determined by that Party. Therefore, companies/institutions conducting bio-prospecting activities are expected to require the PIC of the provider countries. The latter are the best placed to enforce the PIC requirement on their territory. The Commission strongly encourages stakeholders from the EC to respect the prior informed consent requirements of provider countries. The respect of PIC will be facilitated if provider countries clearly identify who, under their legal order, is entitled to give prior informed consent.

A number of mechanisms are under discussion in different international fora which could be implemented by countries with users under their jurisdiction in order to help preventing the use of genetic resources obtained without PIC. Such mechanisms could be envisaged for the different phases of the ABS process: the access phase (in the field or from *ex situ* collections), the import of the genetic resources, the research and development phase, the application for intellectual property rights, the final product approval etc. International discussions in the CBD, in the TRIPs Council and in the WIPO IGC have focussed, in particular, on mechanisms related to intellectual property such as a disclosure requirement for patent applicants and on a certificate of origin for genetic resources and TK.

Existing disclosure requirements

The EC is conscious of the fact that the intellectual property system "plays a practical role in promoting the sharing of the benefits from access to genetic resources and associated TK".[16] Requirements that can entail the disclosure of origin of genetic resources and TK already exist under EC law and European intellectual property law. In line with established patent principles, three cases are provided for: the so-called enabling disclosure; the relevant prior art; and the identification of the true inventor(s).

In relation to the enabling disclosure, Article 13(1)(b) of the EC Directive 98/44/EC states that where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purpose of patent law unless the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited. Therefore, in case of resources which are rare or exotic, the disclosure of the country of origin may be necessary[17] in order to allow a person skilled in the art to reproduce the invention. This is not the case for resources that are readily available.

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16 WIPO Draft technical study on disclosure requirements related to genetic resources and traditional knowledge, document prepared by the secretariat for the 5th session of the Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO/GRTKF/IC/5/10, Annex I, 8.

17 There is no automatic link between the exotic origin of a genetic resource and the obligation to disclose its origin. One can imagine that, in some cases, a person skilled in the art can be able to reproduce an invention without indication of the source of origin of the genetic resource and only by using information contained in the application.

With regard to relevant prior art, the 'background art' that typically must be disclosed in patent applications may include references to traditional uses of the biological material and its properties in its country of origin. Rule 27(1)(b) of the European Patent Convention requires that the content of the description of the patent should indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and for the examination, and, preferably, cite the documents reflecting such art.

Concerning the identification of the true inventor, Article 81 of the European Patent Convention requires that "the European patent application shall designate the inventor. If the applicant is not the inventor or is not the sole inventor, the designation shall contain a statement indicating the origin of the right to the European patent". If a patent is granted for an invention which is substantially based on existing TK - of a kind which is itself inventive - belonging to a person or group of persons which are not identified as inventors, this could have substantial legal implications, such as invalidation or revocation of the patent. In other words, remedies are available under existing patent provisions to TK holders whose TK has been misappropriated.

Moreover, under EC law, a disclosure requirement is also foreseen under Regulation 2100/94 on Community Plant Variety Rights. Article 50 of the regulation requires applicants for a community plant variety right to state the geographic origin of the variety. However, this disclosure is limited to the variety and does not cover the parent material from which the new variety was developed.

It is apparent that the above-mentioned disclosure requirements may contribute to preventing the use of genetic resources or TK without PIC. However, in particular in the case of the enabling disclosure described above, it is clear that the disclosure of the country of origin of the genetic resources will not take place in all cases. The existing requirements under intellectual property law do not provide for an undertaking or evidence of PIC to be furnished.

Possible further disclosure requirements

In order to make intellectual property and biodiversity regimes mutually supportive, use could be made of the flexibility which already exists under intellectual property law. In the framework of the on-going discussion in the TRIPs Council on the relationship between the TRIPs Agreement and the CBD, the EC has agreed[18] to examine and discuss the possible introduction of a system, such as a self-standing disclosure requirement, that would allow Members to keep track, at global level, of all patent applications with regard to genetic resources for which they have granted access.

Therefore, the EC and its MS have already shown their willingness to contribute constructively to find a multilateral approach to the issue of disclosure. Multilateral action would be more effective as disclosure requirements would better achieve their purpose if implemented widely. Moreover, a multilateral solution would also create a level-playing field for all patent applicants. However, multilateral solutions often need a long time to be developed and are dependent on someone taking the lead.

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[18] Communication by the EC and its Member States to the TRIPs Council on the review of Article 27.3 (b) of the TRIPs Agreement, and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore.

In the context of the implementation of the Bonn Guidelines there is indeed a possibility for Parties to the CBD of introducing a disclosure requirement in their legal systems, unilaterally, independently from the setting up of an international system. The EC is a regional group of industrialised countries: action at EC level, while not being a substitute for a multilateral system, would have important practical effects as it would apply to a wide range of patent applicants. In this respect, a disclosure requirementwould be helpful. Provider countries would also know that a disclosure requirement would help them enforcing their national laws on prior informed consent. This could in fact comfort a policy of giving European companies better access.

Thus the Commission believes that there should be a debate over the possible unilateral development, under EC law, of **a self-standing obligation for patent applicants to disclose the origin of genetic resources**, along the line of what has been proposed in the above-mentioned Communication to the TRIPs Council. Therefore, the information to be provided by patent applicants would be limited to information on the geographic origin of genetic resources or TK used in the invention which they know or have reason to know. When the country of origin is not known, the patent applicants' obligation would be to indicate the research centre, gene bank or entity from which they acquired the resources.

Such a disclosure requirement could not be retroactive and could not act, *de facto* or *de jure*, as an additional formal or substantial patentability criterion. Legal consequences of the non-respect of the requirement would need to lie outside the ambit of patent law, such as for example in civil law (claims for compensation) or in administrative law (fee for refusal to submit information to the authorities or for submitting wrong information). Furthermore, the Commission intends to also look into the feasibility of a similar disclosure requirement in the context of plant variety rights.

Should a disclosure requirement be developed at EC level, this should not diminish the commitment of the EC to contribute constructively to finding multilateral solutions. The Commission believes that the EC and its MS should be ready to discuss, in the relevant international fora, the possibility of introducing under intellectual property law the same **disclosure requirement** presented above but **as a formal condition for patentability** and not only as a self-standing obligation. The consequences of the non-respect of such a formal requirement could lie both within and outside the patent law system. In relation to patent law, they could include the non-processing of the patent application until the patent applicant has provided the required declaration, and the invalidation or revocation of the patent if the incorrect declaration of the source is due to fraudulent intention. Outside patent law, they could give rise to distinct sanctions to be determined at national level as in the case of a self-standing obligation.

The formal disclosure requirement would not require patent offices to judge whether prior informed consent requirements have been complied with at the point of access. The latter could be a daunting task for patent offices, as it would entail the enforcement from their part of legal obligations established under another jurisdiction. Such a task would be more appropriately left to courts where the validity of a patent can be challenged. However, even if the failure to meet the disclosure requirement does not have immediate consequences during the patent examination (e.g. because the fraudulent behaviour is not discovered), still it could have major consequences when the patent is enforced.

A complementary measure that could make the disclosure requirement an even more effective incentive to comply with PIC would be the introduction of a simple notification procedure to be followed by patent offices. The latter, every time they receive a declaration disclosing the origin of genetic resources or TK, could notify this information to the Clearing-House Mechanism of the CBD. The information would therefore be available to all CBD Parties as well as to the general public. The introduction of such measure should not lead to an unnecessary administrative burden for the patent offices.

The two types of disclosure requirements described above would be a strong incentive to comply with the prior informed consent required under the law of the provider country. In the case of a formal disclosure requirement, whose consequences would also lie within patent law, it will be necessary to clarify whether it could be accommodated within the existing rules of the TRIPs Agreement, the Patent Co-operation Treaty (PCT) and of the Patent Law Treaty (PLT).[19]

The certificate of origin

Another means to help preventing the use of genetic resources and TK without the PIC of their provider could be a certificate of origin. The latter is not only relevant in the field of intellectual property but in relation to the whole chain of the ABS process: it could accompany the genetic resources from the collection phase until the marketing of the product which makes use of them. However, an entry point for checking that PIC has been provided is constituted by the possibility of requiring patent applicants to present a certificate of origin when they apply for a patent on an invention which makes use of genetic resources or TK. In this way, they would not only disclose the origin of genetic resources and TK, as proposed above, but also provide evidence of the fact that they were lawfully acquired.

CBD Decision VI/24 C 3 f) recognises the need for further information gathering and analysis on a range of issues including the "feasibility of an internationally recognised certificate of origin system as evidence of prior informed consent and mutually agreed terms". National access laws in the different countries Parties to the CBD vary widely where they exist at all. The same applies to the requirements that access applicants have to fulfil. Therefore, at present, there is no single document which could be used in all Parties to the CBD in order to provide evidence of PIC. In some cases, such document would be a MTA, in some others an authorisation provided by a public authority or a concession or a licence, etc.

If a requirement to submit documentary evidence of PIC for patent applicants were to be introduced, it would be facilitated by a clear, simple and harmonised system for certifying access such as a standard MTA. However, genetic resources and their uses can be very

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[19] The Patent Co-operation Treaty (PCT) determines the standards that apply to form and content of international patent applications. Rule 51 *bis* of the PCT provides (under (i)(a)) that "the national law applicable by the designated Office may require the applicant to furnish, in particular: (i) any document relating to the identity of the inventor, (ii) any document relating to the applicant's entitlement to apply for or be granted a patent". Article 30 of the PCT, on the confidential nature of the international application, prohibits national offices to allow access to the international application by third parties before certain dates determined therein, unless requested or authorised by the applicant. In addition, Article 6 of the Patent Law Treaty (PLT) states that no Contracting Party shall require compliance with any requirement relating to the form and contents of an application different from or additional to those contained in the PCT (Article 6.1 i) and ii)) or those prescribed in the implementing regulations of the PLT (Art. 6.1 iii)). Article 10 of the PLT is also relevant since it addresses the consequences of non-compliance with formal requirements for patent applications. Non-compliance may not be a ground for revocation or invalidation of a patent except when it occurred as a result of fraudulent intention.

diverse, and it is not realistic to develop a 'one fits all' MTA. It will be necessary to let stakeholders enjoy sufficient flexibility in order to adjust an MTA on a case by case basis.

Therefore, the Commission considers that the EC and its MS should be open to further discuss in the CBD framework the development of such a certificate of origin. However, whatever the outcome of these discussions, the EC stresses the fact that if a requirement for patent applicants to provide documentary evidence of PIC were to be introduced, it should be limited to a transparency obligation. In other words, it shall not be for patent offices to examine the substantive aspects of the document: they would limit their control to the provision of evidence of PIC. Courts would do a substantive assessment of these documents in case litigation arose. Moreover, it will be necessary to analyse whether and how such certificate of origin could be accommodated within the existing body of international intellectual property law[20].

7.4. Co-operating with CBD Parties to address infringements of ABS agreements

Addressing infringement of ABS agreements often involves a 'choice of law', i.e. determining what is the applicable law and the competent forum. These issues are in principle settled at the moment in which PIC is provided for access. For instance, MTAs should contain, as suggested by the Bonn Guidelines, provisions on the choice of law and on dispute settlement. If this is not the case, criteria exist under private international law to determine the applicable law and forum.

However, problems can arise even when it is clear what are the applicable law and the appropriate forum. In some cases, even when the law and jurisdiction of the provider country are established (e.g. by national law or by contract), it might be difficult to enforce a judgement establishing the violation of national law by a foreign company when the latter has no assets in the provider country. On the other hand, when the competent forum is that of the user, courts will be called upon to enforce within their jurisdiction foreign laws.

These examples show that enforcement problems in relation to ABS national laws and agreements can well arise. Possibilities to prevent these situations need to be further studied on the basis of experience gained under international law in the enforcement of foreign judgements and in the intellectual property field in relation to the issue of entitlement to apply for or be granted a patent.

One alternative dispute resolution system that could help addressing these problems is arbitration. For instance, it could prove helpful, under the terms of an MTA, for parties to agree to submit their disputes to a specific arbitration system available under international law whose decisions would be enforceable in a great number of States. Arbitration procedures are normally faster and less expensive than court proceedings and could therefore prove more attractive than court proceedings.

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[20] In particular, Article 6.6 of the PLT should be taken into account. Under this provision, a Contracting Party may require that evidence in respect of any matter referred to in Article 6 paragraph (1) or (2) (form and contents of an application, and request form) or in a declaration of priority, be filed with its Office in the course of the processing of the application only where that Office may reasonably doubt the veracity of that matter.

Another problem that could arise in relation to ABS disputes concerns the possibility for providers to obtain information and access to justice in the countries where the users are located. In this respect, countries' ABS focal point could play a facilitator role by providing information, including on the legal system of their country. Moreover, controversies between providers and users located in different countries could be presented to the CBD Conference of the Parties and mediated by national authorities.

7.5. Developing voluntary certification schemes

In relation to the possibility of developing voluntary certification schemes for organisations abiding by ABS rules, the EC Eco-Management and Audit Scheme (EMAS) offers an interesting potential.[21] EMAS is a voluntary scheme for organisations willing to commit themselves to evaluate and improve their environmental performance. It is open to any organisation in the public and in the private sector in the EU, in the European Economic Area, and in accession countries (on a provisional basis). The use of a voluntary certification scheme is not to be read as a dilution of users' obligations under the CBD. Such a scheme would serve the purpose of helping users to improve their overall environmental performance, including in relation to ABS but would not alter their legal obligations.

Under EMAS, 'significant environmental aspects' arising from activities, products and services over which an organisation has management control or influence are to be identified in accordance with Annex VI. The latter requires organisations to consider both direct and indirect environmental impacts and mentions among the former 'use of natural resources and raw materials' and 'effects on biodiversity'. Significant environmental aspects are at the centre of an organisation's management system and of the evaluation and improvement of its environmental performance by setting objectives and targets. They are also relevant within the environmental statement that organisations have to prepare in accordance with Annex III.

The Commission has developed Guidance on the identification of the environmental impacts and assessment of their significance.[22] Companies and/or institutions dealing with genetic resources and related TK and wishing to register for EMAS should identify significant direct and indirect impacts of their activities on the conservation and sustainable use of genetic resources and related TK.

Therefore, the principles contained in the Bonn Guidelines could be incorporated in organisations' environmental policies and environmental management system to be developed under EMAS and could then be reflected in their environmental statement. The independent environmental verifiers accredited under EMAS would control the reliability, credibility and correctness of the data and information in the environmental statement. The Commission could raise the awareness of national bodies competent for the registration of organisations under EMAS with regard to the CBD requirements to be fulfilled by companies dealing with genetic resources.

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[21] Regulation (EC) No 761/2001 of the European Parliament and of the Council of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), OJ L 114/1.

[22] Commission Recommendation No 2001/680/EC of 7 September 2001 on guidance for the implementation of Regulation (EC) No 761/2001 of the European Parliament and of the Council allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), OJ L 247/1.

The application of EMAS to the ABS field could also contribute positively to the on-going debate in the CBD, on the setting up of an international certification system for genetic resources. It could provide arguments in favour of using the international standard ISO 14001:1996, in particular for organisations outside the EU, if this standard was enhanced by a number of important additional elements.

The EMAS Regulation contains ISO 14001 as its basic management system in its Annex 1-A and goes beyond ISO in relation to public transparency, credibility and environmental performance. These EMAS features concern, *inter alia*: (i) the environmental statement of EMAS, (ii) a public register of participating organisations in each country, (iii) legal compliance with other (national) environmental legislation and (iv) the obligation to improve the environmental performance of the organisation instead of improving the management system. An ISO 14001 that would include these elements would help to achieve CBD objectives outside the EU whereas EMAS would be used within the EU. Another option would be to extend EMAS to other countries and world regions. The Commission is presently investigating whether and how this can be achieved.

8. EC DEVELOPMENT AND RESEARCH POLICIES

Another avenue that the Commission will pursue in order to implement the Bonn Guidelines in the Community and to foster their implementation in third countries is their integration into the EC development and research policies.

With regard to development policy, the Commission will examine means to incorporate into its standard contracts for economic/development co-operation the basic principles of the Bonn Guidelines when such contracts involve the use of genetic resources and/or traditional knowledge.

Moreover, the Commission has already taken some policy initiatives in the area of ABS and development which have the potential of contributing to the implementation of the Bonn Guidelines in developing countries.

In the **Biodiversity Action Plan for Economic and Development Co-operation,**[23] aimed at integrating biodiversity into development co-operation projects and programmes - including through support to NBSAPs - section 3.4 addresses the 'Equitable Sharing of the Costs and Benefits from Biodiversity Use'.

To link the CBD's objective of equitable benefit-sharing with the international development target on poverty, the Action Plan goes beyond the CBD's wording by incorporating costs as well as benefits, and ecosystem and species levels of biodiversity in addition to genetic resources. Actions 11 and 12 specify support for, amongst others, national capacity-building in defining biodiversity-related intellectual property rights and formulating laws enabling equitable benefit-sharing, as well as the development of participatory frameworks for and capacity building of community-based organisations and NGOs in negotiating equitable benefit-sharing. Action 13 supports improvements of legal frameworks to give more secure ownership of, and access to, land and natural resources for local people.

The Commission is presently assessing the implementation of this Action Plan and a report is planned for mid-2004.

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[23] COM(2001) 162 final.

Furthermore, in 2002 the Commission adopted the **Communication on Life Science and Biotechnology. A Strategy for Europe.**[24] The latter contains an Action Plan which specifically addresses the issue of access and benefit-sharing in its Action 26 which provides the following:

"The Commission and the Member States will support the **conservation and sustainable use of genetic resources** in developing countries and their **equitable sharing of benefits arising** from their use by:

a) supporting the development and enforcement of effective **measures to conserve, to use sustainably and to provide access to genetic resources and traditional knowledge**, as well as to share equitably the benefit arising from them, including income generated by intellectual property protection. Support for local communities is vital to **conserve indigenous knowledge and genetic resources**.

b) supporting the **participation of delegates from developing countries in the negotiations of relevant International Conventions**.

c) supporting measures to **promote greater regional co-ordination** in legislation to minimize disparities in access, benefits and also trade in products derived from genetic resources, in accordance with international commitments".

In the field of research, under the **Sixth Framework Programme for Research and Technological Development** (2000-2006), the EC supports research and technological development related to genetic resources, including actions supporting the implementation of the above-mentioned Action Plan on Life Science and Biotechnology.

According to the decision 1513/2002/EC of the European Parliament and the Council[25] research activities carried out within the Sixth Framework Programme have, where relevant, to respect international conventions and codes of conduct, as well as EU and national legislation. Therefore, the CBD and the Bonn Guidelines are among the references to be taken into account by applicants when submitting research proposals for funding under priority 5 - Food quality and safety.

The full implementation of the above mentioned actions in the field of development and research policy, will contribute to the response from the EC to the capacity building needs identified by the CBD Draft Action Plan on Capacity Building for Access to Genetic Resources and Benefit-sharing.[26] The latter identified, *inter alia*, as key areas requiring capacity-building: the development of ABS policy, legislative and regulatory frameworks; the strengthening of participation to decision-making and of negotiation skills; the clarification of rights and claims of indigenous and local communities; the support to indigenous and local communities to assess, inventor and monitor genetic resources and TK; regional and sub-regional collaborative arrangements. It will be particularly important to help developing countries to designate institutions which serve as focal point and/or Competent National

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24 COM(2002) 27 final.

25 Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006)

26 Available on http://www.biodiv.org/doc/meeting.asp?wg=ABSWSCB-01

Authority to ensure more co-ordinated, timely and cost-effective implementation of ABS measures.

Finally, in response to the Council Conclusions on indigenous peoples of December 2002,[27] the European Commission is committed to mainstream indigenous peoples issues into the EC policies involving, where relevant, indigenous peoples at all stages of EC-funded projects' cycle. The Commission will select a number of pilot countries with EC-funded development programmes in order to develop more concrete ways to include indigenous peoples as a part of civil society in all phases of the project cycle through partnership, co-operation and consultation. Efforts will be made to promote capacity building of organisations representing indigenous peoples, including in relation to protection of their traditional knowledge and the implementation of the Bonn Guidelines.

9. EC ACTION IN INTERNATIONAL FORA

The EC has stated on several occasion its commitment to further developing a transparent international regime on access and benefit-sharing. The implementation of the Bonn Guidelines and, in turn, the achievement of the ABS objective of the CBD depends not only on single Parties' initiatives as those discussed in this Communication but also on further efforts of the international community in a number of international fora.

The latter include the FAO IT-PGRFA, WIPO, the TRIPs Council, and UPOV. The EC and its Member States already play an active role in the development of a standard MTA in the context of the IT-PGRFA and in the full implementation of this agreement. In the context of WIPO, the EC should provide further support to *sui generis* systems for the protection of TK and to measures in the field of intellectual property which can contribute to track compliance with PIC as those described above. The EC should defend this position also in the TRIPs Council discussions on the relationship between this agreement and the CBD as well as under the UPOV Convention.

[27] Council Doc. 13466/02.