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SECOND REPORT OF THE EUROPEAN COMMUNITY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

THEMATIC REPORT ON ACCESS AND BENEFIT-SHARING

LIST OF ACRONYMS

ABS – Access to genetic resources and benefit-sharing
ACP – African, Caribbean and Pacific states
CEC – Commission of the European Communities
CGIAR – Consultative Group on International Agricultural Research
CHM – CBD Clearing House Mechanism
COP – Conference of Parties
EBRCN – European Biological Resource Centres Network
EC – the European Community as a party to the CBD alongside the EU Member States
EU – the European Union
EPC – European Patent Convention
EPO – European Patent Office
IPRs – Intellectual Property Rights
IT – FAO International Treaty on Plant Genetic Resources for Food and Agriculture
MATs – Mutually agreed terms
MOSAICC – Micro-organisms Sustainable Use and Access Regulation International Code of Conduct
MTA – Material Transfer Agreement
NBSAP – National Biodiversity Strategy and Action Plan
PIC – Prior informed consent
PGRFA – Plant genetic resources for food and agriculture
TRIPs – WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD – United Nations Conference on Trade and Development
UPOV – The International Union for the Protection of New Varieties of Plants
WIPO – World Intellectual Property Organisation
WTO – World Trade Organisation

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EXECUTIVE SUMMARY

(i) Scope and mandate of this report

The Convention on Biological Diversity (CBD) provides a legal framework for the acquisition and use of genetic resources and the traditional knowledge, innovations and practices of local and indigenous peoples relevant for the conservation and sustainable use of biological diversity. Upwards of 50 countries around the world have introduced or are developing legal, administrative and policy measures to implement this framework.

This report responds to Decisions V/19.8 and VI/24 F of the CBD Conference of Parties (COP), requesting Parties to submit information on measures and arrangements to implement the Convention's provisions on access to genetic resources and benefit-sharing (ABS), and on the associated role of intellectual property rights (IPRs).

Europe is an important user of genetic resources from around the world, as well as a provider. The European Union (EU) possesses significant *ex situ* collections, and commercial demand for access to genetic resources spans a wide range of sectors including pharmaceuticals, biotechnology, botanical medicines and cosmetics.

The report describes how the European Community's approach to ABS has evolved through negotiations within a variety of multilateral fora, legal, administrative and policy measures taken by the Community, as well as actions by stakeholder groups.

The present report should be read in conjunction with EU Member State's own thematic reports to the CBD on benefit-sharing. Whereas the EC's existing involvement with ABS relates to the internal market (e.g. aspects of IPRs), bilateral and multilateral negotiations, trade, international development co-operation and support to stakeholder initiatives, the EU Member States retain sovereign control over access to their genetic resources. As parties to the CBD, some have introduced measures to this effect – principally administrative and policy measures, including the designation of ABS focal points. Access to genetic resources in EU Member States is otherwise subject to a range of other laws whose prime objectives relate to property, trespass, statutory protection of species, and site protection.

(ii) European Community (EC) involvement with ABS at the multilateral level

The EC has contributed to the negotiation of multilateral instruments and guidelines on ABS, specifically: the **CBD Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilisation**; and the **FAO International Treaty on Plant Genetic Resources for Food and Agriculture**. International agreement in 2002 on both these instruments paves the way for the EC and the EU Member States to develop concrete measures on ABS over the coming years.

The EC also contributes to deliberations in other international fora over the links between benefit-sharing and IPRs. These include the **WIPO**[1] **Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore**, the **WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the OECD and UPOV**. During 2001 and 2002 the Community, together with the EU Member States, formally submitted its views on aspects of these issues to the CBD Secretariat and to the TRIPs Council.

(iii) EC legislative and policy measures on ABS

A small number of EC legislative and policy measures directly address the CBD's provisions on ABS and the traditional knowledge, innovations and practices of local and indigenous peoples.

With respect to policy, the **1998 European Community Biodiversity Strategy** 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 bioprospecting. The **2001 EC Biodiversity Action Plan for Economic and Development Cooperation** refers to the need to support capacity-building in developing countries, so as to enable them to share the benefits from utilisation of genetic resources. The parallel **EC Biodiversity Action Plan for Agriculture** highlights access to enhanced material by the original providers of genetic resources.

The EC has yet to introduce comprehensive legislation governing ABS and related traditional knowledge. **Directive 98/44/EC (6 July 1998) on the legal protection of biotechnological innovations** 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 seeks to support compliance with national legislation in the source country of biological material and with any contractual arrangements governing the acquisition and use of that material.

(iv) Other relevant EC legislation and policy

A number of other EC legislative and policy measures could contribute to the implementation of the CBD's provisions on benefit-sharing. These include regulations and directives on **geographical indications** and **community plant variety rights**, as well as on the **conservation and characterisation of plant genetic resources for food and agricultural (PGRFA)**. Measures in support of **research and technology transfer** may also be relevant.

(v) EC support for stakeholder actions on ABS

[1] World Intellectual Property Organisation.

The EC also supports the implementation of institutional policies and codes of conduct on ABS by stakeholder groups, including for *ex situ* collections. Specifically, the EC supported the development of the **Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)** by the Belgian Co-ordinated Collections of Micro-organisms (BCCM), together with 16 other organisations from around the world. In addition, the EC has supported a small amount of policy research on ABS, including on the commercial demand for access to genetic resources.

(vi) Parallel stakeholder measures on ABS

The EC's existing array of measures should be considered alongside other stakeholder initiatives to develop policies and codes of conduct, complementary of both the CBD and national ABS legislation. Such 'user' measures have been pioneered by botanic gardens, culture collections, as well as pharmaceutical and biotechnology companies.

(vii) Next steps

The EC's commitment to implementation of the Bonn Guidelines and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture calls for a review of existing Community, Member State and stakeholder measures – including gaps and opportunities. Such a review would provide the basis for an integrated EU approach to ABS, as both a provider and significant user of genetic resources and associated traditional knowledge.

1. INTRODUCTION

This report maps progress by the EC in implementing the CBD's provisions governing access to genetic resources and the fair and equitable sharing of benefits arising from their use (ABS). The report also examines measures to encourage benefit-sharing arising from the utilisation of the knowledge, innovations and practices of indigenous and local communities. This includes evolving Community policy on the links between intellectual property rights (IPRs) and benefit-sharing.

Europe is historically an important user of genetic resources in both research and product development, as well as a provider of such resources. Europe is home to a large number of *ex situ* collections, including microbial culture collections and botanic gardens. Many of these collections play a significant role in research and technology transfer for the conservation and sustainable use of genetic resources. Some have pioneered institutional policies to facilitate the legal acquisition, use and transfer of genetic resources in line with the CBD and applicable national laws – both as individual institutions and as members of broader networks that exchange material amongst themselves.

Commercial demand for access to genetic resources spans a wide range of sectors including the seed industry, horticulture, crop protection, pharmaceuticals, biotechnology, natural personal care and cosmetics. The level of demand within the EU across each of these 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. Excluding traditional pharmaceutical and biochemical companies, European entrepreneurial life sciences industry generated revenues of EUR 8679 million in 2001 alone.[2]

The EC therefore believes that work on access to genetic resources and benefit-sharing (ABS) has important implications for, and should contribute to, the conservation and sustainable use of biodiversity. As early as 1995, the EC commissioned a study of potential measures to implement CBD Articles 15 and 16, the results of which were circulated at CBD COP3[3]. The EC's approach to ABS has since evolved through negotiations within a variety of multilateral fora, as well as through a range of legal, policy and administrative measures by the Community, Member States and individual stakeholder groups.

[2] Ernst & Young (2001) *Eighth Annual European Life Sciences Report*.

[3] Environmental Resources Management, *Identification of Community Measures for the Implementation of Articles 15 and 16 of the Convention on Biological Diversity: Draft Final Report*, Part B. June 1996. Prepared for CEC DG XI.

2. SCOPE, MANDATE AND PREPARATION OF THE REPORT

This report responds to:

(i) Decision V/19.8 of the 5th meeting of the CBD Conference of Parties (COP5), inviting Parties to submit to the Executive Secretary of the Convention reports on benefit-sharing for consideration at COP6.

(ii) Decision VI/24F on Information Relating to ABS Arrangements, requesting Parties to make available to the Executive Secretary information on measures adopted to implement ABS, as well as case studies on implementation of ABS arrangements.

Pursuant to Decision V/19.8, the Executive Secretary to the Convention disseminated Guidelines for Detailed Thematic Reports on Benefit-Sharing. The guidelines list questions relating to matters identified by the CBD Panel of Experts on Access and Benefit-Sharing. These request the **views** of parties on the links between intellectual property, traditional knowledge and genetic resources.

As stated by the Declaration of Competencies annexed to the EC decision to ratify the CBD the EC is competent *alongside* the EU Member States with respect to implementation of the Convention[4]. The questions posed in the Executive Secretary's Guidelines are the subject of ongoing and evolving discussion amongst the Community's institutions and Member States, as well as with the private sector, research institutions and civil society. These discussions are influenced in turn by developments at the international level.

Therefore, while the report takes into account the Executive Secretary's Guidelines, it does not attempt to present the specific views of the Community or the European Union (the EC together with its Member States) in response to the listed questions. Instead, the report describes how the Community's involvement, expertise and experience on ABS and IPRs is evolving through legal, administrative and policy measures adopted by the Community itself, its Member States and stakeholder groups, as well as through intergovernmental processes.

The report was prepared in consultation with Member States' CBD and ABS focal points, as well as stakeholder groups including *ex situ* collections and companies. Consultations were undertaken through telephone interviews and email correspondence.

[4] In accordance with the Treaty of Rome establishing the European Economic Community.

3. EC LEGAL AND POLICY MEASURES ON ACCESS AND BENEFIT-SHARING

In 1995, the EC commissioned a study[5] of potential measures to implement CBD Articles 15 and 16. This highlighted 3 areas for potential EU action:

(i) promoting multilaterally coordinated implementation of CBD Articles 15 and 16 in appropriate international fora;

(ii) providing financial and technical support to capacity building and technology transfer initiatives, as well as awareness raising and education; and,

(iii) amending or developing Community legal instruments.

Recommended measures for EC and Member State action included support for voluntary codes of conduct and contractual guidelines for ABS, *sui generis* systems, certificates of origin, fair trade labelling, technology transfer, as well as information exchange, training and education. Subsequent legal, policy and administrative measures by the EC are described below.

Only a handful of EC legal and policy instruments take specific account of the CBD's provisions on ABS and traditional knowledge. However, a number of related measures have the potential to complement their implementation. It is understood that the EC plans to examine these in order to operationalise the recently adopted Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilisation (CBD Decision VI/24A).

3.1 EC Policy Measures

3.1.1. Policy measures on the conservation and sustainable use of biodiversity

Two sets of policy instruments take account of ABS within the context of the CBD: the EC Biodiversity Strategy and subsequent Action Plans; and the Guiding Principles and Strategic Approach to Biodiversity in Development. These are described below.

The **European Community Biodiversity Strategy** was adopted in 1998 (COM(98)042) as an element of the 5th Environmental Action Programme "Towards Sustainability". Its second strategic theme specifically addresses ABS and sets out three recommendations.

[5] Environmental Resources Management, *Identification of Community Measures for the Implementation of Articles 15 and 16 of the Convention on Biological Diversity: Draft Final Report*, Part B. June 1996. Prepared for CEC DG XI.

First, the Strategy recommends that the Community should promote appropriate multilateral frameworks for ABS. The EC responds to this through its commitment to negotiating, and now ratifying and implementing, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the Bonn Guidelines on ABS (as adopted by Decision VI/24).

Second, the Strategy recommends that the EC should promote guidelines for bilateral co-operation on a voluntary basis, especially where only some countries have or need access to genetic resources in question. The EC has worked to achieve this through its support for the development of institutional policies and codes and conduct on ABS, including the MOSAICC initiative for microbial collections (see Section 5.1, Box 2).

Third, the Strategy recommends support to countries of origin of genetic resources to develop national strategies on bioprospecting and access, taking into account relevant multilateral frameworks and instruments. This complements provisions of the Bonn Guidelines on ABS (Decision VI/24) relating to the development of overall ABS strategies which may form a component of National Biodiversity Strategies and Action Plans (NBSAP). It also supports CBD COP6 discussion of Draft Elements for an Action Plan for Capacity-Building (Annex to the Bonn Guidelines), which suggests integration of capacity-building for ABS within the framework of NBSAPs and related initiatives and strategies.

The EC Biodiversity Strategy called for a number of action plans to integrate biodiversity into the ongoing work of other sectors. The **EC Biodiversity Action Plan for Economic and Development Cooperation** was adopted in March 2002. This aims to address institutional capacity constraints within the European Commission, integrate biodiversity into development cooperation projects and programmes (including through support to NBSAPs) and to promote EC/EU coordination, e.g. through support to the Tropical Biodiversity Advisers Group (TBAG) (see below). Section 3.4 of the Action Plan 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 10 through 14 specify support for, amongst others, national capacity-building in defining biodiversity-related IPRs and formulating laws enabling equitable benefit-sharing, as well as capacity building of community-based organisations and NGOs in negotiating equitable benefit-sharing.

The **EC Biodiversity Action Plan for Agriculture** (section 4.5.2) also addresses benefit-sharing, recognising that the main centres of agricultural biodiversity are in developing countries. It highlights compensation to local farmers who are the ultimate providers of this material, including access to enhanced material, and sharing of benefits arising from enhancement. It stresses the interlinkage with the benefit-sharing provisions of the Action Plan for Economic and Development Co-operation.

The **Guiding Principles and Strategic Approach to Biodiversity in Development** were developed by the Biodiversity in Development Project BDP (a partnership between the European Commission, DFID and IUCN), with the involvement and guidance of the EU Tropical Biodiversity Advisers' Group (TBAG). EC policy advisers and task managers and developing country representatives were also consulted. Consistent with the Biodiversity Action Plan for Economic and Development Cooperation, Principle B of the Guiding Principles promotes the fair and equitable sharing of the costs and benefits from biodiversity conservation and sustainable use (including at ecosystem and species levels), nationally, regionally and internationally. This is broken down into three components: support to income-generating activities that encourage the sustainable use; positive incentives for conservation and sustainable use; and international, long-term funding mechanisms for effective programmes and projects. The Guiding Principles and Strategic Approach do not have the status of official documents but are used by the Commission and Member State development co-operation agencies to increase coherence over biodiversity issues.

3.1.2. Policy measures on research and technology transfer

The EC Declaration Ratifying the Biodiversity Convention highlights technology transfer and access to biotechnology in accordance with CBD Article 16 and in compliance with IPRs. The Declaration also states that the Commission and its Member States will encourage the use of the Convention's financial mechanism to promote the voluntary transfer of IPRs held by European operators. This includes granting of licences through normal commercial mechanisms and decisions, while also ensuring adequate and effective protection of property rights. No other EC policy measure specifically addresses research and technology transfer under the CBD. There are, however, some of potential relevance.

The **Innovation and SME**[6] **Programme** funded under the 5th Researh and Technology Development Framework Programme (1998 – 2002)[7] could in theory support joint research under an ABS agreements. The Programme aims to create an innovation friendly environment in Europe by encouraging information exchange on research and technology, and establishing links between research and innovation financing, including through the Community Research and Development Information Service (CORDIS)[8].

The **Partnership Agreement between the Members of the African, Caribbean and Pacific (ACP) States and the European Community and its Member States (Cotonou Agreement)**, could also enable technology transfer under ABS partnerships between EU institutions and countries that provide genetic resources and related

[6] Small and medium-sized enterprise
[7] <www.cordis.lu/innovation-smes/home.html>
[8] <www.cordis.lu/>

traditional knowledge. The **Compendium on Co-operation Strategies**[9] provides for scientific, technical and research co-operation[10].

Specifically, the Co-operation Strategy[11] aims to support:
(a) the development and implementation of R&D projects and programmes established by ACP States;
(b) activities aimed at consolidation of appropriate indigenous technology and the acquisition and adaptation of relevant foreign technology;
(c) scientific and technical co-operation between ACP States themselves and between ACP States and other developing countries and the EU; as well as
(d) the design of policies, incentive structures and institutions that enable the development of innovative capacity and competitiveness.

The Co-operation Strategy also specifies that ACP/EC collaboration shall continue to stimulate partnerships between both users and generators of knowledge, based on a step by step refined analysis of existing research capacities and needs. The Strategy highlights development of ACP capacity to manage science and technology for sustainable economic and social development, and for protecting and conserving the environment and natural resources. This includes the development of the infrastructure, skills and knowledge base necessary for ACP States to acquire, adapt and generate environmentally sound technologies.[12]

Sectoral agreements on environment and natural resources are also developed in bilateral or regional agreements of the EU with third countries, for instance in the EU-Mexico agreement.

3.2 EC Legislation

3.2.1. Legislation relating to IPRs and traditional knowledge

Directive 98/44/EC (6 July 1998) on the legal protection of biotechnological innovations is the only EC legal instrument that specifically takes into consideration the CBD's provisions on ABS, encouraging recognition of the geographical origin of biological material used in biotechnological inventions on patent applications. The Directive harmonises and clarifies existing national legislation, and was introduced to improve patent protection for biotechnological innovations in an attempt to enhance the competitiveness of EU's biotechnology industry.[13]

[9] The compendium of texts on co-operation strategies provides a detailed reference as regards objectives, policy orientations and operational guidelines in specific areas or sectors of co-operation, as provided for in article 20(3) of the ACP-EC Partnership Agreement.
[10] Compendium Section 3.2, Articles 97 – 105.
[11] Compendium Section 3.2, Article 102(a) – (d).
[12] Compendium Section 3.2, Article 105(a).
[13] <europa.eu.int/comm/dg15/eu/intprop/indprop>

Recital 27 of the Directive 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 of such material, if known.*…. It is therefore a possible contribution to tracking compliance with prior informed consent (PIC) and mutually agreed terms (MATs) on which access to the resources was granted.

Alongside Recital 27, Recital 55 of the Directive requires Member States to give weight to CBD Article 8j when introducing law, regulations and administrative procedures to implement the Directive. Recital 56 takes note of COP Decision III/17, calling for further work on the links between IPRs, the TRIPs Agreement and relevant CBD provisions relating to technology transfer, the conservation and sustainable use of biodiversity and the equitable sharing of benefits arising out of the use of genetic resources..
As elements of the Directive's preamble, both Recitals 27 and 56 are non-binding, intended only to assist interpretation of the Directive's binding articles. Recital 27 is in line with CBD Decision VI/24C on the Role of IPRs in the Implementation of ABS Arrangements. The Decision invites Parties and Governments to *encourage* the disclosure of the country of origin of genetic resources.

Directive 98/44/EC is implemented within the framework of the 1973 European Patent Convention (the EPC). The EPC is not an EC institution. The EPC establishes standard rules governing a single procedure for the grant of European patents in its Contracting States, spanning both EU and other European countries. The EPC also establishes the European Patent Office (EPO) tasked with granting European Patents.[14] The EPC's Implementing Regulations were amended in 1999 to take into account Directive 98/44/EC. Under these regulations, Directive 98/44/EC and its preceding recitals provides a supplementary means to interpret the provisions of the EPC and its implementing Regulations. Recital 27 may therefore be taken into account in the examination of patent applications both by national patent offices in EU Member States and by the EPO.

Directive 96/9/EC of the European Parliament and of the Council (11 March 1996) on the legal protection of databases makes no reference to the CBD, though it may help to secure compliance with requirements for PIC and MATs for access. The Directive extends copyright protection[15] to the content of databases, and potentially enables the protection of information derived from the collection and use of genetic resources and the associated traditional knowledge, innovations and practices. Databases are defined as collections of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means. To qualify for protection, the database must be the author's own intellectual creation, whether by selection or arrangement of contents. The Directive also extends *sui generis* protection in

[14] European Patents provide protection in more than one Contracting State and have the same effect as national patents.
[15] The Directive grants the author the right to authorise, amongst others: reproduction; translation, adaptation, arrangement and any other alteration; distribution, communication, display or performance to the public; as well as first sale in the Community (Article 5).

respect of databases involving a substantial investment in obtaining, verifying or presenting contents (finance, time, effort or energy).[16]

Protocol No 3 on the Sami people[17] **of the Act of Accession of Austria, Finland and Sweden to the EU (1994)** is of potential relevance to implementation of the CBD's provisions on Article 8(j), though it makes no specific reference to the Convention or to traditional knowledge. The Protocol grants the Sami exclusive rights to reindeer husbandry notwithstanding the provisions of the EC Treaty. Article 2 of the Protocol provides that it may be extended to *any further development of exclusive Sami rights linked to their traditional means of livelihood*.

3.2.2. Legislation governing the conservation and sustainable use of agricultural genetic resources and associated traditional knowledge

The 1996 Global Plan of Action (GPA) for the Conservation and Sustainable Utilisation of Plant Genetic Resources for Food and Agriculture promotes, amongst others, the fair and equitable sharing of benefits arising out of the use of PGRFA, and of associated traditional knowledge. This includes both *in situ* and *ex situ* material. The EC's existing legislative framework works to implement a wide range of activities identified by the GPA,[18] and some are of potential relevance to future implementation of the Bonn Guidelines on ABS (CBD Decision VI/24A).

Council Regulation No 2100/94 (27 July 1994) on Community Plant Variety Rights might facilitate benefit-sharing. Applicants for a Community Plant Variety Right are required to state the geographic origin of the variety. In addition, farmers retain the right to save and reuse proprietary seeds on their own holdings, while paying equitable remuneration to the holder of the right at a rate lower than the amount charged for licensing production. *Small farmers* are exempt from paying remuneration. Finally, compulsory licensing is permitted in the public interest, though this remains to be defined in terms of the CBD.[19]

Regulations relating to the geographic origin and specific character of agricultural products and foodstuffs could work to protect associated traditional knowledge under certain circumstances.

Council Regulation No 2081/92 (14 July 1992) on geographic indications enables groups and natural or legal persons to register *designations of origin* and *geographical indications* for agricultural products and foodstuffs. Both terms describe the region, specific place or (exceptionally) a country where an agricultural product or foodstuff

[16] This grants the holder the right to prevent extraction and re-utilisation of the whole or a substantial part of the contents of a protected database.
[17] Indigenous peoples of Northern Norway, Sweden and Finland
[18] Gerasimos Apostolatos, *EC Activities to implement the Global Plan of Action.* European Cooperative Programme on Crop Genetic Resource Networks <www.ecpgr.cgiar.org/publications/gpaeur/eurcom.htm>.
[19] The regulation gives two examples of when public interest might require compulsory licensing: first, the need to supply the market with material offering specified features; second, to maintain the incentive for continued breeding of improved varieties (Recital 20).

originates.[20] A third country may apply for the registration of a designation in its territory and the European Commission has the authority to negotiate agreements with third countries for the reciprocal protection of designations.

Similarly, **Council Regulation No 2982/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs** enables groups to register the specific character of an agricultural product or foodstuff produced using traditional raw materials, or characterised by traditional composition, mode of production and/or processing. As with geographical indications, a country outside the EU may, at the request of its producers, apply for a Community certificate of specific character.

There are, in addition, potential ABS dimensions to proposed and existing regulations governing seeds, and the conservation and characterisation of PGRFA.

Directive 98/95/EC on conservation varieties (14 December 1998)[21] promotes the conservation and sustainable use of threatened landraces and varieties that arise from *in situ* conservation and are naturally adapted to local and regional conditions. The Directive creates the legal framework enabling these varieties to be grown and marketed. This includes their official acceptance as *conservation varieties* in the common catalogue, taking into account the results of unofficial tests, knowledge gained from practical experience during cultivation, reproduction and use, as well as detailed descriptions of the varieties and their relevant denominations.[22]

The Commission has also proposed a **Council Regulation on the conservation, characterisation, collection, utilisation of genetic resources in agriculture and amending Regulation (EC) 1258/1999**[23]. This renews a programme of action implemented under Council Regulation 1467/94 and will direct assistance towards the conservation (*ex situ* and *in situ*), characterisation, collection and utilisation of genetic resources of importance to agricultural production. It will support implementation of the EC Biodiversity Action Plan for Agriculture, co-ordination of national action programmes, and information exchange between Member States and the Commission.

An independent expert group established to assess the previous programme of action under Regulation 1467/94 examined amongst others, whether projects were in line with

[20] A designation of origin refers to the quality or characteristics of an agricultural product or foodstuff, which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors. A geographical indication refers to the specific quality, reputation or other characteristics of an agricultural product or foodstuff, which are attributable to the defined geographical origin. Both terms also refer to quality and characteristics attributable to production, processing and preparation in the defined geographical area.

[21] *amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species*.

[22] Art. 6. 17.

[23] COM (2001) 617, Volume I. Brussels, 31.10.2001.

the CBD. [24] The expert group noted that, beyond obligations on conservation under the CBD, access to and utilisation of genetic diversity is *a matter of prime importance*. The expert group concluded that benefit-sharing under the CBD's should be studied carefully within the framework of the EC.[25] The expert group recommended that legal aspects, including the IPRs and the CBD's provision on the use of genetic resources, must be handled in co-ordination with the Commission, and that collaborating EU Member States should adhere to common rules when operating project under the regulation.

While the proposal for a new regulation makes no specific reference to ABS, it establishes a new action programme *with a view to achieving implementation of the Convention on Biological Diversity*[26] and highlights co-ordination of national programmes with international negotiations within the CBD and FAO[27]. The proposal also provides for a committee on genetic resources to assist the Commission both in management of activities funded under the Regulation and in discussing on *other questions related to genetic resources*.[28]

3.2.3. Legislation affecting research and technology transfer

The EC Declaration Ratifying the Biodiversity Convention highlights technology transfer and access to biotechnology, to be carried out in accordance with CBD Article 16 and the principles and rules of IPRs, in particular multilateral and bilateral agreements signed by parties to the CBD. No EC legislation has been introduced specifically to facilitate technology transfer under the CBD, though the following measures are potentially relevant.

With respect to trade and technology transfer, **Article 81(3) of the Treaty of Rome as amended by the Treaty of Amsterdam** allows exemptions to the general prohibition on restrictions to competition within the common market. Exemptions are permitted for certain agreements, decisions and practices which contribute to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit. This might include agreements between EU and non-EU undertakings. **Regulation 240/96 (31 January 1996) on the application of Article 85(3) of the Treaty to certain categories of technology transfer agreements**

[24] COM (2001) 617, Volume II. *Report from the Independent Expert Group to the Commission on implementation of Council Regulation (EC) No 1467/94 on the conservation, characterisation, collection and utilisation of genetic resources in agriculture.*
[25] The expert group also noted that joint projects do not automatically render joint use of genetic resources that come from different countries. They highlighted the Nordic Gene Bank as a possible model: this operates ecoregionally, establishing a common gene bank for the cultivated plants of each Nordic country. For further information, see: <www.ngb.se/Library/pdf/JubileeBook/NordicPGR.pdf>
[26] COM (2001) 617, Volume I. Brussels, 31.10.2001 - Article 1.
[27] COM (2001) 617, Volume I. Brussels, 31.10.2001 - Article 3(a)
[28] COM (2001) 617, Volume I. Brussels, 31.10.2001 - Explanatory Memorandum and Article 12.

is designed to encourage the dissemination of technical knowledge in the EC and allows for block exemptions for patent and know-how licensing agreements.[29]

With respect to research, the Commission has tabled a **proposal for a Decision of the European Parliament and the Council concerning the rules for the participation of undertakings, research centres and universities and for the dissemination of research results for the implementation of the EC framework programme 2002-2006**[30]. Proposed rules for dissemination and use include provisions on ownership, protection and access to knowledge arising from research funded by the EC within the 2002-2006 framework programme for research, technological development and demonstration activities. These proposed rules do not, however, incorporate provisions on ABS in the context of the CBD.

3.3 EC support for ABS policy research and implementation

3.3.1. Policy research

In 1999, the European Commission supported research on demand for access to genetic resources for commercial development, and how the benefits that subsequently arise are shared. The research sought to provide governments and other organisations with information on corporate practices and perspectives on ABS. The research examined a range of sectors, spanning the seed industry, horticulture, crop protection, biotechnology, natural personal care and cosmetics. The results have been published as a book.[31]

Following an EC call for tenders on 29 June 2001, a study is being undertaken on the inter-relations between IPR regimes and the conservation of genetic resources. The call requested research into the extent to which the conservation and sustainable use of biodiversity can provide a policy justification for (i) establishing IPR or *sui generis* regimes for the protection of traditional knowledge and (ii) designing or limiting IPRs on biotechnology. The final report will be available at the end of 2002.

3.3.2. Support for stakeholder implementation

To date the EC has supported stakeholder implementation of ABS measures by *ex situ* collections.

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[29] Environmental Resources Management, *Identification of Community Measures for the Implementation of Articles 15 and 16 of the Convention on Biological Diversity: Draft Final Report*, Part B. June 1996. Prepared for CEC DG XI.

[30] COM (2001) 822 final, Brussels, 10.01.2002. The Decision 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) was adopted on of 27 June 2002, OJ L 232/1.

[31] ten Kate, K. and S. A. Laird (1999), *The commercial use of biodiversity. Access to genetic resources and benefit-sharing, Earthscan*, London.

Between September 1997 and June 1999, the EC supported the development of the **Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)** (see also Box 2). The MOSAICC initiative was launched by the Belgian Co-ordinated Collections of Micro-organisms (BCCM), which led a consortium of 16 organisations involved in microbiology and the use of micro-organisms from the EU and around the world. MOSAICC is a voluntary code of conduct (i) to facilitate access to microbial genetic resources in line with the CBD and other applicable national and international law[32], and (ii) to ensure that the transfer of material takes place under appropriate agreements between partners and is monitored to secure benefit-sharing. MOSAICC is a living document and, like the CBD Bonn Guidelines on Access and Benefit-Sharing, is open to further improvement.

There are also ABS dimensions to EC-funded programmes aimed at integrating European *ex situ* collections and associated information. As of November 2001, the EC has supported **the European Biological Resource Centres Network (EBCRN)**. The project addresses issues raised by the OECD Initiative on Biological Resource Centres (BRCs) requiring culture collections to adapt to support biotechnology for the 21st century. The project aims to create a network of biological resource centres, initiated with a minimum of 11 living organism collections, holders of nucleic acids, probes etc. and associated data and databases. It will also collate and disseminate information on legislation on access to, and distribution of, living organisms through the EBRCN central web site.[33] The EBRCN is currently adapting MOSAICC to develop its own Material Transfer Agreement, equivalent to the Uniform Biological Material Transfer Agreement introduced in the United States in 1995 by the National Institutes of Health (NIH) and the Public Health Service (PHS).[34]

As of November 2001, the EC has also supported **BioCASE (Biodiversity Collection Access Service for Europe)** - a consortium of 34 centres with expertise in biodiversity research, biological collections, and biodiversity informatics, forming a complete network of country nodes. BioCASE will enable access to specimens and related data in participating centres, and will support ongoing EU taxonomic projects by providing an access point for voucher information. The project will contribute towards development of the Global Biodiversity Information Facility and the EC's CBD Clearing House Mechanism, by facilitating access to information on European biodiversity as well as on collections originating in extra-European countries.[35]

[32] Including the 1997 Budapest Treaty on the International Recognition of the Deposit of Micro-Organisms for the Purposes of Patent Procedure, and the 1994 WTO Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPs Agreement).
[33] Community Research and Development Information Service (CORDIS) <www.cordis.lu/en/home.html>
[34] Pers. comm. Ir Philippe Desmeth, BCCM International Cooperation Programme Officer (15 May 2002)
[35] Pers. comm. Dr. Marie Gebhardt, BioCASE Project Administration (11 June); Community Research and Development Information Service (CORDIS) <www.cordis.lu/en/home.html>

4. EC INVOLVEMENT IN RELEVANT INTER-GOVERNMENTAL PROCESSES

4.1 Key fora and negotiating positions

At the intergovernmental level, the EC addresses ABS and traditional knowledge in relation to:

- the work of the **CBD Ad Hoc Working Groups on ABS and Article 8(j)**;
- the negotiation and implementation of the **FAO International Treaty on Plant Genetic Resources for Food and Agriculture**, based on the principle of a multilateral approach to access and benefit-sharing, consistent with IPRs, and the rights of farmers and the CBD;
- relevant work in WIPO, in particular the **WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore**; and,
- other work that has or may be undertaken in the **WTO**, **OECD**, **UNESCO** and **UPOV**.

Within these fora, EC negotiating positions have emphasised:

(a) **Coherence and mutual supportiveness** between the work of different intergovernmental fora and in their implementation (including the development of ABS strategies at the country or regional level).

(b) **Participation of a wide range of stakeholders** who are providers and users of genetic resources and related traditional knowledge, in particular indigenous and local communities. This includes the need to strengthen awareness of stakeholder needs and practices, as well as their participation in both multilateral policy dialogue and national implementation.

(c) **Coordinated and demand-driven capacity building**, as a component of benefit-sharing, and for the development and implementation of ABS measures including national legislation.

(d) **Facilitated access to genetic resources**, including through easily applicable and transparent access application systems, and future extension and diversification of the list of crops under the FAO International Treaty on PGRFA.

(e) **Further investigation of options for verifying compliance** with national ABS laws and contracts, e.g. by encouraging patent applicants to present evidence of PIC and benefit-sharing agreements for genetic resources used in claimed inventions.

(f) That **IPRs are only one of many complex aspects of ABS.** The EC also believes that IPRs are only one of several instruments that can be used by providers of genetic resources to obtain benefits.

(g) **Development of an international model to protect traditional knowledge**, including the need to establish a legal definition for 'traditional knowledge' and whether such rights should operate at the individual, collective or common level.

(h) **Need for further analysis of the extent to which existing forms of IPR might protect traditional knowledge**, and of the impact of IPRs on traditional uses of genetic resources. This includes patents as well as other forms of protection including plant varieties and geographical indications.

(i) **Ways and means of protecting traditional knowledge through its recognition as prior art**.

(j) **Further work on limitations to IPR protection as a contribution to benefit-sharing**, including research exemptions, the farmers' privilege and compulsory licensing.

Sections 4.2 and 4.3 below explore the EC's involvement in the negotiation of **multilateral instruments such as the guidelines on ABS**, and international deliberations over the **links between ABS and IPRs**. The information presented summarises a combination of EC communications and EU position statements. The text in italic is directly quoted.

4.2 Multilateral instruments and guidelines for ABS

4.2.1. CBD Bonn Guidelines on ABS

The EU welcomes the adoption of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilisation under Decision VI/24. The EC was actively involved in their development and negotiation within the CBD Ad Hoc Open-Ended Working Group on ABS, and preceding meetings of the CBD Expert Panel on ABS. The EC, in consultation with Member States, will review existing legal, policy and administrative measures as a first step towards putting the Guidelines into practice. The following summarises the EU's position with respect to aspects of the Guidelines' implementation.[36]

(i) **Coherence (at multilateral and national levels)**

[36] Based on EU position statements at Bonn, 22 to 26 October 2001.

The EU believes that the Guidelines should be applied in a manner *coherent and mutually supportive* of, in particular, the FAO International Treaty on PGRFA, as well as of the work of the WIPO Intergovernmental Committee.

The EU agrees that national ABS systems *should be based on an overall ABS strategy at the country or regional level, as appropriate. Such a strategy could help ensure that the legislative, administrative or policy measures that Parties introduce support the objectives of the Convention* and *should be integrated with the National Biodiversity Strategies and Action Plans*.

(ii) **Stakeholders**

The EU stresses the diversity of stakeholders who are often both providers and users of genetic resources and believes that *special attention should be paid to indigenous and local communities as they have an important role in the conservation and sustainable use of biodiversity*. The EU highlights the following priorities related to the involvement of stakeholders:

- *facilitate the creation of a national networks of stakeholders*
- *bottom-up approach*
- *transparency*
- *link with national policy on conservation and use of genetic resources and related traditional knowledge*
- *strengthening stakeholder capacity* for the *conservation, sustainable use and exchange of genetic resources and associated knowledge*.

The EU believes that *measures developed according to the guidelines should provide for:*
- *awareness and information on national and international legal and institutional frameworks* and of *stakeholder needs and practices*.
- *participation of stakeholders in the drafting, implementing and reviewing of* ABS *measures and in negotiations aimed at deciding if access to genetic resources will be given and on which terms*.

(iii) **Capacity-building**

The EU welcomes the emphasis on capacity-building at national and international levels … as an integral part of any package of measures to assist in the development … and implementation of ABS *arrangements. A programme of capacity-building programme should be demand-driven, avoid duplication and be complementary to other initiatives in order to enhance synergy in institution building, and take into account the scarcity of human resources in the Parties concerned.*

(iv) **Compliance, dispute settlement and remedies**

The EU also welcomes the provisions of the Bonn Guidelines relating to means to verify compliance (including requesting evidence of PIC and an agreement over benefit-

sharing), settlement of disputes, as well as remedies for violations of national legislative, administrative or policy measures on ABS.[37]

4.2.2. FAO International Treaty on Plant Genetic Resources for Food and Agriculture

The EU strongly welcomes the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture (IT), which, as the first legally binding instrument concerned with sustainable agriculture, *is a landmark*.[38] The EU and its Member States intend to sign as soon as possible and the EU would encourage all members of the FAO Commission to do likewise.

The objectives of the IT are sustainable agriculture and food security. It *also secures the role of the CGIAR and its ex situ collections*. However, the IT will also make a *significant contribution to the implementation of the CBD* through the multilateral system for facilitated access to Plant Genetic Resources for Food and Agriculture and benefit-sharing. The benefits included in the multilateral system, including information exchange, technology transfer and capacity building, as well as the provisions on commercial benefit-sharing, *comprise a substantial package*.[39]

The EU considers that the IT *is not subordinate to other international agreements, emphasises that* the IT *and other international agreements are mutually supportive and stresses that the relevant preambular paragraphs of* the IT *should be interpreted in this way, so ensuring that* it *contributes to world food security*. The European Community and its Member States also *interpret Article 12(3)(d)*[40] *as recognition of the fact that* PGRFA *or their genetic parts or components that are the outcome of innovation may be subject to IPRs, provided the criteria for such rights are met*. This would comply fully with permanent facilitated access to plant genetic resources for food and agriculture in the multilateral system.[41]

The EU *remains convinced that the list of crops must be extended and diversified, as quickly as possible, particularly to include crops of crucial importance for tropical and subtropical regions*. Only in this way will the IT have maximum impact on securing world food security.[42]

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[37] EU position statements at Bonn, 22 to 26 October 2001 (proposal for replacement of paras 63 to 70 of the Secretariat paper). Decision VI/24, Bonn Guidelines, Section V 'Other Provisions' D – F.
[38] European Region Statement on the adoption of the International Treaty on PGRFA.
[39] European Region Statement on the adoption of the International Treaty on PGRFA.
[40] Article 12(3)(d): *Recipients shall not claim any intellectual property or other rights that limit facilitated access to the plant genetic resources for food and agriculture, or their parts or components, in the form received from the Multilateral System.*
[41] European Region Statement on the relations between the Treaty and other International Agreements; Statement of the Presidency on behalf of the European Community and its Member States, Item 7 – International Treaty on PGRFA, Conference 31st Session, Rome, 2 – 13 November 2001.
[42] European Region Statement on the adoption of the International Treaty on PGRFA.

The EU is committed to working with the Commission on Genetic Resources for Food and Agriculture, acting as the Interim Committee for the IT, and, upon entry into force of the IT, with its Governing Body to ensure full and transparent implementation of the IT as soon as possible. Among the priority tasks to enable implementation of the IT is the preparation of the standard Material Transfer Agreement referred to in Article 12.4 (for exchanges of genetic resources under the Multilateral System).[43]

4.3 Intellectual property rights and benefit-sharing

4.3.1. CBD deliberations on ABS and IPRs

On 2 February 2001, the EC and its Member States submitted views to the Executive Secretary of the CBD on *Intellectual property rights, access to genetic resources and the sharing of benefits arising from their use*[44] in response to Decision V/26 paragraph 15(a). **The statement does not constitute an EU position.**

The EU statement *attached great importance to the complex relationship between ABS and IPRs*, given that IPRs on end products can be *a crucial incentive for the creation of some types of benefits*. *They provide the incentive for private companies to invest in the creation and development of new products and processes*. However, the EU stressed that IPRs *are not, as such, … mechanisms to share benefits resulting from the use of the original genetic resource* and that monetary benefits are only generated after commercialisation of the protected matter[45].

The EU statement addressed:
- IPRs and the protection of traditional knowledge;
- the scope of the protection afforded by IPRs to inventions using genetic resources; and,
- IPRs as an instrument for the implementation of the Article 15.7 of the CBD.

(i) **Protection of traditional knowledge**

The EU statement to the Executive Secretary recognised that most IPR systems, in their present form, are not geared to the protection of all aspects of traditional knowledge. The EU statement highlighted:

- the importance of establishing a legal definition for 'traditional knowledge'.
- the need to *determine whether such rights should be established at the individual, collective or common level*.

[43] Statement of the Presidency on behalf of the European Community and its Member States, Item 7 – International Treaty on PGRFA, Conference 31st Session, Rome, 2 – 13 November 2001.
[44] European Commission, Directorate-General Environment (Directorate A – General and international affairs. Env.A.4 – Development and environment). *Intellectual property rights and access to genetic resources and the sharing of benefits arising from their use*, Brussels, 2 February 2001.
[45] ibid

- the need for further analysis of *the extent to which existing IPRs (patents, plant varieties, geographical indications, copyright, industrial designs, trademarks and the protection of confidential information) are able to meet the objectives of protecting traditional knowledge,* and of *the possibility of establishing new 'sui generis' property rights*.
- the need to *clarify how the granting of an IPR to a third person may affect local communities and indigenous populations, directly or indirectly, in continuing to apply their historical and customary practices.*

These concerns were subsequently addressed by CBD COP6, through:
- Decision VI/24C requesting the Executive Secretary (together with WIPO and the CBD Ad Hoc Open-Ended Intersessional Working Group on 8j) to undertake further information gathering and analysis on the relationship between IPRs and customary laws and practices.
- Decision VI/10 F which, amongst others: requests the Ad Hoc Open-Ended Intersessional Working Group on 8j to address *sui generis* systems; calls for pilot projects and feasibility studies to evaluate the effectiveness of existing IPR regimes as well as mechanisms to protect traditional knowledge; and urges Parties and Governments, with the assistance of WIPO, to account for traditional knowledge in the examination of novelty and inventive step in patent applications.
- Decisions VI/24 C and VI/20 H, encouraging WIPO and the CBD parties to collaborate to protect traditional knowledge, and urging WIPO to provide the CBD COP with the results of its deliberations of relevance to access to genetic resources and benefit-sharing related to traditional knowledge.

At CBD COP6[46], the EU welcomed progress on the CBD Work Programme on Article 8j, as established by Decision V/16. The EU hopes this *will strengthen respect and protection of traditional knowledge relevant to the conservation and sustainable use of biodiversity*. Amongst others, the EU prioritises Task 12 to develop guidelines that will assist Parties and Governments in the development of legislation or other mechanisms, as appropriate, to implement Article 8(j) and its related provisions. The EU believes that *it is important to study and develop synergies between 8j and the CBD Bonn Guidelines*. Furthermore, it encourages *continuation of the process of convergence and dialogue which is taking place between the CBD and other bodies working on subjects related with 8j, such as WIPO, UNCTAD, UNESCO, WTO and FAO*.

(ii) **Scope of protection afforded by IPR to inventions using genetic resources**

The February 2001 EU statement to the Executive Secretary noted that previous CBD documents had identified a number of issues relating to patents. However, the EU also emphasised the need to *fully consider other forms of protection, including plant breeders' rights and geographical indications*. The EU suggested further work on:
- the *impact of IPRs on the use of genetic resources employed in the development of protected inventions, particularly traditional uses of the genetic resources*; as well as,

[46] COP6 EU position statement on Article 8j and related provisions, 7 April 2002.

- *limitations to the protection afforded by IPRs*, including research exemptions and farmers' privileges. The EU noted arguments within the CBD in favour of compulsory licences on terms preferential to provider countries and communities, or for biodiversity conservation purposes.

Decision VI/24C addresses these concerns, requesting the Executive Secretary (together with WIPO and the Ad Hoc Open-Ended Intersessional Working Group on 8j) to further analyse the impact of IPRs on access to and use of genetic resources and scientific research. At COP6, the EU also highlighted *the importance of addressing ways and means of recognising prior art as a noteworthy tool for identifying restrictions in issuing patent and other* IPRs *with a view to protecting and respecting traditional knowledge, innovations and practices, as presently addressed by the WIPO working group on traditional knowledge*.[47]

(iii) **IPRs as an instrument for implementation of Article 15.7 of the CBD**

The EU statement to the Executive Secretary noted *that CBD delegations tend to view IPRs as:*

- *a possible economic incentive*; i.e. that filing or granting of an IPR on an invention that makes use of a genetic resources could trigger benefit-sharing, either within the terms of agreements between providers and users of genetic resources, or under national procedures and legislation governing IPRs; and,
- *a legal instrument for verifying compliance with the CBD*, whereby proof of Prior Informed Consent for access is a condition of granting an IPR, or where non-compliance with Mutually Agreed Terms for access could be punished by cancelling related IPRs, or through civil action for damages or criminal proceedings.

With respect to proof of PIC as a means of verifying compliance, the EU notes that *evidence of PIC could also be provided by means of an information system* and that *other options could also be studied*.

Decision VI/24C also addresses these concerns. Amongst others, the Decision:

- invites Parties and Governments to encourage disclosure on IPR applications of the country of origin of genetic resources and relevant traditional knowledge used in the claimed invention, to help track compliance with PIC and MAT for access;
- requests the Executive Secretary (together with WIPO and the Ad Hoc Open-Ended Intersessional Working Group on 8j) to undertake further information gathering and analysis on the consistency, applicability and efficacy of country of origin and PIC disclosures on IPR applications.
- invites WIPO to prepare a technical study for presentation to COP7 on methods (consistent with obligations in treaties administered by WIPO) for requiring disclosure on patent applications of genetic resources, associated traditional knowledge and their source, as well as evidence of PIC.

[47] COP6 EU position statement on Article 8j and related provisions, 7 April 2002.

- encourages WIPO to make rapid progress in the development of model intellectual property clauses, which may be considered, for inclusion in access agreements during negotiations of MATs.

4.3.2. WIPO deliberations on ABS and IPRs

The EC and its Member States contribute actively to the work of the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore.

(i) Efficacy of existing IPR instruments in the protection of traditional knowledge

With respect to the efficacy of existing IPR instruments in the protection of traditional knowledge, *the EU recognises the recent work of the Intergovernmental Committee and encourages this organisation to continue working to develop an international regulatory system that effectively and appropriately protects traditional knowledge in synergy with the CBD and other relevant international bodies*.[48]

At the 2nd session of the Intergovernmental Committee in December 2001, the European Community welcomed WIPO's Progress Report on Traditional Knowledge as Prior Art[49], considering it a useful contribution towards examining existing criteria, and the need for possible new criteria, for more effective integration of traditional knowledge documentation into searchable prior art (Task B.3 of the Committee). The European Community thinks that it is important to examine the means of making information on traditional knowledge available to patent offices, e.g. through databases or registers, so that patent examiners can take such information into account when examining prior art. The EC also thought it necessary to take into account the work of WIPO in the context of other committees, notably the Standing Committee on Patent Law (SCP) and to establish close consultations with users and other stakeholders.[50]

(ii) Intellectual property clauses of contractual ABS agreements

In addition, the EU welcomed the report of the WIPO Secretariat on Operational Principles for Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing,[51] highlighting a number of specific elements.[52]

- The EU agreed with the limitation of the work of this Committee to the IP-specific elements of contractual agreements for access, leaving other aspects of such agreements to relevant international fora and processes.

[48] COP6 EU position statement on Article 8j and related provisions, 7 April 2002.
[49] WIPO/GRTKF/IC/2/6
[50] Summary of European Community position statement, 2nd session WIPO Intergovernmental committee.
[51] WIPO/GRTKF/IC/2/3
[52] Summary of EU position statement, 2nd session WIPO Intergovernmental committee.

- On the institutional background to the Intergovernmental Committee (paragraph 9), the EU agreed with the need to work closely with other relevant intergovernmental fora.
- On principles for the development of guide contractual practices and model IP clauses, the EU stressed the need for coherence and mutual supportiveness with other work on genetic resources, including the FAO, the CBD and the WTO. The EU emphasised that the guide practices and model IP clauses should be of a non-binding character.
- With respect to stakeholders, the EU pointed out that local and indigenous peoples should be closely associated with work to develop guide contractual practices and model clauses, and stressed the need to consult user groups.
- The EU also supported a proposal for a complete and systematic survey of IP clauses in ABS agreements.

4.3.3. WTO TRIPs deliberations on ABS

The EU remains committed to participating constructively and in a positive manner in discussions on the relationship between the WTO Agreement on Trade-related aspects of Intellectual Property Rights (TRIPs) and the CBD, within the context of TRIPS Article 27.3(b). To this end, a **Communication to the TRIPs Council from the EC and Member States on the relationship between the CBD and TRIPS Agreement**[53] was submitted on 3 April 2001, as part of the Review of the Provisions of Article 27.3(b). Following the agreement in 2001 on the Doha Development Agenda, the EC and Member States tabled a new **Communication 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 CBD and the protection of traditional knowledge and folklore (17 September 2002)**.[54]

The EC has also established an **Issue Group on TRIPs** to facilitate broader stakeholder consultation. This periodically convenes the Commission and civil society representatives, including industry associations and NGOs

The April 2001 Communication to the TRIPs Council addressed: the legal relationship between the CBD and the TRIPs Agreement; the interaction between the two instruments; requirements for disclosure of origin on patent applications; as well as the protection of traditional knowledge. The content of the 2001 Communication on these issues is summarised below. Then follows a summary of the above-mentioned 2002 Communication which builds upon the first one.

(i) Legal relationship between the CBD and the TRIPs Agreement

The EU communication to the TRIPs Council points out that neither the CBD nor the TRIPs Agreement specify that they are subject to each other. The EC and its Member

[53] WTO IP/C/W/254 of 3 April 2001.
[54] WTO IP/C/W/383 of 17 September 2002.

States believe that *there is nothing in the provisions of either agreement that would prevent a State from fulfilling its obligations under both*. The CBD *does not prohibit patents on inventions using genetic resources* and the TRIPs Agreement in turn *does not prevent signatories from exercising their right to regulate ABS, to require* PIC *or to share in the benefits*. Nor does the TRIPs agreement prevent states from enacting *sui generis* systems to protect traditional knowledge. The EU believes that they should accordingly be implemented in a mutually supportive way.

(ii) **The interaction between the two instruments**

The EU Communication does, however, state that *there is considerable interaction between the rights referred to in TRIPs Agreement and the subject matter of the CBD*, and in particular in relation to TRIPs section 5 on patents. CBD Article 16 obliges states to ensure that IPRs are 'supportive of and do not run counter' to the objectives of the CBD, while also requiring technology transfer to be consistent with 'the adequate and effective protection of IPRs'. The EU is therefore in favour of granting the CBD Secretariat ad hoc observer status in the TRIPs Council, as well as enhanced co-operation between the WTO and CBD Secretariats.

The EU Communication also argues that IPRs, and in particular patents, *are only one of several instruments that can be used by providers of genetic resources to obtain benefits from commercial operators who depend on genetic material to develop new products. Patents can be used as an instrument between the parties to agreements on access to genetic resources to secure remuneration to the provider country for the use of genetic resources on a long-term basis*. In this context, the EU argues that *intellectual property is only one of many complicated aspects concerning* ABS.

The Communication also argues that *the TRIPs Agreement leaves scope to WTO Members to determine the degree of exclusivity conferred by patents. Members remain free to provide for exclusions to patent protection for research*, as well as to plant variety protection for further plant breeding and the farmers' privilege. The EU notes that these provisions *contribute to the sharing of benefits arising from innovation on (plant) genetic resources.*

(iii) **Disclosure of origin on patent applications**

The EU does not, however, favour incorporating into the TRIPs Agreement overly complex requirements *which would oblige patent applicants to provide, in their application, an official certificate of the source and origin of genetic resources and associated traditional knowledge used, evidence of fair and equitable benefit-sharing, and evidence of PIC from government or local communities for the exploitation of the subject matter of the patent*. The EU notes that only a few countries have introduced access legislation. *Hence, only a few countries are currently in a position to deliver such certificates.*

Nevertheless, the Communication states that the EU is open to examining the *possible effects of the patent system and to look into different ways of how to positively support states in achieving the objectives of the CBD, in particular benefit-sharing, while maintaining existing standards and the level of intellectual property protection, and not unduly increasing the burden on patent applicants*, taking into account negotiations within the CBD.

The EU also regards disclosure of origin as *complementary* to national legislation as the main legal instrument governing ABS. In this respect, the EU stresses the need for *easily applicable and transparent access application systems*.

(iv) **Protection of traditional knowledge**

The EU Communication points out that nothing in the TRIPs agreement prevents states from enacting *sui generis* systems to protect traditional knowledge within the spirit of CBD Article 8(j). The EU therefore supports *the development of an international model for the legal protection of traditional knowledge* as is now being discussed by the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore. The EU Communication argues that, *once a model is in place, attention can then be focussed on how and to what extent the protection of traditional knowledge can be included in the TRIPs Agreement*.

In the meantime, the Communication highlights the need to explore ways *to make more information available on traditional knowledge to patent offices (through databases or registrations), to allow patent examiners to take them into account as prior art*. The EU points out that, *except for certain cases, traditional knowledge can not, in itself, respond to the basic criteria for patentability*. However, the Communication argues that the use of traditional knowledge in further innovations may be *perfectly patentable* where it meets the relevant criteria, not withstanding accompanying national requirements to obtain the authorisation of and share benefits with the ownership of the traditional knowledge from which the invention is derived. Finally, the Communication highlights *the complementary role that can be played by geographical indications in protecting traditional products under certain circumstances*.

The EU Communication concludes that the answer to developing countries concerns over TRIPs Article 27.3(b) *does not necessarily lie within the scope of the Article itself*, but in:

- *developing appropriate international instruments to achieve the objectives of the CBD (in particular ABS and the protection of traditional knowledge)*, e.g. as later achieved through the negotiation of the Bonn Guidelines, *and those objectives of the TRIPs Agreement which, in the view of the developing countries, have not sufficiently been promoted by the industrialised countries (e.g. transfer of technology and know-how).*
- *providing technical assistance to developing countries to implement the CBD through sound and effective internal legislation*; and,
- *through the negotiation of possible measures within the IPR system (in particular within the context of the WIPO and, where relevant, the TRIPs Agreement) aimed at*

facilitating benefit-sharing and protecting sovereign access rights (e.g. to insert a provision on the disclosure of origin or to develop protection of traditional knowledge).

(v) The EC 2002 Communication to the TRIPS Council (executive summary)

This text addresses the issues dealt with under Paragraph 19 of the Doha Declaration, which instructs the TRIPs Council to continue the review of Article 27.3(b) TRIPs, and to examine the relationship between TRIPs and CBD and the protection of Traditional Knowledge (TK) and folklore, and other relevant new developments. It reflects the EC's stated willingness to commit to this process in a spirit of openness, with the aim of finding ways of interpreting and implementing the TRIPs Agreement in a way to support the objectives of the CBD.

The review of Article 27.3(b)

This review deals, *stricto sensu*, with the patentability of biotechnological inventions and the protection of plant varieties. This subject has an important link with development issues in agriculture, so the development dimension must be fully taken into account.

The European Communities and their Member States (hereinafter "the EC") see no reason to amend Article 27.3(b) as it now stands. The TRIPs Agreement allows members sufficient flexibility to modulate patent protection as a function of their needs, interests or ethical standards. In this connection Article 27.3(b) - in conjunction with Article 27.2 (exclusion from patentability of inventions the commercial exploitation of which is necessary to protect ordre public or morality) and Article 27.1 (patentability criteria) - provides considerable leeway.

The EC have already indicated that they are prepared to discuss certain technical issues related to Article 27.3(b). However, in the EC's view, trying to clarify the definitions of technical terms such as "micro-organism" in the TRIPs Council may not be the best way forward. Firstly, because it would be extremely difficult to agree on precise definitions in that context, and, secondly, because it is questionable whether more precise definitions are really necessary, given that they would reduce the flexibility of WTO Members.

The relationship between the TRIPs Agreement and the CBD

From a legal perspective there is no conflict between the CBD and the TRIPs Agreement. However, it would be wrong to put on end to all discussion by saying that, in the absence of legal incompatibility, there cannot be a problem with the implementation of both Agreements. There is considerable *interaction* between both agreements, so TRIPs and CBD can and should be implemented in a mutually supportive way. The TRIPs Council should focus on ways and means of doing this.

At national level, sound regulation (through legislation or administrative or policy measures) on access and benefit-sharing (ABFS) under the CBD is essential to guarantee legal security for all parties involved and to protect the rights of providers of genetic

resources. Further details can be settled through contractual arrangements. Legislation/policy measures and contracts are complementary instruments for ensuring fair implementation of the CBD.

Further synergies between the implementation of these agreements can be worked out at international level by ensuring policy coherence in all forums which deal with issues relevant to the interplay between TRIPs, the CBD and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. In this respect the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing adopted at the 6th Conference of the Parties in The Hague on 19 April 2002 are an important evolution.

Disclosure of origin

The EC agree to examine and discuss the possible introduction of a system, such as for instance 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. The EC see merit in a system that would ensure transparency and would allow the authorities of countries granting access to their resources to keep track of patent applications linked to the use of these resources.

Under such a system, the information to be provided by patent applicants should be limited to information on the geographic origin of genetic resources or TK used in the invention, while such a disclosure requirement should not act, de facto or de jure, as an additional formal or substantial patentability criterion. Legal consequences to the non-respect of the requirement should lie outside the ambit of patent law.

Protection of TK

Preventive approaches to avoid misappropriation of traditional knowledge and to stimulate the sharing of benefits could be dealt with by the TRIPs Council. We need to explore methods of documenting and sharing information on TK, such as databases and registers, in order to allow patent examiners to take them into account in prior art searches. When TK is used as a basis for further innovations, disclosure of the original TK from which inventions are derived would be an important way of ensuring that holders of traditional knowledge share in the benefits.

The EC support further work towards the development of an international *sui generis* model for legal protection of TK in WIPO. At this stage, the TRIPs Council is not the right place to negotiate a protection regime for a complex new subject matter like TK or folklore. This is an issue where the WTO should ideally be able to build on the work done by the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore. Depending on the outcome of the WIPO process, the TRIPs Council will have to determine whether this result warrants further work in the WTO.

Effective sui generis protection of plant variety rights

The absence of a definition of this concept means that Members have a considerable degree of flexibility in determining how their legislation meets the standard of effectiveness, thus allowing them to design a protection regime that is appropriate to their specific national situation. Although the UPOV Convention meets the standard of effectiveness in Article 27.3(b), other protection models may be equally effective.

This paper explores the criteria that any regime establishing rights over plant varieties must fulfil (for example, a clear definition of the protectable subject matter and the conditions for granting protection, the availability of enforcement procedures, etc.).

Farmers' rights and farmers' exemptions

Farmers' exemptions (*i.e.* exceptions to plant variety rights or patents allowing farmers to save, use, exchange or sell seeds of protected varieties or seeds) can, under certain circumstances, be justified under Article 27.3(b) of the TRIPs Agreement, or under Article 30 of the TRIPs Agreement. The special situation of least developed or developing countries could be addressed by specific exceptions allowing subsistence farmers or small farmers to save, replant, exchange, share and resell seed, provided they do not use the commercial denomination of the variety. Farmers with significant commercial interests should remain subject to more stringent rules.

5. BEST PRACTICE ON ACCESS AND BENEFIT-SHARING IN THE EU

5.1. Institutional policies and codes of conduct

5.1.1. Initiatives by research institutions and networks

Scientific research institutions and in particular networks of *ex situ* collections in the EU 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 positive framework) to assist in the development and implementation of ABS arrangements. They constitute an effective measure to increases user transparency, while providing sufficient flexibility to respond to the circumstances of specific research sectors. Box 1 examines measures adopted by European botanic gardens. Box 2 outlines initiatives by microbial culture collections. Box 3 describes measures taken by European germplasm collections.

Box 1 ABS measures by European Botanic Gardens

(1) ***Principles on access to genetic resources and benefit-sharing for participating institutions***

In 1997, under the auspices of the Convention & Policy Section of the Royal Botanic Gardens, Kew, and funded by the UK Department for International Development, a pilot project for botanic gardens was launched. Representatives of 28 botanic gardens from 21 countries participated in the project, which involved four workshops. Botanic Gardens Conservation International (BGCI) and the International Association of Botanic Gardens (IABG) also took part. The aim was to develop harmonized policies/guidelines for botanic gardens on access to genetic resources and benefit-sharing. The project group agreed upon "Principles on access to genetic resources and benefit-sharing for participating institutions" . Botanic gardens and similar institutions are invited to endorse these non-legally binding Principles and to develop their own institutional policy to set out how the Principles will be implemented. An Explanatory text contains the Principles, Common Policy Guidelines which participating institutions may use as guidance in the development of their institutional policies and an Explanatory Text containing illustrations, suggestions for implementation and examples of agreements (Latorre García *et al*. 2001). Currently, botanic gardens from the UK, Cameroon, Ghana, South Africa, Brazil, China, Mexico, Germany, India, Colombia, Australia, Russia and the USA have endorsed the Principles. The list of participating institutions is updated regularly and may be found on <www.rbgkew.org.uk/conservation>.

(2) ***The Code of Conduct and Access and Benefit-Sharing System for Botanic Gardens***

At the end of 1996, the German Ministry of Environment funded a research and development project on botanic gardens and their contribution to the implementation of the CBD, based at the Bonn botanic garden (Barthlott et al. 2000, Rauer et al. 2000). A main objective of this project was to promote the process of discussing ABS issues within the botanic gardens of the German-speaking network (Verband Botanischer Gärten e.V., VBG).

Representatives of 34 botanic gardens from Austria, Germany and German-speaking Switzerland took part and developed a "Code of Conduct for Botanic Gardens and similar collections governing the acquisition, maintenance and supply of living plant material" (see Appendix 2). An exchange circuit has been established for Botanic Gardens that have endorsed the Code. The circuit facilitates the exchange of genetic resources for non-commercial purposes between these gardens. The list of botanic gardens that have endorsed the German Code is published on the German Network's web page <http://www.biologie.uni-ulm.de/verband/cbd/list.html>and is regularly updated.

The exchange-circuit is based on CITES practice and has been presented to the international level as an "Access & Benefit-Sharing System for Botanic Gardens". The concept of an international circuit has since been endorsed by members of the European Consortium of Botanic Gardens, the platform for official representatives of national botanic gardens networks in the EU. The international circuit would facilitate the world-wide exchange of material for non-commercial use by botanic gardens that have pledged to implement the CBD, without need for bilateral agreements between organisations.

(3) PlantNet conservation policy

PlantNet is the national network of botanic gardens, arboreta and other documented plant collections for Britain and Ireland. It seeks to promote botanical collections as a national resource for research, conservation and education, as well as to facilitate networking and training. PlantNet has made a general policy commitment to implementing the CBD. The PlantNet conservation policy states that "while botanic gardens have much to offer and gain from the [CBD], there are also obligations (such as gaining government permission to access genetic resources) which botanic gardens must honour."

Amongst others, PlantNet aims seeks to ensure that plant collections are collected, maintained and managed in accordance with the CBD by providing information on the Convention to its members and promoting understanding of its provisions.

To achieve this, PlantNet will:

- organise training courses for members on the CBD and its implementation;
- provide information to bodies coordinating CBD implementation nationally and internationally;
- participate in national and international activities in the development of policies for botanic gardens and other plant-collection holders, with regard to the CBD and specifically in regard to material transfer and benefit-sharing;
- consider the role of PlantNet's members in sharing benefits derived from the use of plant collections, particularly countries that are rich in biodiversity but poor in resources to conserve them.
- assist individual collection holders in developing their own institutional policies and practices in accordance with the CBD.

Sources: (i) F. Latorre García, C. Williams, K. ten Kate & P. Cheyne (2001) Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit-Sharing, Common Policy Guidelines to Assist With Their Implementation and Explanatory Text. RBG Kew; (ii) von den Driesch, M., F. Klingenstein, W. Lobin, B. van den Wollenberg Access and Benefit-Sharing System for Botanic Gardens, compiled for the Sixth meeting of the CBD Conference of Parties, 7 – 9 April 2002; (iii) pers. comm. Simon Thornton-Wood, PlantNet Coordinator (May 24 2002).

Box 2 ABS measures by European culture collections

(1) ***Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)***

The MOSAICC initiative was launched in 1997 by the Belgian Co-ordinated Collections of Micro-organisms (BCCM), with the support of the Directorate General XII for Science, Research and Development of European Commission. MOSAICC is a voluntary code of conduct (i) to facilitate access to microbial genetic resources in line with the CBD and other applicable national and international law[55], and (ii) to ensure that the transfer of material takes place under appropriate agreements between partners and is monitored to secure benefit-sharing. MOSAICC is a living document and, like the CBD Bonn Guidelines on Access and Benefit-Sharing, is open to further improvement.

MOSAICC seeks to assist microbiologists by enabling them to secure Prior Informed Consent for access, in line with CBD Article 15.5, as well as to negotiate a Material Transfer Agreement for access to and transfer of genetic resources and associated technology, fair and equitable benefit-sharing, and scientific and technical co-operation (CBD Articles 15.4, 15.6, 15.7, 16, 18 and 19). MOSAICC aims to assist countries providing microbial genetic resources by suggesting procedures to issue PIC, as well as to monitor the transfer of genetic resources, enabling fair and equitable sharing of the possible benefits arising from their utilisation. MOSAICC also provides recommendations and model documents (MTAs, as well as access application forms and certificates) to be considered as guidelines for optimal implementation of the CBD. The Code and its accompanying documents can be downloaded from <www.belspo.be/bccm/mosaicc>

The Code was drafted through a process of consultation, initially between 12 partners from European and Southern institutions. 5 successive drafts were developed, taking into account comments on its potential application and utility. MOSAICC provides a basis for microbial collections to develop their own institutional policies and material transfer agreements (MTAs), and is increasingly seen as means, both to facilitate the legal transfer of material, and to strengthen the position of culture collections when negotiating ABS agreements.

(2) ***CAB International (CABI) Policy on Access to Ex Situ Genetic Resources***

As an intergovernmental organization (headquartered in the UK) whose member governments[56] are signatories to the CBD, CABI complies with the spirit and provisions of the Convention with regard to ABS and IPRs. CABI's Policy on Access to *Ex Situ* Genetic Resources addresses the receipt and supply of microbial strains, as well as the sharing of benefits arising out of their use, in line with applicable national and international law. In addition, CABI has developed a model MTA, as well as a position statement on patenting, IPR and ownership issues under the CBD.

[55] Including the Budapest Treaty on the 1997 International Recognition of the Deposit of Micro-Organisms for the Purposes of Patent Procedure, and the 1994 WTO Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPs Agreement).

[56] CABI is owned and administered by its member governments; there are currently 41, mostly from the developing world, but membership is open to all governments who wish to participate. The UK is the only EU Member State that is a member.

(3) Wider uptake of MOSAICC and CABI initiatives within the EU

The European Biological Resources Centres Network (EBRCN), funded by the EC (see section 3.3(b)), is currently drawing on MOSAICC and the CABI MTA to develop its own material transfer agreement. This will allow for material transfer between institutions on standard terms, in a similar fashion to the Uniform Biological Material Transfer Agreement (UBMTA)[57] developed by the United States National Institutes of Health (NIH) and Public Health Service (PHS).[58]

The Belgian Co-ordinated Collections of Micro-organisms (BCCM) has developed an MTA in line with MOSAICC, to be implemented subject to the approval of the Belgian Ministries of Economic Affairs and Research. The MTA is supplementary to existing regulations governing the import and export of biological material, including phytosanitary standards.

Sources: (i) pers. comm. Ir Philippe Desmeth, BCCM International Cooperation Programme Officer (15 May 2002); <www.belspo.be/bccm/mosaicc>; (ii) pers. comm. David Smith, CAB International (16 May 2002).

Box 3 ABS measures by European germplasm banks

Under the **European Cooperative Programme on Crop Genetic Resources Networks ECP/GR**, a task force is currently preparing a model Material Transfer Agreement (MTA) for distribution of germplasm, for programme-wide adoption. The task force also plans to discuss whether the ECP/GR can offer a framework to establish a regional multilateral system of exchange and benefit sharing, comparable to the system agreed upon within the framework of the FAO International Treaty on PGRFA. This would encompass all collections within the public domain of the ECP/GR members/participants.

The **Centre for Genetic Resources in the Netherlands** has also adopted a MTA for distribution of germplasm from its genetic resources collections. Under this MTA, *the recipient agrees not to claim ownership over the material to be received or over material that is essentially derived from the material received, nor to seek intellectual property rights over that germplasm or related information*. This implicitly protects traditional knowledge where appropriate. The MTA was discussed and adopted by the Ministry of Agriculture, Nature Management and Fisheries. In addition, a Material Acquisition Agreement (MAA) has been adopted to define conditions under which CGN staff may collect germplasm in other countries for export to the Netherlands.

Source: pers. comm. Bert Visser, Centre for Genetic Resources the Netherlands (20 February and 6 May 2002).

[57] See: <www.niehs.nih.gov/techxfer/ubmta.htm>

[58] The UBTMA allows for the transfer of materials between non-profit institutions using a boilerplate Implementing Letter. The Implementing Letter contains a description of the material and a statement indicating that the material is being transferred in accordance with the terms of the UMBTA. It must be executed by the provider scientist and the recipient scientist, and receive all necessary institutional endorsements. The Association of University Technology Managers (AUTM) serves as the repository for signed UBMTA Master Agreements. <www.uchicago.edu/adm/ura/guidelines/G300/302G.html>

5.1.2. Corporate policies

A small number of European pharmaceutical and biotechnology companies have developed corporate policies on ABS though, with declining interest in natural products research, these appear to be of less importance to corporate strategy today than they were 10 years ago. A number of sectors including horticulture and botanical medicines continue to exert significant demand for genetic resources but have still to develop 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 positive 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 a companies R&D strategy, by helping to identify likely partner countries, main suppliers and collaborators and the monetary and non-monetary cost of partnership[59]. Two of the most prominent examples in Europe are the Novo (Box 4) and Glaxo Smith-Kline (Box 5) policies.

Box 4 The Novo Nordisk/Novozymes ABS policy

In 1995, the Danish company Novo Nordisk A/S developed a policy for the acquisition of natural resources for pharmaceutical and enzyme development. The policy affirmed state sovereignty over genetic resources and acknowledged *that benefits arising from the utilisation of natural resources by any other party should be shared fairly and equitably with the donor country*. Under this policy, Novo Nordisk undertook to develop research agreements with provider organisations in compliance with national and international law, as well as to provide documentary evidence of *all necessary authorisations and permits* to use and dispose of the acquired material. It also committed Novo to benefit-sharing. In 1997, the company set out *Guiding Principles for Novo Nordisk's implementation of the Convention* which also applied to its enzyme business (now a separate company). The policy and guiding principles were developed by a joint Environmental and Bioethics Committee covering the Company's health care and industrial enzymes businesses.

Novo Nordisk's *Environmental and Bioethics Report* (1998) took stock of implementation and identified two key requirements for successful cooperation over CBD implementation: (i) an effective system for securing prior informed consent (PIC) with minimum bureaucracy; and (ii) users need to be able to identify whose PIC is needed. The report pointed to limited implementation of procedures at the national level. The report sets out examples of monetary and non-monetary benefits in relation to material covered by the CBD.

Published targets are used to secure implementation of the CBD. The target for 1998 was to develop formal corporate requirements on access to and use of genetic resources in line with the CBD. The target for the next year was that all patent applications and publications submitted from 1999 onwards should state the country of origin of genetic material. The

[59] ten Kate, K and S. A. Laird (1999), *The Commercial Use of Biodiversity. Access to genetic resources and benefit-sharing*, Earthscan, London, page 331.

target for 1999-2000 was to develop procedures to monitor implementation of the company's commitments on ABS. This included evaluation of external contracts for access.

The company's health care and industrial enzyme businesses have subsequently demerged into Novo Nordisk and Novozymes. Both, however, continue to uphold their commitment to compliance with the CBD and its provisions on ABS in both word and spirit. This includes efforts to obtain prior informed consent under mutually agreed terms, even in countries where national ABS law has not been introduced.

Sources: (i) pers. comm. Lene Lange, Science Director and spokesperson on Biodiversity issues, Novozymes A/S (10 June 2002); (ii) ten Kate, K and S. A. Laird (1999), *The Commercial Use of Biodiversity. Access to genetic resources and benefit-sharing*, Earthscan, London, page 307; and (iii) <www.novo.dk/environm/er97/bio/biodiversity.html>

Box 5 GlaxoSmithKline public policy position on the CBD (approved February 2002)

The GlaxoSmithKline (GSK) policy position in ABS acknowledges that all nations have sovereignty over the biological resources and indigenous knowledge within their territorial boundaries. Equally, unauthorised or unrestrained removal of natural materials from their indigenous habitats can harm the ecology and economy of the country concerned. However, it also states that, since the merger of SmithKline Beecham and Glaxo Wellcome in January 2001, there is increasing focus on drug discovery using high-throughput screening of synthetic chemical compounds. The company now has limited interest in access and screening natural materials.

Nevertheless, natural product screening still takes place under outsourced programmes with collaborative partners, e.g. in Brazil (see Box on "Extracta") and the Centre for Natural Product Research in Singapore. Natural material samples are screened by GSK's partners and are selected on the basis of common characteristics or because of reported chemical or biological properties. Samples are tested for activity against a specific biological target, to identify potential leads for medicinal chemistry. GSK also uses natural products in several therapeutic screens. The areas of interest include cancer, inflammation, the central nervous system and infectious, metabolic, respiratory and gastrointestinal diseases

In these and all future screening activities, the company supports the principles enshrined in the CBD. The policy position commits GSK to benefit-sharing with countries of origin in the event that a commercial product is developed. Benefit sharing may amount to payment of fair and reasonable royalties or other means determined by mutual agreement on a case-by-case basis. GSK has a number of patents based on natural products and it is possible that more patents will arise from its screening programmes.

Specifically, GSK has undertaken to:

- only work with organisations and suppliers with the expertise and legal authority to collect plant and other natural material samples. These include botanic gardens, universities and research institutes around the world.
- ensure that the governments in developing countries are informed of and consent to the nature and extent of any proposed natural materials collecting programme.

- protect biodiversity by classifying samples of plants and other organisms taxonomically and only investigate species if their supply is reproducible and sustainable.
- work with small quantities of natural materials to discover bioactive principles. Where possible further supplies of lead compounds and derivatives are synthesised by the company's own medicinal chemists.
- develop sustainable harvesting procedures where further supplies of the active compounds cannot be synthesised.
- where appropriate, collaborate with the appropriate organisations to educate and train local peoples in collecting/screening skills.
- ensure an agreed benefit is returned directly or indirectly to the country of origin in the event of GSK developing a commercial product based on a natural material.
- only transport potentially hazardous R&D material under contained use conditions and in accordance with the CBD's Cartagena Biosafety Protocol.

Source: pers. comm. Mark Rhodes, Director, EHS Strategy and Advocacy, GSK (17 April 2002).

5.2 Examples of benefit-sharing arrangements

This section outlines examples of benefit-sharing arrangements involving the collection and use of genetic resources and associated traditional knowledge by research institutions and companies in the EU. The examples include commercial and non-commercial arrangements.

5.2.1. Non-commercial benefit-sharing arrangements

Research institutions and *ex situ* collections in the EU often maintain a broad portfolio of non-commercial ABS arrangements with a variety of partners around the world. Non-commercial arrangements are executed under a variety of agreements, ranging from informal memoranda of understanding, e.g. between *ex situ* collections, to legally binding ABS agreements between research institutions and the providers of genetic resources and associated traditional knowledge (see Box 6). The benefits shared under these agreements span training, technology transfer, joint fieldwork and research, as well as capacity building for *in situ* and *ex situ* conservation. Box 7 provides examples of collaborative research and benefit-sharing across a range of collaborative activities by the Royal Botanic Gardens, Kew.

Box 6 ABS agreements for non-commercial research

The Millennium Seed Bank at the Royal Botanic Gardens, Kew, UK enters into full Access and Benefit-Sharing Agreements (ABSAs) with source country governments for field collections of both live and herbarium specimens in collaboration with in-country partner institutions. ABSAs are legally binding, signed by appropriate government agencies as well as project partners. ABSAs include specific terms on benefit-sharing including bilateral research, training and capacity-building (see Box 7). RBG Kew has also set up Memoranda of Understanding with key partner institutions. MoUs are non-legally binding agreements, setting out the general terms of conditions of collaboration. MoUs are generally used for taxonomic research involving Herbarium specimens and not for living material. Both ABSAs and MoUs complement the Principles on access to genetic resources and benefit-sharing for participating institutions (see Box 1).

Other research institutions and *ex situ* collections make use of similar agreements. For example, the Netherlands Centre for Genetic Resources (CGN) maintains a back-up collection of rice accessions under a MoU with the Rokupr Rice Research Station in Sierra Leone. CGN is also party to agreements concluded with SEARICE (the Philippines) and Can Tho University (Vietnam) for molecular analysis of farmers' varieties of rice. These agreements specify the conditions under which CGN acquired material and, in the case of SEARICE, includes PIC from the communities concerned. In addition, CGN has concluded Material Acquisition Agreements with government officials in Uzbekistan and Kyrgyzstan for an international multi-crop collecting mission.

Sources: (i) CBD Implementation Unit, Conventions and Policy Section, RBG Kew; and (ii) pers. comm. Bert Visser, Centre for Genetic Resources the Netherlands (20 February and 6 May 2002).

Box 7 Examples of collaborative research and benefit-sharing by the Royal Botanic Gardens, Kew

COUNTRY/Initiative	Partners	Dates	Project description	Collaborative research and benefit-sharing
The Millennium Seed Bank CBD-compliant Material Acquisition Agreements with partner countries	A wide range of public and semi-autonomous seed banks, botanical institutions and universities supported by prior informed consent from relevant national governments in 12 countries (Australia, Burkina Faso, Chile, Egypt, Jordan, Kenya, Lebanon, Madagascar, Mexico, Namibia, South Africa, USA)	2000-	Aims to collect and conserve 10% of the world's seed-bearing flora (principally from drylands) by 2010. Works by means of bilateral research, training and capacity-building relationships world-wide.	Assisting partners to meet their CBD obligations; directly addressing country priorities in National Biodiversity Strategy Action Plans (NBSAPs); collaborative collecting programmes; strengthening of in-country capacity (infrastructure). Wide range of seed conservation services offered to international partners: long-term duplicate storage of seeds, with secure funding; access to MSB research laboratories for collaborative research on seed conservation issues, and complementary facilities at RBG Kew (Herbarium & library, SEPASAL database); coordinated data-exchange with partners within one-country projects, and favoured access by partners to many results from wider strategic research and conservation work; formal courses in seed conservation techniques, as part of the International Diploma in Plant Conservation Techniques; post-graduate training opportunities at MSc, MPhil and PhD level; focused in-country workshops
BRAZIL Plantas do Nordeste	Associação Plantas do Nordeste, a consortium of research and teaching institutes in NE Brazil, University of São Paulo, Brazilian and UK governments	1992-	Multidisciplinary research programme contributing to the identification and sustainable use of plant resources in Northeast Brazil. Aims to generate, mobilise and update high quality information on plant species, their uses, distributions and ecological characteristics, fundamental for carrying out effective practical measures on biodiversity conservation and sustainable development.	RBG Kew involvement includes: an information dissemination and training project (including repatriation of information from Kew databases); a herbarium specimen data and image repatriation scheme at Kew; collaborative field surveys and conservation monitoring; production of Floras, florulas, checklists and online databases; development of a sustainable fuelwood utilisation project and survey of forage grasses; supervision of PhD research and participation in postgraduate training programmes
CAMEROON Conservation of Plant Diversity in Western Cameroon	National Herbarium of Cameroon; Earthwatch; NGOs including Bamenda Highlands Forest Project; Kilum Ijim Forest Project	1996-	Aims to survey the flora of Western Cameroon, provide information to conservation bodies and resource planners, and support and strengthen the National Herbarium of Cameroon as a centre for plant biodiversity assessment and taxonomic research	Joint collecting expeditions, production of conservation checklists including red data assessments, species database and specimen databases, training workshops on plant identification and inventory techniques, Kew diploma course on Herbarium Techniques taught at the National Herbarium, and repatriation to the National Herbarium of data and images of historical Cameroon specimens at RBG Kew
INDONESIA Papuan Plant Diversity Project	Universitas Negeri Papua	2001-2004	Aims to restore and expand the Herbarium at Manokwari, increase self-sufficiency by establishing cadre of highly motivated botanists trained to develop and maintain the collections, build plant diversity research and conservation capacity and initiate collaborative links with relevant institutions (including those in Papua New Guinea).	Herbarium renovation, acquisition of material, and establishment of collections database; specimen naming and repatriation of data at RBG Kew by UK project co-ordinator; study visits to RBG Kew and between Manokwari and Papua New Guinea, participation in international meetings and publications in peer-reviewed journals by staff, leading to development of independent and collaborative research on Papuan plant diversity; university lectures, field trips, workshops and Kew diploma course in Herbarium Techniques in Papua; production of field guides to palms and seed plant families
MADAGASCAR CBD-compliant Protocol covering all current projects	Ministry of Higher Education; L'Association Nationale pour La Gestion des Aires Protégées; FJKM/SAF; Ministère de la Recherche Scientifique**;** Projet d'Appui aux Exportations Agriccoles de la Coopération Française; Projet Masoala; Recherches Forestières et Piscicoles, Antananarivo (TEF); WWF Madagascar; Silo National des Graines Forestières (SNGF) ; **USA** Missouri Botanical Garden ; **France** Muséum National d'Histoire Naturelle Paris ; **Belgium** The National Botanical Gardens of Belgium	2001-	Current taxonomic research projects in Madagascar aim to produce systematic revisions of five major but poorly known plant groups of high species diversity and develop systematic research capacity of partners Threatened Plants Appeal project aims to conserve highly threatened species (focus on palms, orchids and succulents) in collaboration with a range of Malagasy partner institutions and to build capacity for conservation and sustainable use	Outputs include joint fieldwork, training in species inventory skills, collaborative production of checklists, identification keys and generic accounts with conservation ratings; and intensive training of PhD and MSc students Joint field surveys and monitoring, development and improvement of national and local collections and capacity for *in situ* and *ex situ* conservation, joint development of cultivation protocols, training in ecological requirements of native species, practical conservation, and horticulture

5.2.2. Commercial benefit-sharing arrangements

The commercialisation of a natural product is likely to involve a number of institutions, and different types of benefit may be generated at different stages of the R&D process. A company responsible for the final development and sales of a product may not directly transact with the original providers of a genetic resource or associated traditional knowledge. Rather, it may work through an intermediary institution responsible for field collections, research and discovery, e.g. an *ex situ* collection, university or a commercial laboratory. Benefits reach providers through a chain of licensing and other agreements (see Boxes 8 and 9) and, in some cases, through mechanisms such as trust funds (see Box 10).

Box 8 GlaxoSmithKline and Extracta Laboratories, Brazil

GlaxoSmithKline (GSK) works under a collaborative research agreement with Extracta Laboratories in Brazil. Established in 1999, the project has identified eight targets of interest indigenous to the Amazon Rainforest. These are currently being screened against therapy areas of relevance to the region, in an Extracta Laboratory in Rio de Janeiro. Research and "milestone" payments (totalling a potential pay-out of several million pounds) have been written into the three-year contract between GSK and Extracta. If any of the candidates identified are subsequently commercialised by GSK, Extracta will in addition receive a percentage of the net profits from sales. Technology transfer underpins the deal. GSK has provided the cell-lines for Extracta's screening programmes and a number of Brazilian scientists have undertaken secondments to GSK R&D facilities in the UK as part of the agreement. However it was *also* agreed that Extracta had to have in place legally binding contracts with their suppliers. These provide for agreed rates of return, not only for collection, but also in the event of a sample becoming or leading to the launch of a new drug. Suppliers of biological material to Extracta include government organisations, academia and local communities.

Source: pers. comm. Mark Rhodes, Director, EHS Strategy and Advocacy, GSK (17 April 2002).

Box 9 Use of San traditional knowledge in the commercialisation of *Hoodia*

This case involves a UK-based biopharmaceutical company Phytopharm plc. As with GSK in the Extracta case (Box 8), the company remains at arm's length from the negotiation of benefit-sharing with the original providers of traditional knowledge.

For thousands of years, the San (bushmen) of the Kalahari have used species of the succulent *Hoodia* genus (*Asclepiadaceae*) to stave off hunger and thirst. In the 1970s, as part of wider research into traditional uses of local species, the South African Council for Scientific and Industrial Research (CSIR) began investigating *Hoodia*. The CSIR is one of the largest research organisations in Africa, performing 12% of all industrial R&D on the continent; 40% of its funding comes from government, and 60% from clients.

At the time of collections, the CSIR did not sign an agreement with the San. CSIR isolated an appetite-suppressing compound known as P57 from the plant and, in 1998, signed a licensing agreement with Phytopharm plc. Soon after, Phytopharm licensed the further development of P57 to the US pharmaceutical company Pfizer, in return for $32 million in license fees and milestone payments. Although CSIR stood to benefit from laboratory facilities as well as milestone and royalty payments under its agreement with Phytopharm, no arrangement was yet in place to benefit the San for their traditional knowledge.

Following protests in 2001 and five months of talks, the San have now entered into a Memorandum of Understanding with CSIR – the original collector. This acknowledges the need to provide benefits for the use of traditional knowledge should a commercial product be developed, but does not include specific details of this benefit-sharing package. The MOU acts as the basis for negotiation and most importantly recognises the San as the originators and custodians of traditional knowledge associated with the use of *Hoodia*. It is considered a first step towards reaching a full agreement, which is hoped to be in place by September 2002. Benefits under negotiation between the CSIR and the San include royalties, bursaries, jobs derived from large-scale cultivation and raw material sourcing, and exchange of knowledge.

Sources: (i) Barnett, Antony, 2001, *In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin*, Observer, 17 June 2001; (ii) Kahn, Tamar. 2002. *Prickly Dispute Finally Laid to Rest: San reach Agreement with CSIR over Use of Appetite-Suppressing Cactus*, Business Day, Johannesburg, Opinion, March 22, 2002; (iii) John Madeley on the Bushmen's battle with business over a diet pill made from a Kalahari plant, Financial Times, December 1, 2001; (iv) Wynberg, Rachel. 2002. 'Institutional Response to Benefit-Sharing in South Africa'. In Laird, SA (ed) *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*. Earthscan, London; (iv) Wynberg, Rachel. In press. *Drugs from the Desert: Spreading the Benefits from Bioprospecting*; (v) ten Kate, Kerry and Sarah Laird, forthcoming.

Box 10 Benefit-sharing by the International Locust Control Programme, *Lutte Biologique contre les Locustes et les Sauteriaux* (LUBILOSA)

The case outlines the development and commercialisation of a biological pest control product, and associated benefit-sharing mechanisms, within the framework of a multilateral programme spanning African and European partners.

In 1989, an international, collaborative research programme, Lutte Biologique contre les Locustes et les Sauteriaux (LUBILOSA), was formed to investigate environmentally-safe and target-specific biological locust control. LUBILOSA's work focused on isolates of insect-killing *Metarhizium* fungi, some of which target locusts and grasshoppers. The LUBILOSA programme was funded over twelve years by four donor agencies including the British Department for International Development (DfID) and the Canadian (CIDA), Swiss (SDC) and Netherlands (DGIS) development agencies. LUBILOSA is co-ordinated by CABI Bioscience – an intergovernmental, not-for-profit organisation headquartered in the UK. The partnership also involved the German development agency Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), the Comité Inter-Etats pour la Lutte contre la Secheresse dan le Sahel (CILSS) and the International Institute of Tropical Agriculture (an International Agricultural Research Centre) based in Benin.

The discovery process involved the collection and screening of 180 samples of *Metarhizium* fungi from locusts and grasshoppers across Africa, leading to the discovery of an especially virulent strain of *Metarhizium anispoliae* var *acridum* from Niger, subsequently labelled IMI 330189. This was chosen for further evaluation. In 1991, CABI Bioscience filed a UK patent on an oil-based suspension formulation of IMI 330189 for ultra-low volume spraying. Efficacy trials were conducted in 12 African countries including Niger, Benin, Mali and South Africa. In Niger, participatory trials were conducted with local farmers, and their response to IMI330189 was assessed in collaboration with local development NGOs. Ecotoxological trials were conducted in collaboration with the South African Plant Protection Research Institute (PPRI) as well as by GTZ scientists in Mauritania.

Following evaluation and recommendation of IMI 330189 by the FAO Pesticides Referee Group, LUBILOSA has developed a 'two-technology' approach to production in order to meet future demand. The first involves the use of locally-available, 'intermediate' technology, as piloted at IITA in Benin. But in light of estimates that sufficient quantities of the biopesticide were needed to cover 50,000ha per year, LUBILOSA also sought a private-sector licensee to expand production beyond the Benin plant. In 1998, LUBILOSA entered into an exclusive licensing agreement with Biological Control Products SA (Pty) Ltd (BCP), a South African biopesticide company, to produce and market IMI 330189 in member states of the Southern African Development Community (SADC). In 1998, BSP successfully registered IMI 330189 in South Africa under the trademark Green Muscle®. Green Muscle has subsequently been registered for use in the Sahel, and negotiations have been initiated for production for the West African market.

Although initial collection work had not taken place under formal ABS agreements, LUBILOSA has generated a number of benefits which are shared amongst the programmes' African and European partners. These include:

- access to myco-insecticide technology;
- royalties generated from the sale of Green Muscle;
- capacity building through LUBILOSA's collaborative research and training programme;
- research funding;
- environmental safety; and,
- benefits to farmers.

With respect to royalty sharing, a Green Muscle Trust Fund (GMTF) has been established in South Africa by BCP and CABI Bioscience (acting on behalf of LUBILOSA). One-third of the 7.5% royalty levied by LUBILOSA on BCP's sales of Green Muscle will be paid into the GMTF and reinvested to build capacity in biopesticides research, development and manufacture by South African institutions. 5% of the sales of any product developed with the support of a GMTF grant will accrue to the Fund. A further 2.5% of royalties on sales of Green Muscle in other SADC countries accrue to a separate, pan-African trust fund (the LUBILOSA Trust Fund).

The LUBILOSA Trust Fund was established alongside the GMTF to ensure the fair sharing of benefits among the various African countries that have contributed to the development of Green Muscle, including Niger. The remaining two-thirds of the 7.5% royalty levied by LUBILOSA on BCP's sales of Green Muscle will accrue to this trust fund to support the development and use of biopesticides across Africa. A proportion of royalties levied on sales of Green Muscle by commercial licensors in other parts of Africa will also accrue to this fund.

Source: pers comm. Dr David Dent, CABI Bioscience (17 June 2002); ten Kate, K. and S.A. Laird (1999), *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit-Sharing*. Earthscan, London. Pages 217 – 224.