Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Final report - Annexes

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[1] Please note that the country studies have been conducted in the second half of 2011 and have not been updated since then. Therefore the country studies may not take into account recent legislative and policy developments in the countries studied.

ANNEX 1: COUNTRY REPORTS: EU MEMBER STATES

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Belgium

1 INTRODUCTION

Belgium is primarily a user country, as genetic resources are primordial to keep its leading role in the international pharmaceutical trade. The country is the world's third largest importing country of biopharmaceutical products and the world's one-but-largest exporter (UN Comtrade, 2010). The biopharmaceutical sector is thus a major player in the Belgian economy. It provides the country with more than 30,000 jobs and accounts for up to 40% of private R&D funding. The sector is strongly dependent of international activities and international transfer of genetic resources. Belgium also has a considerable market share in horticulture products and roughly exports 4 to 5% of the world's agricultural products.[2] Its prime location in the heart of Western Europe and the importance of the port of Antwerp, in the north of the country, make it an excellent global trans-shipment station.

The Belgian situation is particularly complex since most competences relating to biodiversity and territorial issues are scattered around the Federal Government, the Regions and the Communities. The three Regions (Flemish Region, Walloon Region and Brussels Capital Region) have the greatest responsibility in biodiversity-related issues, as they are in charge of territorial matters. The Federal Government pilots the international dimension, even though the three regions each provide a regional focal point to the CBD. The three Communities are responsible for culture, research, education and public awareness. For international environmental matters, these different levels coordinate through the Coordinating Committee for International Environment Policy (CCIEP).

In the 1980s, the Belgian Government created the Belgian Co-ordinated Collections of Micro-organisms (BCCM), which now comprises seven Belgian biological resource centres (BRC)[3]. In 1992, the BCCM obtained the International Depositary Authority (IDA) status from

[2] http://www.fas.usda.gov/gainfiles/200501/146118432.pdf

[3] The collection of fungi and yeasts of biomedical importance (BCCM/IHEM) of the Mycology Laboratory (Scientific Institute of Public Health); the collection of fungi and yeasts of agro-industrial importance (BCCM/MUCL) (Université Catholique de Louvain); the bacteria collection (BCCM/LMG) of the Laboratory for Microbiology (Ghent University); the plasmid collection (BCCM/LMBP) of the Laboratory of Molecular Biology (Ghent University); the Diatoms Collection (BCCM/DCG) of the Laboratory for Protistology & Aquatic Ecology (Gent University); the Mycobacteria Collection (BCCM/ITM) of the Mycobacteriology Unit (Institute

the World Intellectual Property Organisation (WIPO), created under the Budapest Treaty to allow for deposits of microorganisms to be recognized as internationally patented. Other important public gene banks operate outside of the BCCM, like the National Botanic Garden of Belgium and the Walloon Agricultural Research Centre.[4]

Belgium ratified the CBD in 1996, after ratification by the three Regions, the three Communities, the federal Parliament and the federal Senate. The Convention entered into force for Belgium in 1997. FAO's International Treaty of Plant Genetic Resources for Food and Agriculture (IT-PGRFA) has been ratified in 2005.

Belgium signed the Nagoya Protocol (hereafter, 'the Protocol') on 20 September 2011. The implementation and ratification of the Protocol is a high political priority for Belgium. Belgium aims to be a Party at the first Meeting of the Parties (MoP). To prepare for implementation of the Protocol, the Belgian federal state together with the three regional authorities has commissioned a study on the implementation of the Protocol. These authorities are in this respect represented by their respective environment ministries. The study, which is expected to kick-off in December 2011 and to take eight months, aims to identify and evaluate the potential consequences for the internal Belgian legislative and other rules resulting from the signing and ratification of the Protocol. Implementation in Belgium includes implementation at the level of the Federal State and the level of the Communities and Regions. An advisory committee, consisting of representatives of the federal and regional environmental ministries, has been established to award, advise and supervise the study. Prior to this study, it had already carried out a first screening of potentially relevant legislative and other measures.

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

Within Belgium currently no legislation exists with respect to access and benefit sharing (ABS). Policy measures are broadly limited to informing stakeholders about ABS and developing voluntary codes of conduct.

2.1.1 User-side legislative and policy measures

Belgium has not introduced comprehensive legislation concerning ABS. A federal law of 28 April 2005 amending the patent law of 18 March 1984 and transposing Directive 98/44/EC on the legal protection of biotechnological inventions (the biopatents Directive) is the only Belgian legislative instrument that specifically takes into consideration the CBD's provisions

of Tropical Medicine); the Polar cyanobacteria Collection (BCCM/ULC) of the Centre for Protein Engineering (University of Liège).

[4] http://www.cra.wallonie.be

on ABS.[5] Whereas the Directive only encourages the recognition of the geographical origin of biological material used in biotechnological inventions on patent applications, the Belgian law goes a little bit further as it introduces a formal requirement for disclosure of geographical origin, if it is known. In theory, non-compliance with this requirement could result in the patent application not being processed. In practice, however, the Belgian patent office does not check compliance with this requirement as it does not have the authority to do so. The law foresees the further elaboration of this provision through implementing measures, but these have never been adopted. As a result, it is unlikely that an application will not be handled because of a failure to disclose the origin of the genetic resources involved or because the information submitted is wrong (Hoare and Tarasofsky, 2006; Richerzhagen, 2010; Van Overwalle, 2005).

Belgium does not have any measures in place to ensure that genetic resources used within in its jurisdiction have been accessed in accordance with prior informed consent (PIC) or that mutually agreed terms (MAT) have been established, where required by provider countries. Nevertheless, some other user-related measures have been taken.

In 2006 the Government adopted the National Biodiversity Strategy 2006-2016, a document spelling out a range of 15 strategic objectives and 78 operational objectives that aim to reduce and prevent the causes of biodiversity loss. Strategic objective 6 wants to contribute to an equitable access to and sharing of benefits arising from the use of genetic resources by building national capacity and implement the Bonn Guidelines on ABS (CCIEP, 2006).

In parallel, the Government ordered a study to assess the awareness of Belgian users concerning the CBD and the level of implementation of ABS dispositions and the Bonn Guidelines in their activities. The main results indicate that the Convention is better known in upstream activities (e.g. fundamental research) than in downstream activities (e.g. commercial products). Collections and research sectors, both private and public, have a good understanding of the CBD, while other sectors, predominantly composed of private actors, have little or no knowledge. Concerning the implementation of ABS dispositions, the report shows that PIC-related dispositions seem to be relatively widespread, whereas benefit-sharing provisions are nearly inexistent. When benefit-sharing does occur, it mostly implies research cooperation with the providing country (Frison and Dedeurwaerdere, 2006).

In 2010 the federal Belgian government adopted the Federal Plan for the integration of biodiversity in four key sectors. ABS-actions within the plan are mainly focused on awareness-raising and capacity building of the private sector. However, the implementation of these actions has been delayed because of the international negotiations on the Protocol. These actions include the organization of biodiversity training sessions for four target groups concerned with the implementation of the sections ‘economy’ and ‘transport’. One of these target groups is the Federal Ministry of Economy, in particular DG market

[5] Wet van 28 april 2005 tot wijziging van de wet van 28 maart 1984 op de uitvindingsoctrooien, wat betreft de octrooieerbaarheid van de biotechnologische uitvindingen, B.S. 13 mei 2005.

regulation, *inter alia* people dealing with intellectual property issues. The training sessions for this specific target group will address the concept of ABS and provide information on the Protocol and its implications in Belgium. The training sessions are due for 2012 (EU, 2011). However, first priority right now for the Belgian governments is the study on the implementation of the Protocol.

Since the adoption of the Protocol, Belgium has informed and consulted the different stakeholders on the implications of the Protocol through the organisation of a stakeholder workshop in the summer of 2011. Belgium will continue and step up these efforts, amongst other in the framework of its impact study on the implementation of the Protocol. As part of this impact study two stakeholder workshops will be organised during the first half of 2012. The aim of the workshops is to identify the wide range of stakeholders concerned with the implementation of the Protocol in Belgium, to make them aware of the content of the Protocol and its obligations, and to give stakeholders the possibility to explain how they think the implementation of the Protocol will affect them (EU, 2011).

As the Government does not consider the country to be hosting indigenous and local communities that fall within the definition of the CBD, there are no policies regarding traditional knowledge (CCIEP, 2006). However, although it is not directly related to ABS, support to help indigenous communities in developing countries implement the Convention on Biological Diversity has been carried out, from 2003 to 2007, by a convention between the Royal Belgian Institute of Natural Sciences and the Federal Directorate-General for Development Cooperation. The convention has been renewed in 2008 and runs until 2012.[6]

2.1.2 Provider-side legislative and policy measures

Belgium has no comprehensive legislation and policies on access to its genetic resources. Nevertheless, some related provider-side policy measures have been taken.

A team at the Belgian Science Policy Office (BELSPO) coordinates the activities of the Belgian Co-ordinated Collections of Micro-organisms (BCCM). Under the auspices of BCCM, a voluntary code of conduct to facilitate access to microbial genetic resources has been developed. BCCM also developed a Material Transfer Agreement for accessing the resources from its public collection. See section 3 for more details on these and other initiatives.

The Belgian Science Policy Office (BELSPO), together with the Ghent University, developed a pilot project using bioinformatics tools (web crawlers and search engines) to access and make available data and information stored in 60 biological resource centres worldwide.[7] A standard format to allow for culture collection catalogue information to be exchanged easily has also been developed. Strains cannot be accessed directly through the common catalogue.

[6] http://www.biodiv.be/info0405/activities/
[7] http://www.straininfo.net

Over the last 15 years Belgium made quite some efforts in raising the awareness of the importance of autochthonous genetic resources of bushes and trees. The Flemish Agency for Nature and Forests organized conferences and workshops and developed study material for different government agencies, local administrations and forest owners on the importance of autochthonous genetic bush and tree material, and on possible measures and initiatives to protect these (EU, 2011).

2.2 Other relevant national legislation

The advisory committee for the Belgian impact assessment study (see above) has carried out a first screening of potentially relevant legislative and administrative measures. Many of these measures do transpose the EU legislation listed in section 5 of the main report such as the biopatents Directives, on the placing on the market of products of biotechnology, pharmaceuticals and cosmetics and seeds, on the use of reproductive material in forestry, and on plant and animal health and breeding. Most of these measures have been taken at the regional level, except for the federal law of 28 April 2005 amending the patent law of 18 March 1984 (see above).

The list (resulting from the first screening) also includes federal and regional legislative/administrative measures on nature protection and sustainable use of components of biodiversity such as:

- Flemish Decree of 21 October 1997 on nature conservation and the natural environment and subsequent implementing decisions;[8]
- Decision of the Flemish Government of 15 May 2009 on species protection and species management (includes for instance provisions regarding ban on collecting species);[9]
- Flemish Hunting Decree of 24 July 1991 and subsequent implementing decisions;
- Decision of the Flemish Government on the implementation of the law of 1 July 1954 on river fishing;[10]
- Decision of the Walloon Government of 27 November 2003 determining exemptions to the bird protection measures;[11]
- Decision of the Walloon Government of 20 November 2003 determining exemptions to animal and plant species protection measures;[12]
- Decision of the Walloon Government of 24 July 2003 concerning the modalities of the collection and analysis of biological data on Walloon populations of wild animal and plant species and natural habitats;[13]

[8] Decreet van 21 oktober 1997 betreffende het natuurbehoud en het natuurlijk milieu.

[9] Besluit van de Vlaamse Regering van 15 mei 2009 met betrekking tot soortenbescherming en soortenbeheer.

[10] Besluit van de Vlaamse Regering van 5 mei 1992 tot uitvoering van de wet van 1 juli 1954 op de riviervisserij.

[11] Arrêté du Gouvernement wallon de 27 novembre 2003 fixant des dérogations aux mesures de protection des oiseaux.

[12] Arrêté du Gouvernement wallon de 20 novembre 2003 relatif à l'octroi de dérogations aux mesures de protection des espèces animales et végétales, à l'exception des oiseaux.

[13] Arrêté du Gouvernement wallon de 24 juillet 2003 relatif aux modalités de récolte et d'analyse des données biologiques sur les populations wallonnes des espèces animales et végétales sauvages et des habitats naturels.

- Federal Law of 22 April 1999 concerning Belgium's Exclusive Economic Zone in the North Sea;[14]
- Federal Law of 22 January 1999 concerning the protection of the marine environment in marine areas within Belgium's jurisdiction.[15]

3 NATIONAL ABS PRACTICES

3.1 Belgian research institutions' practices and policies on ABS

In 1997 the BCCM launched the 'Micro-organisms Sustainable Use and Access Regulation International Code of Conduct' (MOSAICC) initiative. MOSAICC is a voluntary code of conduct to facilitate access to microbial genetic resources in line with the CBD, the TRIPS Agreement and other applicable national and international law, and to ensure that the transfer of material takes place under appropriate agreements between partners and is monitored to secure benefit-sharing (European Community, 2002).

In 2004, a consortium of 15 microbiological resources providers and users, coordinated by BCCM, launched the MOSAICS project.[16] MOSAICS stands for 'Microorganisms Sustainable use and Access management Integrated Conveyance System'. It is funded by the European Commission (DG Research), under the Sixth Framework Program. The consortium includes partners from developed and developing countries, including culture collections, international organizations, branch federations and specialized research institutes. The project aims to give an answer to questions from culture collections on how to implement the various international and national rules regulating the flows and uses of biological resources, from the CBD to the application of intellectual property rights. It aims in particular to develop an integrated conveyance system that has reliable tools to evaluate the economic value of microbiological resources; that disposes of validated model documents with standard provisions to enable tracking via an uncomplicated procedure, widely applied by microbiologists; and, that combines valuation and tracking in one system for trading of microbiological resources, with balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

BCCM uses the general BCCM Material Transfer Agreement (MTA) for getting access to the genetic resources of its public collection.[17] If necessary the MTA can be amended with additional conditions possibly already attached to the biological material. The resources are distributed for a fee covering expenses. The MTA stipulates that anyone seeking to access genetic resources hold by the BCCM has the responsibility to obtain any intellectual property licenses necessary for its use and agrees, in advance of such use, to negotiate in good faith with the intellectual property rights owners to establish the terms of a commercial license.

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[14] Loi de 22 avril 1999 concernant la zone économique exclusive de la Belgique en mer du Nord.

[15] Loi de 22 janvier 1999 visant la protection du milieu marin dans les espaces marins sous juridiction de la Belgique.

[16] http://bccm.belspo.be/projects/mosaics/description.php

[17] http://bccm.belspo.be/services/bccm_mta.php

The National Botanic Garden of Belgium (NBGB) is member of International Plant Exchange Network (IPEN), a network of Botanic Gardens that organises the exchange of living plant specimens. Under the auspices of IPEN and the Royal Botanic Gardens, Kew 'Principles on Access to Genetic Resources and Benefit-Sharing for Participating Institutions' have been developed.

The NBGB and BCCM are discussing the compatibility of their respective approaches.

A general problem Belgian *ex situ* collections such as the NBGB are confronted with is the *de jure* and/or *de facto* absence of national competent authorities in biodiversity-rich countries in the South.

3.2 Company practices and policies on ABS

No corporate policies or practices on ABS have been identified in Belgium so far, neither by the authors of this study nor by the Belgian ABS officials. This could confirm the findings of the 2006 study on the awareness of Belgian genetic resource users indicating that a large majority of private users have little knowledge of the CBD and related topics.

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5 INTERVIEWEES

Delphine Perremans, Biodiversity Expert, Multilateral and Strategic Affairs, Federal Public Service Health, Food Chain Security and Environment, DG Environment, 8 December 2011, Brussels.

Leen Chanet, Legal Policy Officer European and International Environmental Policy, Flemish Environment, Nature and Energy Department, 8 December 2011, Brussels.

Dries Van Eeckhoutte, Legal Policy Officer European and International Environmental Policy, Flemish Environment, Nature and Energy Department, 8 December 2011, Brussels.

Yanne Goossens, Flemish Environment, Nature and Energy Department, 8 December 2011, Brussels.

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Bulgaria

1 INTRODUCTION

Bulgaria is a country that enjoys a comparatively high rate of biological diversity with endemic species representing approximately 5% of vascular plants and 8.8% of vertebrates (CBD, n.d.). Bulgaria's biodiversity includes species and genetic resources, which are widely used for commercial or non-commercial purposes and have economic and environmental importance. Economically important plants and animals include wood forest species, sea and freshwater fish, 200 species of edible mushrooms and several hundred local medicinal plants. Additionally, Bulgaria is home to many traditional and rare cultivars and breeds as well as many wild relatives of cultivated species. There is traditional knowledge regarding both native sorts of agricultural cultures and aborigine breeds of farm animals. Genetic resources (plant and animal) are conserved both *in situ* (i.e. in their natural environment) or *ex situ* (.i.e. under controlled conditions), for example, vivariums, zoological or botanical gardens, dendrariums, live collections, creating banks of seeds, pollen, gametes, embryos, tissue and cell cultures as well (MEW, n.d.).

Bulgaria signed the Nagoya Protocol (hereafter, 'the Protocol') on 23 June 2011. Preparations for its ratification have already begun. Overall, it is envisioned to be carried out in close alignment to the respective legislative process at European level. The existing legislative framework in Bulgaria addresses to some extent the access to certain genetic resources. It needs, however, to be further developed and better coordinated with related policies concerning medicinal plants, forestry products, patents, etc.

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

General provisions arranging the main principles, objectives and measures for the conservation of biological diversity are laid down in the Bulgarian Environmental Protection Act, adopted in 2002[18], while specific provisions concerning biological diversity and the protection of genetic resources are stipulated in the Biological Diversity Act (BDA), also

[18] Environmental Protection Act, Promulgated in State Gazette No. 91/25.09.2002, Corrected, SG No. 96/2002

adopted in 2002.[19] The latter provides a rather generic definition of genetic resources, which states that genetic resources are "*genetic material with real or potential value*". The Protected Areas Act[20] provides also a definition of 'genetic resources' which is somewhat more detailed, i.e. "*materials of plant, microbial or animal origin that contain functional units of heredity and have a real or potential value*."

The BDA lays down provisions governing the *ex situ* conservation of plant and animal species. Section VIII, Art 58(1) and 58(2), prescribes that *ex situ* conservation is carried out through:

- The cultivation and breeding of animals and plants under controlled conditions in the vivarium, zoological or botanical gardens, arboretum, living collections and centres for the propagation and breeding of protected species; and
- The establishment of "seed banks, pollen gametes, embryos, tissue and cell cultures and other collections for preservation of plant and animal genetic resources under special conditions".

According to the law, the *ex situ* conservation is carried out by scientific organisations, legal entities and individuals in compliance with a list of legally binding requirements specified in Art 60(2). The Ministry of Environment and Water keeps a register of organizations and individuals who possess and maintain collections of wild species of local and foreign flora and fauna while the Ministry of Agriculture and Food maintains an institutional registry of organizations and individuals who possess and maintain collections of cultural species of flora and fauna as well as specialized collections of wild tree and shrub species or types of hunting species by local or foreign flora and fauna. Specialized agencies that create and maintain national collections are determined by the Council of Ministers when they carry out and/or coordinate activities of national or international programs related to genetic resources and also when the collections are intended to protect and maintain significant taxonomic diversity of world flora and fauna. The Law does not however provide further provisions regulating the access to and sharing of benefits from these collections.

2.1.1 Provider-side legislative and policy measures

Bulgaria has some provider legislation in place. The BDA in particular contains some provisions on access to Bulgaria's genetic resources.

Art 66(2) of the BDA prescribes that the access to genetic resources shall be granted in compliance with this Act while in the case of resources protected by a patent or any other intellectual property rights – the rules of the respective legislation shall apply. Art 66 (3) stipulates that genetic resources can be used by other countries "*on the basis of advance agreement in writing on the terms and manner of sharing the benefits arising from such transfer under mutually advantageous terms including:*

[19] Biological Diversity Act, Promulgated in State Gazette No. 77/9.08.2002, Last amended in State Gazette No. 19 / 8.03.2011

[20] Protected Areas Act, Promulgated in State Gazette No. 133 / 11.11.1998, last amended on 8.03.2011, entered in to force on 9.04.2011

1. *citation of the natural origin of the material;*
2. *provision by the State user of results of research and technologies obtained from, related to, or derived from the said resources;*
3. *recovery of part of the resources obtained in use of the material, as well as of derivatives or studies for commercial purposes; and*
4. *participation in joint scientific studies*."

The law envisions the *'gratuitous'* provision of genetic resources for non-commercial purposes, which are set to include scientific research, education, conservation of biological diversity and public health. Scientific research is treated in the BDA as a non-commercial activity, which is not the case in other countries which take into account the fact that it can produce commercially usable results. The use of the materials by a third party is also to be regulated by the procedure outlined above. The BDA further stipulates that the specific terms and procedures for the provision of access to genetic resources shall be established by a regulation adopted by the Council of Ministers. Such regulation, however, is not yet adopted.

The Bulgarian government adopted the BDA in 2002 as a direct result of the ratification of the Convention on Biological Diversity (CBD). Art 66 of the BDA governing ABS was included in the BDA since its very first draft in 2002 but has not been further developed in subsequent legislation or implementing measures. According to some, the prescribed provisions governing the access by other countries (Art 66(3)) are formulated quite explicitly while the rest of the provisions (i.e. Art 66 (2), (4) and (5) are vaguer and could be subject to different interpretations (MEW *et al.,* 2003). Others, however, have stressed that this is *"[o]ne of the most clear intentions to regulate access to genetic"* in Europe (CISDL, 2005).

The Ministry of Environment and Water considers that the provisions in Art 66 in their current state are insufficient to regulate the access and benefit sharing of genetic resources in view of the obligations stemming from the ABS Protocol. It is envisioned that the BDA will be amended and include a separate Section, dedicated specifically to ABS. This will be accompanied by a regulation adopted by the Council of Ministers (as envisioned in Art 66) which will specify the rules and procedures for access and benefits sharing from genetic resources. It is foreseen that the preparation of this regulation will start fairly soon.

In the meantime, the Ministry of Environment and Waters has instituted bilateral meetings with main stakeholders. These include the Ministry of Agriculture and Food, the Executive Agency for Selection and Reproduction in Animal Breeding, the Executive Agency for Variety Testing, Approbation and Seed Control, the Forestry Executive Agency, the National Centre for the Protection of Public Health, the Patent Office, the Ministry of Foreign Affairs, the National Institute for Plant Genetic Resources at Sadovo and the Bulgarian National Collection for Microorganisms and Cell Cultures. Meetings are also envisioned to be held with pharmaceutical and cosmetic companies, which are among the main 'users' of genetic resources. So far, there has not been any practice of businesses contacting the Ministry of Environmental and Water regarding the access to genetic resources, therefore, the main industry actors need to be yet identified.

There is also an on-going process of establishing an Inter-institutional Coordination Group, which will comprise the different stakeholders listed above. The group will be tasked with nominating competent national authorities and creating national resource centres for genetic resources.

2.1.2 User-side legislative and policy measures

Bulgaria does not have any user-side legislative and policy measures in place. This means no measures have been taken which target users of genetic resources acquired in other countries which fall under the jurisdiction of Bulgaria.

2.2 Institutional framework

Pursuant to COP 5 Decision V/26 which requests that all signatories to the CBD establish a national focal point and one or more competent authorities to take responsibility for ABS arrangements or provide such information within its jurisdiction, Bulgaria has established a national focal point for this purpose, at the **Ministry of Environment and Water**, Biodiversity Department, National Nature Protection Service. Other governmental institutions are also directly engaged, e.g. the Ministry of Agriculture and Forestry and respective Executive Agencies.

Under the **Ministry of Agriculture and Food**, there are two executive agencies that are tasked with the protection and management of genetic resources. The **Executive Agency for Selection and Reproduction in Animal Breeding** is a national coordinator for animal genetic resources which main tasks include:

- assist the Minister of Agriculture and Forestry in implementing the state policy on breeding, management and conservation of genetic resources;
- operate and maintain the national gene bank;
- manage the state for artificial insemination stations and provides services related to reproduction of livestock;
- manage the state laboratories for analysis of qualitative indicators of animal products for the purposes of selection and provides services to farmers, breeding and other organizations;
- manage the National Reference Laboratory for genetic analysis in livestock;
- supervise the activities of breeding and breeding organizations;
- perform other functions assigned by the Minister of Agriculture and Forestry.

The **Executive Agency for Variety Testing, Approbation and Seed Control**, also under the Ministry of Agriculture and Food, is responsible for carrying out control over the manufacturing, preparation, distribution, trade and storage of seeds and planting material and their certification in accordance with the approved methods, schemes and technological quality characteristics. It issues annually an official catalogue of vegetable, fruit trees and vines varieties. It is also responsible for registering new varieties in the catalogues of the European Union and ensuring the full harmonization of national legislation on seeds and seedlings with the EU *acquis*.

2.3 Other relevant national legislation

In Bulgaria, there are a number of national legislative and policy measures (e.g. in the field of conservation and sustainable use of biological resources, agriculture, forestry, etc.) that include provisions relevant to the access genetic resources and sharing the benefit from their use. The degree to which the issue of access and use of genetic resources is arranged however varies considerably depending on the different policy area. Specific legislative Acts that arrange to some extent the access and use of genetic resources include:

- Medicinal Plants Act
- Forestry Act
- Protection of new Plant Varieties and Animal Breeds Act
- Law on Patents and Utility Model Registration
- Animal Husbandry Act
- Hunting and Game Protection Act
- Genetically Modified Organisms Act

The **Medicinal Plants Act**[21] governs the management, conservation and sustainable use of medicinal plants, including the collection of herbs. Article 6 refers specifically to the conservation of medicinal plants by focusing on the protection of biological resources in their natural environment, including the genetic resources, individual specimens plant species populations and ecosystems, including populations. In Bulgaria, there is a long tradition in using medicinal plants to provide efficient remedies for a wide range of diseases. No specific reference to traditional knowledge is, however, made in the Medicinal Plants Act.

The flora of Bulgaria consists of about 3,565 plant species, from which 750 species (21 per cent) are medicinal plants. The number of plants frequently used in the traditional and official medicine amounts to 250-300 species (BBP, n.d.). Many of these plants provide substances that are of significant practical value and cannot be replaced with synthetic alternatives. In Bulgaria, an average of 6,000 tons of herbs is gathered annually, the majority of which are intended for export. Bulgaria is among the leading countries that export medicinal and aromatic plants (UNSTAD COMTRADE, n.d.). As a result of this and other anthropogenic factors, reserves of rare valuable medicinal plants have either been strongly reduced or destroyed (Hardalova *et al.* n.d.).

The access to medicinal plants is therefore regulated in Section III of the Medicinal Plans Act. The gathering of medicinal plants for commercial purposes is allowed on the basis of a permit. The competent authorities under which jurisdiction the different medicinal plans are placed (e.g. municipal administrations, directorates of national parks) should issue licenses that authorise the collection of medicinal plants and the extraction of genetic material from them. The access to and the collection of medicinal plants and genetic material is subject to

[21] Medicinal Plant Act, Promulgated in State Gazette No 29 from 7 April 2000, last amended in State Gazette No 28 from 5 April 2011.

user fees as specified in article 23. A Ministry Decree[22] sets out a fixed rate based on which the fee on the access to medicinal plants is determined in the license. Beside charges for the gathering of herbs, fees are to be paid for the collection of genetic material, which is intended for cultivated growing of medicinal plants or other purposes. The funds collected from these fees are intended to be used for activities specified in the legislation, for example, activities for maintenance and restoration of medicinal plants and their habitats; research and monitoring of medicinal plants; maintenance specialized card register and information system for medicinal plants; cultivation and processing of medicinal plants; and training, publishing educational materials, conferences on medicinal plants. The Minister of Environment and Water executes the control and monitoring of collection of and access to medicinal plants and genetic resources. A map and a register of medicinal plants provide data on the location, boundaries, dimensions, ownership of the deposits, the state of medicinal plants, stock levels and the degree of use of their resources. The medicinal plants, which natural reserves are considered as critically decreased, are declared as protected under the BDA and their collection is prohibited.

A **Forestry Act**[23] has been recently adopted in Bulgaria. It regulates the conservation, management and use of forest areas in Bulgaria and ensures the sustainable management of forest ecosystems. The objectives of this Act include *inter alia* ensuring and maintaining the ecosystem, social and economic functions of forest areas; maintaining biological and landscape diversity and improving the status of populations of species of wild flora and fauna; and the implementation of international and European commitments to conservation of forest habitat. Importantly, the new law includes provisions (Art 117) for the access to non-timber products some of which contain genetic material of value, e.g. seeds, mushrooms, medicinal and aromatic plants. The use of non-timber forest products for commercial purposes is allowed only if this is foreseen in a forest management plan. With regard to medicinal plants, reference is made to the Medicinal Plants Act (see above). The use of mushrooms, berries, medicinal and aromatic plants for non-commercial purposes is carried out free of charge (Art 119). '*Non-commercial purposes'* however are not explicitly defined.

The director of the state enterprise, tasked with the management of forest areas that are public owned, organizes the access and management of non-timber forest products. According to article 120 of the Forestry Act, this includes: granting access and management of non-timber products in compliance with ordinance 95(1); permitting the lease of certain forest areas; and issuing a permit for use of non-timber forest products. The organization of access and use of non-timber products in the first two cases can be based on contracts for the period of 10 years. The contracts should define the type of products to be extracted, the site of their extraction, the price of extraction, the permitted quantities and the methods for their measurement. The conditions governing the use of non-timber forest products in privately owned forest areas are determined by their private owners.

The Forestry Act also regulates the export and import of unprocessed timber material and

[22] Ministry Decree N 94, Promulgated in State Gazette No 46/2000

[23] Forestry Act, promulgated State Gazette N19 from 8 March 2011, entered into force 9 April 2011, last amended in State Gazette N43 from 7 June 2011

wild mushrooms. The export of timber and wild mushrooms is permitted after the issuance of a certificate for export. The certificate is valid for three months from the date of issue. In the case of wild mushrooms, the law determines the necessary documents that the exporter should present in order to receive a certificate. These include: document for the price paid for the collection of non-timber forest products, a lease or an invoice issued by the owner; foreign trade contract and / or invoice; document certifying a paid fee for the certificate; template model of an export certificate completed by the exporter. The Minister of Agriculture and Food or a person authorized by the Minister has the competence to issue or refuse to issue a certificate for export. Denial could be appealed under the Administrative Code.

The **Protection of New Plant Varieties and Animal Breeds Act**[24] has also some relevance to ABS. It regulates the rules and procedures related to the creation, protection and use of new plant varieties and animal breeds. The bodies who participate in the procedure for the protection of new plant varieties include the Executive Agency for Variety Testing, Approbation and Seed Control and the Patent Office of Bulgaria. Plant varieties and animal breeds are protected by a certificate, issued for 30 years for animal breeds as well as tree and vine varieties, and 25 years for all other varieties. For plant varieties the certificate is issued to the physical entity that discovered or developed the new variety and filed first a request for a certificate to the Patent Office. In the case of new animal breeds, the certificate is owned by the Bulgarian state, the Ministry of Agriculture and Food in particular (Art 15). Art 18 arranges the rights of the certificate holder which include: the production or reproduction of new plant varieties and animal breeds; preparation for the purpose of reproduction; sale or other marketing; export; import; and storage.

As indicated in the BDA, in the case of genetic resources protected by a patent or any other intellectual property rights – the rules of the respective legislation shall apply. Art 7a of the Bulgarian **Patent Act**[25] stipulates provisions regulating biotechnologies that are subject to a patent. It prescribes that inventions related to a product consisting of or containing biological material or a method by which is produced, processed or used are patentable. A patent certifies the exclusive right to the invention, which includes the right to use the invention and to dispose of the patent. The use of the invention by others is prohibited without the consent of the patentee. The right to use the invention includes the production; sale; trade with the object of the invention, including import; the use the object of the invention and the application of a patented method. Art 20 however specifies some limitations of the patent protection, *inter alia* the use of the discovery for research and development purposes as well as a one-off preparation of medicines in a pharmacy following doctor's prescription.

The **Animal Husbandry Act**[26] arranges the organization and management of livestock, including the management of genetic resources and their utilization for the production of

[24] Protection of New Plant Varieties and Animal Breeds Act, Promulgated in State Gazette No84 from 4.10.1996, last amended in State Gazette No 30/2006.

[25] Law on Patents and Utility Model Registration, promulgated State Gazette No 27 from 2 April 1993, last amended State Gazette No 19 from 9 March 2010

[26] Animal Husbandry Act, Promulgated in State Gazette No. 65 / 8.08.2000, last amended on 25.01.2011

animal products (Art 1(2). It also arranges the role and responsibilities of the Executive Agency for Selection and Reproduction in Animal Breeding which is in charge of the management of genetic resources and the management of the national gene-bank (see section 2.2).

Hunting and Game Protection Act[27] lays down common provisions which govern *inter alia* the conservation of wildlife, genetic resources and biodiversity with a view to enhance sustainable development of game reserves, the enrichment of the fauna and the preservation of ecological balance in the environment. In order to increase game reserves, maintain game diversity and preserve the gene-bank, game stations for public hunting and game bases for intensive management are being created.

Indirectly, the **Law on Genetically Modified Organisms** (GMOs) relates to genetic resources. It regulates the use of GMOs under controlled conditions, their release in the environment, the sale of GMOs on the market, the transfer of GMO, the import and export as well as the control over the enlisted activities.

3 NATIONAL ABS PRACTICES

In the absence of a developed and coherent regulatory framework on ABS in Bulgaria, there are existing national practices, which seek to arrange the access to genetic resources for non-commercial purposes such as research and scientific investigations. For example, upon requests for access to genetic resources, the Ministry of Environment and Waters issues **official letters** which regulate the granting of access to them. These letters do not include provisions regulating the sharing of benefits because they regulate the access to genetic resources for non-commercial uses. However, it is a common practice to prescribe in the letters that the findings and conclusions from the research and scientific investigations undertaken are made available to environmental authorities at the Ministry. So far, such official letters have been issued upon:

- A request for reproduction of plants, incl. establishing a tissue culture (marsh snowdrop-Leucojum aestivum, haberleya-Haberlea rhodopensis, (Tulipa hageri), Bay Willow (Salix pentandra);
- A request for the export of specimens of wild goats, to help population restoring in the neighbouring country; and
- A request for water sampling to investigate the microbial biodiversity of Black sea.

Further to this, there are scientific bodies and gene banks which are members of various established international and/or European networks and partnerships dealing with access to genetic resources. The access to genetic resources from their collections is therefore consistent with established international practices and Material Transfer Agreements.

The National Institute for Plant Genetic Resources in Sadovo

[27] Hunting and Game Protection Act, promulgated in State Gazette N78 from 26 September 2000, last amended in State Gazette N19 from 8 march 2011

The National Institute for Plant Genetic Resources at Sadovo has been a place for the collection and conservation of plants species from over a century; its collections contain count of 2,900 grain cultures, 410 grain-bean and 2,150 vegetable cultures, gathered from different regions of the country (MEW). There are about 60 animal breeds, majority of which are close relatives to their wild predecessors; 38 of them are endangered. The Institute is a member of the International Plant Exchange Network and adheres to the rules and procedures on access to genetic resources endorsed by the network.

Bulgarian national collection for microorganisms and cell cultures

The BNCMCC is a state-property scientific organisation, founded in 1983. It is an international depositary authority of microbiological objects - maintains over 8000 strains including bacteria, actinomycetes, yeasts, fungi, plasmid-bearing microorganisms, animal and plant viruses, and animal cell cultures. They belong to more than 550 species from 204 genera and most of them could be found only in NBIMCC. The preserved strains are useful for and are applied in education, research investigations, health services, industry and agriculture. It is a member of the European network of centres for biological resources and the European Culture Collections' Organisation (ECCO). The BNCMCC adheres to the 'core' Material Transfer Agreement (MTA), approved by the ECCO board in February 2009, which sets out the traceability, fair and equitable benefit sharing, intellectual property rights, quality, safety and security of the supply of samples from the biological material that ECCO holds in its public collections (ECCO, 2009).

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5 INTERVIEWEES

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European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: France

1 INTRODUCTION

Country profile

France played an active role in the Nagoya Protocol (hereafter, 'the Protocol') negotiations and is more directly concerned with ABS issues than many EU Member States as it is both a user and a provider country. Its main industries making use of genetic resources are found in the pharmaceutical, cosmetic, agro-food, biotechnology and horticulture sectors. Research of genetic resources is conducted both for commercial purposes and by academic and other public research institutions.

The country's primary role as an *in situ* provider of genetic resources concerns its extensive Overseas Territories, where 80% of its biodiversity is located. These straddle three oceanic regions (Atlantic, Pacific, Indian) and two continents (America, Antarctica) and total around 2.6 million inhabitants, with a land surface of about 120,000 km^2 and a marine area of around 10 million km^2. 98% of vertebrate animals and 96% of vascular plants endemic to France are found in the 22% of its territory located overseas (Gargominy, 2003). Valorisation of traditional pharmacopeia and marine biodiversity is one of the pillars for locally-driven economic development in the Overseas Territories, prioritised by the French Government (CIOM, 2009).

Mainland France is also a provider, principally of marine genetic resources harvested in the Mediterranean Basin. In addition, France is a major *ex situ* provider through its extensive collections of wild and domesticated genetic resources.

Several Overseas Territories have indigenous and local communities that are concerned by the implementation of the Protocol as holders of traditional knowledge associated with genetic resources and/or as rights holders on land where genetic resources are located.

Mainland France and its Overseas Territories are bound by the international obligations accepted by France under the CBD and in time, the Protocol, unless expressly provided to the contrary. However, the division of environmental competencies between the national government and the Overseas Territories is complex as the latter have variable and evolving legal status, with regard both to the French State and the EU.

The French State does not have the power to adopt a unified ABS framework applicable to all territories. It has competence for management of natural resources – and may transfer its powers, as appropriate - for the 5 *départements et régions d'outre-mer* (DROM) in which

national law is directly applicable (Guyane, Guadeloupe, Martinique, Réunion and Mayotte) and also for the collectivities of Saint-Martin, Saint-Pierre-et-Miquelon, Clipperton and the French Austral and Antarctic Territories. A future national ABS framework developed by the French State would *a priori* apply to the five DROM and, if expressly provided to this effect, to these four collectivities. In contrast, Nouvelle-Calédonie, Polynésie française, Saint-Barthélemy and Wallis et Futuna are *a priori* free to develop their own ABS frameworks.

From an EU perspective, Guyane, Guadeloupe, Martinique and Réunion are EU Outermost Regions. Six others (all except Saint-Martin, Saint-Barthélemy and Clipperton) have the status of EU Overseas Countries and Territories.

Intention and attitude towards the Nagoya Protocol

France signed the Protocol on 20 September 2011. No date has been set for ratification although it is hoped this can be completed by 2014 i.e. ahead of CBD COP 12.

Protocol implementation is considered a high priority. In May 2011, pursuant to the National Biodiversity Strategy 2011-2020 (SNB 2011), the government made two ABS-related commitments to promote "economic valorisation of biodiversity compatible with the conservation of biodiversity in the Overseas Territories". It undertook to establish a working group to draw up proposals by mid-2012 for a national legal framework on ABS with a view to ratifying the Protocol, and also to support existing or new business clusters in the field of biodiversity. However, this timeline does not imply a target date for adoption of national ABS legislation or for the Protocol ratification by France.

The *Ministère de l'écologie, du développement durable, des transports et du logement* (MEDDTL), as the ABS Focal Point for France, has set up an inter-ministerial working group which meets monthly to guide this process. It comprises representatives of the ministries of Agriculture, Industry, Overseas Territories (*Outre-Mer)*, Foreign Affairs, Research and Health (the latter attends on a case by case basis where relevant matters are discussed e.g. related to pathogens). The national intellectual property institute (*Institut nationale de la propriété intellectuelle*) is also a member. Depending on the Protocol provisions under discussion, membership/consultation will be enlarged on an *ad hoc* basis to include stakeholders from industry federations, research bodies and non-governmental organisations (NGOs).

The French government recognises the need to introduce dedicated legislative measures as there is currently no national ABS framework, although local legislation has been adopted in some Overseas Territories (see 2). The form that national legislation might take is under consideration and there is no obvious precedent but it seems likely that new legislation will be introduced rather than building on existing provisions. The working group is understood to focus less on the distinction between 'user' and 'provider' and more on 'internal' (French genetic resources with the State as main provider: legislation to apply equally to French and non-French users) and 'external' (use by French natural and legal persons of foreign genetic resources). Whatever legal framework is developed, all French stakeholders will be bound by ABS requirements adopted in Overseas Territories competent for this purpose.

Simplicity is a priority for the future French framework. There is a clear preference to channel implementation through existing organisations rather than creating a new body to

apply the legislation. Limiting institutional complexity is seen as essential to minimise costs and administrative disruption. The MEDDTL considers that France already has a strong environmental administration with an adequate range of competencies across existing bodies. The most suitable mechanism still needs to be determined (formal inter-ministerial body, a mix of central and local bodies, delegation to a single ministry…) and will depend on the future legislative context. Government stakeholders do not exclude the need for multiple systems e.g. with domesticated genetic resources separately administered by the agriculture ministry.

A feasibility study on ABS frameworks in the Overseas Territories, commissioned by MEDDTL's Sustainable Development Directorate, was published on 14 September 2011 (FRB, 2011). It provides information and insights on mechanisms and scope for an ABS regime aligned with the Protocol. The study focuses on the provider perspective and examines in depth the three Overseas Territories that have adopted or are well advanced in developing locally applicable legislation (see 2). It does not address issues related to compliance by French users with the national laws of other provider countries (definition of fraudulent acquisition, sanctions etc. where bioprospecting is conducted in other countries). The study proposed options and recommendations regarding future ABS frameworks in both Overseas Territories and mainland France. These will be considered by the inter-ministerial working group but are in no way binding on the government.

Linked to this study, a ministerial seminar on ABS in the Overseas Territories was held on 28 June 2011 as the first stage of concertation with stakeholders, supported by live videoconferencing with overseas entities (MEDDTL, 2011a, see also 2.1.2). Three priority areas identified by the Minister for Overseas Territories included:

"support for economic innovation and development" through ongoing development of research centres and business clusters to promote local valorisation of biodiversity;

"conservation of natural resources" in which nature parks, reserves, the SNB, the IFRECOR Coral Reef Initiative and (from 2012) the IFREBIOM Overseas Territories Biodiversity Initiative will play a key role;

"cultural aspects" and the need to recognise and valorise traditional knowledge.

On 'grandfathering' (temporal scope of the Protocol), France closely follows the Protocol in considering that its provisions are not retroactive. However, it has identified new uses of genetic resources acquired before the Protocol entry into force as a key issue and supports benefit sharing on a voluntary basis (Morandeau, 2011).

France has not yet given detailed consideration to possible coverage of synthetic biology within the scope of genetic resources. Provisionally, it considers that this could be treated for legal purposes as a use along with others foreseen under the Protocol.

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

2.1.1 User-side legislative and policy measures

France has no general national legislation applicable to the whole of its territory to implement ABS provisions under the CBD, Bonn Guidelines and/or the Protocol (FRB, 2011). The full suite of user-related provisions (scope, benefits coverage, compliance and monitoring) therefore needs to be developed.

Government stakeholders indicate that the future framework will seek to further develop the list of benefits annexed to the Protocol in order to redistribute benefits in favour of biodiversity whilst ensuring a workable balance between conservation and economic valorisation. They also highlight the need to facilitate and provide incentives for research, including ease of access to scientific publications.

For Overseas Territories with competence for natural resource management, it is not possible for the French State to 'ensure' fair and equitable benefit sharing. However, it could support this goal by developing model contracts and clauses for specific contexts.

All of the main French public research bodies carry out work in the Overseas Territories, in particular the Centre for Agricultural Research for Development (CIRAD), NRS, the French Research Institute for Exploration of the Sea (IFREMER), the French National Institute for Agricultural Research (INRA), the Development Research Institute (IRD) and the National Museum for Natural History (MNHN). French researchers seeking to use genetic resources located in Overseas Territories are bound by local access requirements where in place. Two Overseas Territories have adopted implementing legislation pursuant to Art 15, CBD (*Province Sud, Nouvelle-Calédonie*; *Guyane*) although only the former's is operational. In addition, measures are under development in French Polynesia.

No arrangements have yet been made for checkpoints at key stages along the genetic resources value chain. The feasibility study identifies three options 1) funding bodies for research; 2) bodies responsible for authorising a product's commercialisation; 3) the intellectual property office, subject to administrative and financial capacity.

Technical matters related to compliance and extraterritoriality will need to be addressed with the Ministry of Justice e.g. to provide for and address challenges related to mutual recognition.

2.1.2 Provider-side legislative and policy measures

National legislation

Genetic resources are considered to be implicitly covered by Art L.110-1 of the Environment Code which broadly provides that components of biodiversity constitute a national common heritage ("*Les espaces, ressources et milieux naturels, les sites et paysages, la qualité de l'air,*

les espèces animales et végétales, la diversité et les équilibres biologiques auxquels ils participent font partie du patrimoine commun de la nation"). This definition covers resources in terrestrial, aquatic and marine systems. Traditional knowledge associated with genetic resources does not have an equivalent status.

To date, France has generally interpreted 'common heritage' to include races and varieties. In the ABS context, government stakeholders recognise the need to define the scope of genetic resources clearly to provide clarity on coverage of domesticated genetic resources used for agri-food development. A specific procedure may be developed for domesticated genetic resources not covered by the FAO framework but this will depend partly on regulatory impact assessment.

Government stakeholders consider that the existing 'common heritage' classification could provide a legal basis to designate the State as the competent national authority and as genetic resources access provider, subject to the rights of third parties with physical ownership/control of the relevant area. Recognition of the State as genetic resources provider could provide leverage for greater benefits for biodiversity conservation and sustainable use because the State would contract directly with the user. This could also have advantages for business in terms of administrative streamlining i.e. to avoid individual genetic resources contracts with multiple owners on small parcels.

Under such a framework, authorisation by the French State would be deemed as equivalent to the prior informed consent. However, this approach would *a priori* be non-contractual as it would involve a simple administrative permit. To incorporate contractual elements into the mechanism, a preliminary negotiation phase would be needed i.e. the application form would give rise to a two-way procedure with the State responding to proposals from the applicant, requesting further information and eventually reaching agreement on *'prescriptions'* (permit conditions) which would be deemed as equivalent to the mutually agreed terms and could provide additional legal security for users.

Since 1997, the French government has operated the principle of decentralising administrative decision-making. However, it could derogate from this principle under a future legal framework if it could demonstrate the need for centralised decision making (*Circulaire du 7 Mars 1997 relative à la mise en œuvre du plan de réforme de l'État: déconcentration des décisions administratives individuelles*).

The inter-ministerial working group is considering the possibility of differentiated procedures for different uses of genetic resources e.g. simplified procedures for non-commercial research, with a come-back/review provision if the purpose changes. One approach would be to set out general principles, then decide whether further simplification is appropriate for certain types of research. The group also envisages multi-year permits for similar activities conducted by the same organisation (specific to the institute/structure concerned under a partnership contract with the Ministry) but has not decided whether such permits would be limited to non-commercial research or also open to industry.

Overseas Territories

French legislation first referenced ILC (*communauté autochtone et locale*) in the Overseas Territories Act 2000 (*Loi d'orientation pour l'outre-mer n° 2000-1207 du 13 décembre 2000*), using the wording of Art 8(j) CBD. However, the term is not defined and does not have legal content, making it difficult to determine exactly what the concept covers in Overseas Territories. On the ground, property and/or collective use rights have been attributed in varying ways in different territories and these are recognised or taken into account in some applicable laws. Indigenous and local communities' representation and consultation thus needs to be handled separately for each territory (FRB, 2011). However, traditional knowledge is not yet clearly addressed in ABS legislation/policies.

New Caledonia has split competence for ABS implementation. Under the *Loi organique de 1999 relative à la Nouvelle-Calédonie*, environmental competence is devolved to the provinces whereas indigenous and local communities, traditional knowledge and customary property rights are a territory competence in association with the *Sénat coutumier*. The New Caledonian government is currently developing territory-wide proposals for traditional knowledge.

The **South Province** adopted dedicated local legislation in 2009 (*Délibération 06-2009 du 18 février 2009 relative à la récolte et à l'exploitation des ressources biochimiques et génétiques*, codified in Art 311-1 et seq. of its Environment Code), building on proposals from a working group of local authorities and researchers. Access permit applications are decided by the Provincial Environment Directorate which is responsible for ensuring compliance with sampling conditions set out in the permit. Local police (*gendarmerie*), national police agents and Customs officials also have powers to enforce the regulations.

With regard to benefit sharing, the 2009 law provides for two thirds of monetary benefits to be returned/directed/paid to the landowner, rather than to traditional populations (c.f. Brazil, Peru). In response to stakeholder concerns, the administration attributes certain difficulties to the divided competence mentioned above (the Provincial Environment Code does not mention traditional knowledge or indigenous and local communities) but affirms that the concept of 'landowner' does not exclude indigenous and local communities. It also notes that the current law does not adequately reflect business realities, whether local or international (MEDDTL, 2011b).

Draft legislation is currently under consideration which would address all ABS issues and clearly specify that property law covers private property, public property and land held under customary rules. For access to genetic resource on customary lands, mutually agreed terms for benefit sharing would be fixed by a customary discussion procedure (*palabre coutumier*) rather than a contract (MEDDTL 2011b).

In **French Guyana**, collective use rights may be attributed in defined areas to indigenous and local communities that traditionally subsist on forest-based products. The French State has delegated competence for ABS to the Amazonian National Park (*Loi N° 2006-436 du 14 avril 2006 relative aux parcs nationaux et portant création du Parc amazonien de Guyane* and Art L.331-15-6 of the Environment Code i.e. predating the Protocol). There is no equivalent framework for the rest of the territory. The Regional Council in French Guyana is designated as the competent authority to grant access permits, subject to a favourable opinion from

the General Council and consultation with the public park management authority. The 2006 Law provides a basis for prosecuting offences related to fraudulent acquisition of resources within the Park.

Implementing regulations have not yet been issued which means that ABS aspects of the 2006 Act are not yet operational. The Park Charter, due to be adopted by end 2012, will set out the strategic parameters for ABS. In the meantime, a draft code of conduct has been developed by the Park for genetic resources users.

In **French Polynesia**, territory-wide ABS legislation was proposed in 2006 but postponed for reasons of government instability (FRB, 2011). However, best practices are in place to promote ABS on a case by case basis. Foreign researchers and teacher-researchers, including EU nationals, are required to obtain a "welcome agreement" from local authorities and to be "invited by a French institute approved for this purpose" (*extrait du Protocole d'accueil d'un chercheur ou enseignant-chercheur étranger de Polynésie française*) to conduct research. This framework to regulate the entry and stay of foreign researchers makes it possible to obtain information on research programmes carried out in-territory and to facilitate some oversight. However, this falls short of an ABS framework because several aspects are excluded e.g. benefit sharing, prior informed consent.

In parallel, some agreements have been concluded between the French Polynesian government and foreign users. Criteria determining whether or not an agreement is necessary relate to the nature of the resource to which access is sought (endemism) and the likelihood that its use will generate benefits. The territory has also fostered partnerships with local researchers as well as training initiatives. In November 2011, French Polynesia will hold a Seminar on Traditional Knowledge which could lead to the adoption of a local ABS Charter.

In summary, ABS coverage is limited to a small number of Overseas Territories and highly fragmented (one province of New Caledonia, one park in French Guyana). The Seminar on ABS in the Overseas Territories (MEDDTL, 2011a) highlighted the need for regional ABS cooperation through inter-territory dialogue and with neighbouring countries (e.g. French Guyana-Brazil) to avoid 'dumping' (unfair competition) or barriers to cooperation.

Identified constraints (MEDDTL, 2011a; FRB, 2011) reflect those raised in the international negotiations of the Protocol e.g. scope of application (definition of genetic resources and their use), identification of genetic resources and/or traditional knowledge providers, and mechanisms for indigenous and local communities participation. Others are more locally specific. Providers consider that control of genetic resources needs to be seen as fair recompense to support sustainable development in the Overseas Territories. Customary authorities should be more closely involved in decision-making processes on scientific and cultural aspects, including traditional knowledge valorisation. Users stress the need for transitional arrangements to manage bioprospecting applications pending development of a formalised ABS framework (FRB, 2011).

Recommendations for ABS frameworks in the Overseas Territories (FRB, 2011) address the need for consistency between national and territory ABS frameworks. To the extent feasible

and to improve transparency for users, access procedures could be based on harmonised principles with common elements on traceability, compliance and intellectual property. Options could include:

- competent authority: at the appropriate territorial level, this could take the form of an inter-service mission or an ad hoc body operating as a one-stop shop representing all stakeholders;
- focal points: ABS correspondents could be designated in each Overseas Territory and networked with the National ABS Focal Point to facilitate exchange of best practices and lessons learnt;
- information obligations: these could be simplified (e.g. reporting at key stages) but coupled with a prior informed consent requirement in the event of a significant change to agreed conditions of use (transfer to third parties, new uses etc.);
- mutually agreed terms: to reduce legal uncertainty, the ABS framework could cover key aspects related to the types of possible benefits to be shared and the timeframe, whilst taking account of uncertainty over future results and benefits to avoid delaying projects.

Government stakeholders recognise the need for national support for monitoring by Overseas Territories and possible minimum common standards for evaluation. Additional tools could include mechanisms to monitor the results of research and development and/or the creation of a traditional knowledge register available for consultation by patent offices. The possibility of designating a single national authority as the administrative body responsible for liaising with the ABS Clearing House Mechanism is not excluded.

2.2 Other relevant national legislation

Government stakeholders interviewed for this report identified a limited number of existing national legislative and policy measures that cover aspects governed by the Protocol. These could contribute to the implementation of the Protocol and will be potentially affected by its implementation.

Habitats/species protection regime

Art L.411-2 of the Environment Code covers mainland France and certain Overseas Territories and forms part of French domestic measures to implement the EU Habitats and Wild Birds Directives. It establishes a restrictive regulatory framework from which derogations may be granted on defined grounds, including for scientific research. There is no reference to genetic resources but these provisions have been used to determine applications for access to genetic resources affecting protected species in mainland France (mainly for non-commercial research by foreign researchers).

This legislation has a fundamentally different aim to the ABS regime as it focuses on a relatively short list of protected species whereas genetic resources are potentially open-ended in their scope. The gaps will need to be addressed through the future ABS framework, raising challenges of policy coherence.

In the absence of legislation, MEDDTL cannot issue formal authorisations that qualify as prior informed consent or mutually agreed terms under Art 15, CBD. However, it is taking steps to build researchers' awareness and promote voluntary best practice for projects concerning non-protected species and habitats. For example, a 2011-2012 letter from MEDDTL viewed for this study (confidential details removed) set out agreed terms for doctoral research on non-protected plant resources, aligned with the Protocol and covering:

- geographic location of collection activities. Additional requirements would apply if the project was modified to require access to protected areas or species (prior consultation of competent body plus derogation procedures);
- purpose and goal of the research (number of specimens, mitigation of environmental impacts, maximum percentage of individuals from a single population);
- duration of access, and of the project as a whole ;
- commercial or non-commercial nature of research (for the latter, the source of funding should be specified). The ABS Focal Point must be contacted if the intended use changes (i.e. non-commercial research becomes commercial and/or genetic resources material is transferred to a third party);
- benefits to be shared. Non-monetary benefits generated included sharing a synthesis of information and results with the Focal Point and the National Museum of Natural History; publishing data on a public database at project end; and making samples available to the relevant university's botanic garden.

MEDDTL does not charge any fee for issuing this type of letter, which students may need to submit to their universities in the context of their research.

Interface between environmental legislation and public health legislation

Inclusion of plants and other medicinal species in the French pharmacopeia, consistent with Art 8(j) and 15 of the CBD, is designated as an objective by Art 56, *Loi n° 2009-967 du 3 août 2009 de programmation relative à la mise en œuvre du Grenelle de l'environnement*). The *Pharmacopée française* defines medicinal plants as plant-based drugs with medical properties (*drogues végétales qui possèdent des propriétés médicamenteuses*). Medicinal plants may also have food, condiment or hygiene applicatiosn. However, under Art L.4211-1 5° of the Public Health Code, the sale of medicinal plants listed in the Pharmacopeia is covered by pharmaceutical monopoly unless derogations are otherwise laid down by regulations.

Marine genetic resources and scientific research

Access is implicitly covered by French legislation establishing the regime for maritime zones under national sovereignty and/or jurisdiction (*Loi n°76-655 du 16 juillet 1976 relative à la zone économique et à la zone de protection écologique au large des côtes du territoire de la République*). This law implements the international regime governing State sovereignty over maritime natural resources, as laid down by the UN Convention on the Law of the Sea (UNCLOS).

The French Ministry of Foreign and European Affairs follows the detailed UNCLOS criteria when considering whether to issue a permit for marine scientific research in French waters. To date, ABS issues have not been explicitly included in consideration of research

applications. Implementing regulations for the 1976 Law, taking account of Art L.251-1 of the *Code de la recherche*, are currently under development to set out permit procedures and conditions for research activities. Government stakeholders indicate that the interface between the Protocol and the existing law of the sea needs to be further analysed with regard to access to marine genetic resources.

Biotechnology

Under EU Directive 98/44/EC on the legal protection of biotechnological inventions, the Preamble (Recital 27) calls for patent applications for inventions based on biological material of plant or animal origin to include, where appropriate, information on the geographical origin of such material, if known. This Recital is non-binding. There is no disclosure of origin requirement in the implementing French legislation (*Loi n° 2004-1338 du 8 décembre 2004 relative à la protection des inventions biotechnologiques*). Any change to the EU legislative framework for biotechnology, linked to development of an ABS framework, would thus have implications for existing French legislation.

3 NATIONAL ABS PRACTICES

France has a range of large and small companies and major public research institutes that are engaged in the utilisation of genetic resources for commercial or non-commercial purposes. The following constraints from a user perspective have been identified (government stakeholder interviews; MEDDTL 2011b; case studies in FRB 2011):

both domestic and foreign commercial researchers highlight problems associated with legal uncertainty, complicated by the lack of ABS focal points. Reference in Overseas Territories to 'biological resources', to cover genetic resources, can lead to ambiguity;

overly long and / or administratively cumbersome procedures can prevent researchers from concretising proposed projects (particularly in Guyana). This can have perverse consequences by limiting investment in research and thus limiting the creation of new knowledge in territories with inadequates legal frameworks;

in order to maintain innovation and business development, Overseas Territories companies sometimes require their research partners (in some cases, from mainland France) to provide a guarantee that access to the relevant genetic resources was carried out in compliance with applicable legislation. However, such guarantees are impossible to provide in the absence of any regulatory framework;

There is concern about possible discrimination linked to the purpose of research;

botanic gardens do not wish to jeopardise established procedures conducted in accordance with the International Plant Exchange Network's Code of Conduct for botanic gardens governing the acquisition, maintenance and supply of living plant material (2003) (http://www.cbd.int/abs/instruments/);

benefit-sharing with indigenous and local communities: French law does not clearly recognise traditional knowledge, populations or certain concepts (customary law, prior informed consent). Other challenges include very wide dispersal of traditional knowledge, making it difficult or illegitimate to confer an exclusive right on a single group. It can be difficult to identify the appropriate negotiating body, particularly in

situations where different persons or institutions claim to speak in the name of one community.

A concrete case in French Guyana illustrates the difficulty in involving indigenous and local communities in registration of patents linked to traditional knowledge. Carapa oil (*Carapa guianensis* Aublet) protects against rain and cold, repels insects, has calming anti-inflammatory properties and soothes muscles. Recently, a patent application was filed for an invention (an anti-cellulite cream) using carapa oil attributes. This raised the question of a) whether the Guyanese local communities were familiar with this particular property or at least, whether their traditional knowledge suggested the possibility of such a use; and b) how broad the future ABS regime should be without disproportionately enlarging its scope to benefit indigenous and local communities (MEDDTL, 2011b).

The government's first ABS Seminar, held on 12 March 2010 in the context of the International Year of Biodiversity, engaged civil society stakeholders from the pharmaceutical and cosmetic industries (Chanel Parfums Beauté, Cosmed, Kenzo Parfums, LEEM, LVMH, Nuxe Laboratoire, Pierre Fabre, Silab, Soliance) (MEEDM, 2010).

Demand for sector-specific codes of conduct appears to be particularly high in the cosmetic sector. At least seven French companies were involved in the creation of the Natural Resources Stewardship Circle (NRSC) in Grasse, France in 2006, which covers the cosmetics, perfume, flavour and fragrance industries. The NRSC adopted best practice Common Guidelines in September 2010, aligned with CBD provisions and based on a Corporate Social Responsibility approach for sustainable development with reference to ethical sourcing. The Guidelines are intended to direct member company interactions with indigenous and local communities and support capacity-building.

The biotechnology industry is rapidly diversifying in France, as illustrated by two examples of commercial genetic resources application below.

Venometech is a new biotechnology company with origins in public research (Université de Nice Sophia Antipolis and the National Centre for Scientific Research (CNRS)). It aims to develop novel therapeutic molecules based on venom compounds to produce medicines for pain relief, cancer and illnesses of the central nervous system. The company employs five people after 2.5 years of operation, with 4-5 research interns on a rolling basis. Its commercial potential is directly linked to access to genetic resources and it ensures full compliance with applicable legislation, including CITES requirements. Its ABS corporate policy supports voluntary compliance with the Protocol benefit-sharing provisions, even before this becomes obligatory. However, the company highlighted major problems linked to the current legal vacuum/complexity surrounding ABS implementation. Due to legislative/procedural barriers to obtaining access permits in third countries, it has opted to conduct collection activities within the EU where possible and is negotiating separately with administrations in different French Overseas Territories. Where necessary, it sources its material for research and development from commercial suppliers (which means that as a purchaser, it would not be bound by the Protocol provisions). The company noted the high number of intermediaries importing biological resources (from which genetic resources could be obtained) for different commercial purposes and the difficulty of finding out whether these were obtained under appropriate permits or not.

Venometech is the lead partner in the VENOMICS FP7 EU health research project (2011-2015) which has commercial and/or academic partner organisations in France, Belgium, Denmark, Spain and Portugal. In the EU context, it noted that research entities could be required to sign an ABS undertaking as a precondition to receiving EU funding for genetic resources research projects, and that harmonisation of access frameworks would facilitate commercial research activities and reduce administrative burdens. However, any future EU framework should retain flexibility for users to negotiate with providers on a case by case basis: minimum standards especially for monetary benefits would not be feasible (stakeholder interview).

In French Polynesia, the Pacific Biotech company currently develops commercial products based on marine micro-organisms harvested in public maritime areas. It has not shared monetary benefits to date but because the process of industrial development is carried out in Polynesia, the territory is considered to benefit 'naturally' from a return proportionate to the success of the business e.g. in the form of job creation and/or tax revenues. In the future, the company envisages projects involving the harvesting of terrestrial plant resources, which would provide a more direct return to people on the ground via the creation of a collection system for raw materials leading to the establishment of a specific economic subsidiary for the atolls concerned. This would generate additional financial resources for local populations whose current income depends on fisheries and coconut cultivation (MEDDTL, 2011b).

4 REFERENCES

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SNB (2011) *Stratégie Nationale pour la Biodiversité 2011-2020 : Engagements de l'Etat 2011-2013*. Document adopted 19 May 2011, Office du Premier Ministre, France.

5 INTERVIEWEES

25 October 2011
Ministère de l'écologie, du développement durable, des transports et du logement (MEDDTL), Paris

Delphine Morandeau (CBD Focal Point)
Chargée de mission biodiversité, Sous-Direction de l'économie des ressources naturelles et des risques, Commissariat Général au développement durable,MEDDTL

Anca Leroy
Chargée de mission – juriste, Direction des Affaires européennes et internationales, MEDDTL

Elen Lemaitre-Curri
Chef de Bureau, Commissariat Général au développement durable, MEDTTL

Vincent Bentata, Direction de l'Eau et de la Biodiversité, MEDDTL

Julien Richard, Ministère des Affaires Etrangères

Jules Wizniak, Chargé de mission – juriste, Direction de l'Eau et de la Biodiversité, MEDDTL.

9 November 2011 (telephone interview)

Pierre Escoubas, Managing Director, VenomeTech
http://www.venometech.com/index_gb.html

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Germany

1 INTRODUCTION

Country profile

Germany is primarily a user of genetic resources. According to an OECD report, Germany had, in 2007, almost 600 companies, whose main field of activity was biotechnology; this is the third highest recorded number in the EU after France and Spain. Health applications are by far the most important segment of the German biotechnology industry. Private sector spending for biotechnology R&D research amounted to 1.2 billion US$ in 2007 (van Beuzekom and Arundel 2009). In the mid-1990s Germany ranked fourth in the list of international importers of plant genetic raw material (Holm-Müller *et al*, 2005).

Germany is a rather densely populated country, and more than half of its surface is used for agricultural purposes. There is a low number of endemic species. At present, 21 endemic animal species are known and a number of endemic subspecies. Additionally, some 85 endemic families of ferns and flowering plants are known.[28] There are no population groups that can be considered as "indigenous and local communities with traditional lifestyles" within the meaning of Art 8 (j) CBD in Germany.[29]

Current state of affairs concerning the Nagoya Protocol

Germany signed the Nagoya Protocol (hereafter, 'the Protocol') on 23 June 2011 and is strongly interested in ratifying it. However, there is concern about some Member States like Spain or Denmark who are willing to ratify before July 2012. The German government fears this could cause conflicts between national ABS rules and potential future EU legislation. Therefore, Germany intends to wait for the implementation proposal as envisaged by the EU Commission for the CBD COP in 2012. There would be still enough time to implement the Protocol until 2015.[30] Furthermore, this approach would allow a harmonization of the implementation among all Member States. A 'hurry ahead' of some would be avoided and quick decision-making on EU legislation supported. The European Medicines Agency (EMA) and/or the European Food Safety Authority (EFSA) could be possible ABS authorities at the EU level in the view of Germany.

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[28] See 4th National Communication of Germany to the CBD, 30 March 2010, http://www.cbd.int/doc/world/de/de-nr-04-en.pdf, p.5

[29] See http://www.cbd.int/countries/?country=de

[30] The EU wants to ratify the Protocol as soon as possible and at the latest in 2015, see COM(2011)244 or http://www.umwelt-online.de/cgi-bin/parser/Drucksachen/drucknews.cgi?texte=0309_2D11.

Among the relevant ministries there are quite consistent views on the importance of implementing the Protocol. For the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (in the following Federal Ministry for the Environment), it is a priority due to its position as CBD and ABS focal point. The objective of implementing the Protocol would, according to the Ministry's view, not only be compliance with international obligations, but also establishing mechanisms to facilitate the use of genetic resources. Other ministries like the Federal Ministry for Economic Cooperation and Development (BMZ) have slightly different preferences. Since 80% of biological diversity is found in developing countries, its use can help to combat poverty in view of the BMZ. Therefore the main aim of this ministry is to support its partner countries in implementing the Protocol, with the aim of ensuring sustainable use, poverty reduction and compliance with access regulation.

As part of a research and development project called 'Preparation and follow-up of COP 10 and preparation of COP 11 of the CBD' a study on the 'Implementation of the Nagoya Protocol' was commissioned by the Federal Agency for Nature Protection. The study will be initiated in November; according to the terms of references the German study is to build on the present study for DG Environment. The Federal Ministry for the Environment regularly organizes a 'round table' to bring different ministries and stakeholder from the private sector, research institutions and civil society together to discuss possible next steps and solutions with respect to the implementation of the Protocol in Germany.

In the past, the government has taken some specific initiatives to implement ABS, notably a clause in the German Patent Act on disclosure of origin or supporting the IPEN network (International Plant Exchange Network, see below). Now, the Federal Ministry for the Environment seeks to bundle all initiatives, prepare a first draft and present it to the other ministries, but is waiting for the efforts of the European Commission.

Suggestions concerning implementation

In the following some views and proposals of the main Federal ministries involved (Environment, Development, Agriculture) regarding the legal and practical implementation of the Protocol are outlined. Above all, the focus lies on user measures, especially on the implementation of Art 15 to 18 NP.

With regard to temporal **scope,** Germany considers especially Art 10 on the 'Global Benefit Sharing Mechanism' not to apply retrospectively. This applies to the period from 1993[31] on and even more for the time before. Concerning the substantive scope of future legislation, Germany has not yet decided on whether to include synthetic biology within the scope of the Protocol. Preliminary, it considers that synthetic biology could be treated for legal purposes as a utilization of genetic resources, in line with the Protocol's terminology.

With regard to the **institutional set up**, the Federal Ministry for the Environment, which is responsible for ABS issues, has recommended the maintenance of the Focal Point within its

[31] The Convention on Biological Diversity (CBD) opened for signature at the Earth Summit in Rio de Janeiro in 1992, and entered into force in December 1993.

ministry to bundle information, provide permits for access and cooperate internationally even more effective. Existing legal and institutional arrangements as contained in the nature conservation laws at the federal level (*Bundesnaturschutzgesetz*) and nature conservation laws of the 16 *Länder* as well as forest, animal protection, hunting and fisheries legislation should be maintained, according to the main Federal ministries.

Concerning **checkpoints**, the Federal Ministry for the Environment considers it quite realistic to have one competent national authority and different checkpoints. One option could be that checkpoints for different relevant market approval procedures as well as monitoring agencies and the national ABS authority would cooperate effectively to ensure users' compliance with potential future 'due diligence' rules. Possible checkpoints could be authorities responsible for product approval, funding agencies like the German National Research Foundation (*Deutsche Forschungsgemeinschaft*, DFG), patent agencies or botanical gardens. Nevertheless, these bodies should not be burdened by too many new tasks resulting from the implementation of the Protocol. To simplify the process these bodies could examine the international certificates of compliance and forward it to the above mentioned competent national authority in case of irregularities, which could then take action. Additional legislation on enforcement, arbitration and penalties is considered essential.

Concerning the implementation of the **compliance rules**, the concept of 'due diligence' could be a possible way to implement the compliance rules of Art 15 to 17 NP. A due diligence rule is laid down already in Regulation (EU) No 995/2010 (the so-called 'timber Regulation'). This Regulation foresees three key obligations: a) it prohibits the placing on the EU market of illegally harvested timber and products derived from such timber; b) it requires EU traders who place timber products on the EU market for the first time to exercise 'due diligence' with regard to the legality of the timber [32]; and c) to allow for the traceability of timber products operators are obliged to keep records of their suppliers and customers[33]. With respect to the Protocol, a due diligence system could regulate the illegal use and trade of genetic resources and/or traditional knowledge in the provider country. Users could be obliged to take measures and develop procedures to inform themselves about the legality of the use and trade of genetic resources. Also obligations for users to develop risk reduction measures could help in case specific information about the legality is not available or the ABS regulations of provider countries do not fulfil the international standards according to Art 6(2) NP.

[32] The three key elements of the 'due diligence system' are: 1) Information: The operator must have access to information describing the timber and timber products, country of harvest, quantity, details of the supplier and information on compliance with national legislation. 2) Risk assessment: The operator should assess the risk of illegal timber in his supply chain, based on the information identified above and taking into account criteria set out in the regulation. 3) Risk mitigation: When the assessment shows that there is a risk of illegal timber in the supply chain that risk can be mitigated by requiring additional information and verification from his supplier. See http://ec.europa.eu/environment/forests/illegal_logging.htm

[33] EUTR_Leaflet_EN, http://www.bmelv.de/EN/Agriculture-RuralAreas/Forests-Timber-Hunting/forests_node.html

The German government considers Art 10 NP and its Global Multilateral Benefit-Sharing Mechanism as particular important. However, some questions remain. In general, it provides a flexible approach for difficult situations when bilateral solutions are not possible or legally inadmissible. Further the mechanism could support the generation of additional funds to preserve biological diversity.

One concrete suggestion for the implementation of the Protocol in Germany is the inclusion of ABS as a further aim into the Federal Law for Nature Protection (§ 1(2) – maintenance of biodiversity).

The establishment of the Clearing House Mechanism (CHM) is seen as another important step towards implementation of the Protocol. Lessons of the Cartagena Protocol CHM are considered to be useful for the new ABS CHM. The new mechanism would connect all national ABS websites to a central platform of the CBD Secretariat.[34] The information laid down in this CHM would be binding for all members as the certificates of compliance (according to Art 17(3)) could serve as proof: based on Art 17(2) an authorization according to Art 6(3)(e) can be altered in a certificate of compliance and would need one administrative act only.

The German government will provide for personnel costs of the new competent national authority. Also, funding could be provided for research institutions in case they fulfill specific obligations concerning ABS. The DFG guidelines could serve as a model in this regard (see below).

The ministries have also pointed out that for user countries, it is very important that provider countries comply with their obligations from Art 15 NP, i.e. to establish a competent national authority responsible for dealing with prior informed confirmed and mutually agreed terms matters.

Stakeholder perspectives

Stakeholders mostly welcome the Protocol. However, there are concerns among the pharmaceutical industry and some stakeholders like semi-public institutions involved in biotechnological or agricultural research.

For example, in the agricultural industrial sector the present situation is considered satisfying and stakeholders are not interested in implementation of the Protocol. The German Industrial Association for Biotechnology (DIB) highlights the lack of perspectives of bioprospecting outside Europe, which is considered difficult. Therefore, the biotechnology industry is focusing on Europe with its existing gene banks and databases. Some of these stakeholders therefore have no interest in a change of the current situation; they see computer-based screening as cost-saving alternative toward using genetic resources. However, some representatives foresee that this may change in the future as markets may be changing. An efficient implementation of the Protocol will then be essential. The German Patent Agency (DPMA in Munich) is not seen as adequate check point by industry

[34] See for instance the German ABS website: http://www.bfn.de/index_abs+M52087573ab0.html

representatives. In their view, it is very difficult for non-scientists to understand the production chain and make fair decisions. Also, according to industry representatives, the so-called 'patent-bashing' does not take into account that a patent portfolio is of enormous importance for small and medium-sized businesses and start-ups.

Furthermore, concerns exist, mainly among medium-sized enterprises, with regard to problems caused by provider countries. Therefore, they stress the importance of Art 6(3) NP (setting forth, inter alia, a legal certainty requirement for access rules and a reliable CHM). Potential users appreciate Art 18 because compliance duties can vary according to the intended use, e.g. academic use, commercial use or basic research.

Researchers working in the microbiological sector are concerned, because in many cases it is not clear at the very beginning of their research what is in the explored micro-organism. They therefore demand that the new legal and administrative framework does not cause unreasonable additional work and expenses. The microbial diversity (existing in the so-called provider as well as in the user countries) has always to be kept in mind when creating such a new system. Research institutions working at the international level need to be able to exchange biological material among each other. Especially institutes administering collections need to be enabled further to fulfil their task[35]: to deposit biological material from all over the world and pass it on under acceptable conditions. The microbiological community already has elaborated some models for 'tracking' samples and for a code of conduct (regarding PIC and MAT).[36] At the European level, they have developed the so-called ECCO Core MTA for the Supply for Cultures[37] for complying with ABS regulations.

According to civil society representatives in Germany, the main issue concerning the implementation of the Protocol is to prevent bio-piracy in the future. In their view, implementing the Protocol quickly would help to dispel concerns of developing countries that user countries are still interested in a 'run' on genetic resources.

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

Concerning user legislation, there is a clause in the German Patent Act on disclosure of origin. Moreover, there are some non-legal measures in place. Government representatives indicate that the future framework will seek to further develop the list of benefits annexed to the Protocol in order to redistribute benefits in favour of biodiversity whilst ensuring a workable balance between conservation and economic valorisation. They also highlight the need to facilitate and provide incentives for research, including ease of access to scientific

[35] See e.g. the recommendations of the OECD Biological Resource Centre (BRC) Initiative.

[36] See http://www.belspo.be/bccm/mosaicc

[37] See www.eccosite.org

publications. The focus of future national legislation and policies will be on the implementation of Art 15 to Art 18 NP.

Concerning provider measures, Germany, like most EU Members, has not adopted specific regulations for access to genetic resources within the scope of the CBD. Germany allows free access to genetic resources in the sense of the CBD; there is no requirement to obtain prior informed consent for interested users. Therefore, the need to draft mutually agreed terms does not exist either. Depending on the location of a genetic resource within the sovereign territory of the Federal Republic of Germany, access is governed by the German Civil Code (BGB) or the Federal Nature Conservation Act.

2.1.1 User-side legislative and policy measures

The only piece of user legislation in force is § 34(a) of the German Patent Act. It was adopted to implement Directive 98/44/EC (the biopatents Directive). § 34(a) of the German Patent Act reads:

"If an invention contains biological material of herbal or animal origin or such material is being used the patent shall include a declaration about the geographical origin if that place is known. The inspection of the registration as well as the validity of the rights based on patents remains unaffected."

However, non-compliance with this article does not affect the further process of access.

There are no further legislative measures relating to ABS in general or traditional knowledge in particular.

In terms of non-legal measures it is worth mentioning that the German national research foundation (*Deutsche Forschungsgemeinschaft*, DFG), has adopted 'Guidelines for Funding Proposals Concerning Research Projects within the scope of the CBD'.[38] These guidelines explain the CBD rules to researchers applying for DFG funding. Applicants for funding involving research using biological material are required to state in their application the status of preparations in the host country, including contacts with national authorities. Applicants are also to certify that they are familiar with CBD rules as described in the guideline and are committed to complying with them. The German Ministry for Education and Research, which also provides significant amounts of research funding, also includes clauses in relevant funding contracts that oblige the recipients of these funds to comply with CBD rules (Quintern, 2005).

2.1.2 Provider-side legislative and policy measures

[38] Available online at http://www.cbd.int/abs/measures/measure.shtml?id=69551

As mentioned above, Germany has no provider legislation in place. There are no prior informed consent or mutually agreed terms requirements. Government representatives also see no need for creating access rules in Germany in the future.

While there is no legislation on access to genetic resources, some legal norms regulate the access to certain animal and plant species, with the purpose of conservation. § 7 Abs. 2 Nr. 13 und 14 of the Federal Nature Conservation Law (*Bundesnaturschutzgesetz*) together with § 44 Federal Nature Conservation Law forbid, among other, the collecting, catching, possessing, selling of certain, species which are specifically protected. Area specific prohibitions on specific activities exist in nature reserves and national parks (§23 ff. Federal Nature Conservation Law). Other public law restrictions regarding access and may demand an authorization are:

- Forest law (especially of the *Länder*);
- Federal Animal Protection Law (e.g. § 12) as starting point to issue statutory instruments, e.g. to allow or prohibit the use of animal genetic resources;
- Hunting and Fisheries law (both Federal and county law).

Additionally private law restricts access to resources on private property or in collections (seed multiplication law, forest law, Seed Marketing Act, patent law).

Germany has a number of collections of plants, animals and micro-organisms, like the 'German Collection of Microorganisms and Cell Cultures' (DSMZ), the 'Inventory of Forest Genetic Resources of Germany' (FGRDEU) or the 'Central Documentation of Animal Genetic Resources in Germany' (TGRDEU)[39]. A standardized authorization process is in place to get access to these collections. Additionally, these institutes offer support in research and economic evaluation of resources. Furthermore, several websites provide free information on genetic resources in Germany (e.g. FloraWeb).

3 NATIONAL ABS PRACTICES

In the following, we provide an overview of ABS practices in Germany.

First of all, it is important to note that the two most important research funding organisations, the DFG and the German Ministry for Education and Research, have policies and guidelines in places to ensure that researchers obtaining funding act in compliance with ABS rules (see above).

Moreover, about 50 botanical gardens in Germany adhere to the International Plant Exchange Network (IPEN).[40] Gardens that wish to join IPEN must sign a code of conduct which sets out responsibilities for acquisition, maintenance and supply of living plant

[39] http://www.bfn.de/service_zugang-sammlungen.html#c6660

[40] See list of members at http://www.bgci.org/resources/ipen/

material and associated benefit-sharing. Under the code of conduct, gardens commit themselves to act in compliance with the CBD and the Convention on International Trade in Endangered Species (CITES) when acquiring, maintaining, and transferring living plant material.[41] The origins of the IPEN code of conduct go back to efforts among botanical gardens in German-speaking countries, which involved funding from the German government for this purpose.[42]

Concerning the private sector, no overarching codes of conduct appear to exist, and we have also not been able to identify specific published corporate policies on the matter. However, relevant sectors of the German industry have supported the adoption of an ABS protocol which provides for transparent and practicable ABS rules, as well as legal certainty for companies.[43]

A 2005 study commissioned by the German Federal Agency for Nature Protection (BfN) focused on users of genetic resources in Germany. Some of the results were that providers from the countries of origin and from other countries were the most important supply sources for users or genetic resources in Germany; collecting activities are carried out predominantly by users at universities and other research institutions, as well as *ex situ* collections and users from the field of horticultural breeding (Holm-Müller et al, 2005). Out of 29 users who indicated they collected and reproduced their material themselves, only one reported ABS experience; however, the share of those who had negotiated mutually agreed terms for access was significantly higher (Holm-Müller et al, 2005). Non-users also indicated that among the reasons why they were not using genetic resources were difficulties in finding a contact person and the fact that regulations were either unknown/uncertain or too strict and complex. Users in addition reported uncertainty as to the fulfilment of contracts as a difficulty. By contrast, actual access did not pose significant problems (Holm-Müller et al, 2005). The study also notes a low level of awareness on ABS rules (Holm-Müller et al, 2005).

In recent years, some cases of 'biopiracy' have received a certain deal of public attention. One is the case of Umckaloabo, a natural product for colds. Umckaloabo is marketed by the German company Dr. Willmar Schwabe, which specialises in plant-based medicines and food supplements. Umckaloabo is based on extracts from two pelargonia species which are found in South Africa. Schwabe had initially obtained a patent from the EPO on a process to extract active ingredients from the plants; however, the patent was revoked later, for lack of

[41] The code of conduct is available at http://www.bgci.org/files/ABS/IPEN/IPEN%20Code%20of%20Conduct.doc

[42] See History of IPEN, http://www.bgci.org/resources/History_of_IPEN/

43 International Chamber of Commerce/German Industrial Association for Biotechnology, *Wirtschaft fordert praktikables und transparentes ABS-Protokoll*, 21. October 2010, http://www.icc-deutschland.de/index.php?id=66&L=0&tx_ttnews[backPid]=176&tx_ttnews[pointer]=3&tx_ttnews[tt_news]=259&cHash=a16636a626&type=98

an inventive step.[44] The firm was publicy accused of 'biopiracy' by, *inter alia*, German and South African NGOs and communities. Schwabe, by contrast, claims to have concluded ABS agreements with 'South African communities' in line with South African regulations.[45] The details of the alleged ABS agreements have not been made public, though. In addition, Schwabe has also established an Umckaloabo Foundation[46] which supports projects in South Africa to the benefit of children and young people.

In the area of development cooperation, Germany has repeatedly supported ABS related projects. For example, in the BioTeam research programme the Federal Ministry of Education and Research (BMBF) assisted a major research and development programme ('ProBenefit', 2003-2008) in developing a fair benefit-sharing model for the use of biological resources in the Amazon lowlands of Ecuador.[47] Another example is the assistance that the German Federal Ministry for Economic Cooperation and Development (BMZ) provided to a regional ABS programme in the Eastern Himalayas.[48]

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44 Patent von Umckaloabo wurde widerrufen, Ärztezeitung 27 January 2010, http://www.aerztezeitung.de/praxis_wirtschaft/unternehmen/article/585971/patent-umckaloabo-wurde-widerrufen.html

45 http://www.schwabe.de/schwabe/News/entries/A_101014.php

46 http://www.umckaloabo-stiftung.de

47 See http://www.probenefit.de

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European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Poland

1 INTRODUCTION

Poland is primarily a user of plant genetic resources, but Poland is also one of the most biodiverse countries in Europe, with potential to be a provider country as well as a user. In Poland, *in situ* conservation has been undertaken to a limited extent in order to preserve old plant cultivars and landraces, but the primary focus has been on *ex situ* preservation, with more than 70,000 accessions of marginal crops, old varieties and landraces, 45 per cent of which are of Polish origin (Bulinska-Radmonska *et al*, 2008). Wild species, including mushrooms, herbs, berries, and medicinal plants are widely collected for commercial sale. Poland imports and exports very little genetic material, according to Bozena Haczek, National Focal Point for the Nagoya Protocol. Where materials are exchanged, these are primarily plants. The Polish Act of Forests (1991, amended 2011) only allows import of seeds or plants for scientific purposes under controlled conditions (e.g. use in the laboratory). There is also limited exchange of plants for agricultural purposes.

The Government of Poland signed the Nagoya Protocol on 20 September 2011 (*hereafter* 'the Protocol'). No actions have yet been taken by the Polish government with regard to implementing the Protocol. The first step will be to develop an inventory of imports and exports of genetic resources and to assess the current regulation to determine whether/how many legislative acts might require amendment in light of the Protocol. This is anticipated to take at least a year to complete. At the present time, the National Focal point is not aware of any initiatives by industry or the research sectors to implement ABS in Poland.

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

COP 5 Decision V/26 requests that all signatories to the CBD establish a national focal point and one or more competent authorities to take responsibility for ABS arrangements or provide such information within its jurisdiction. The Government of Poland has established an ABS focal point under the Department of Nature Conservation, Ministry of the Environment.

2.1.1 User-side legislative and policy measures

Poland does not have any ABS user legislation in place. Poland has, however, ratified the International Treaty for Plant Genetic Resources for Food and Agriculture, which went into force on
May 8, 2005. Poland supports the Treaty's objectives and is committed to implementing the legal framework on conservation for genetic resources. Poland has done work in this context to designate genetic resource material to the Multilateral System of Access and Benefit Sharing (MLS) for crops contained in Treaty Annex I (Bulinska-Radmonska *et al*, 2008). This includes implementation of the standard Material Transfer Agreement (sMTA), which could provide an opportunity for use in the context of the Protocol as well.

2.1.2 Provider-side legislative and policy measures

Poland does not have ABS provider legislation in place.

2.2 Other relevant national legislation

In Poland, there are no laws directly related to access to genetic resources, including those collected in gene banks (Podyma, 2001). Access to genetic resources is governed to some extent by the law of property rights, but in Poland the preference is to allow unrestricted access to genetic resources.

Moreover, there are no legal instruments specifically applicable to traditional knowledge in Poland, and there are some limited opportunities to include traditional knowledge in intellectual property instruments such as patents, copyright, and plant breeders rights (e.g. through breeder's rights and farmer's rights to save seeds) (Podyma, 2001). Existing rights to local, self-government may potentially be used in the service of protecting traditional knowledge.

3 NATIONAL ABS PRACTICES

3.1 Poland research institutions and company practices and policies on ABS

Poland has several research institutions that have adopted procedures that can facilitate access to genetic resources, though there are no known policies directly related to access and benefit-sharing. There are no known company policies related to ABS in Poland.

Plant Breeding and Acclimatization Institute (IHAR)
Collection and conservation of plant genetic resources in Poland have been undertaken since 1951 by the Plant Breeding and Acclimatization Institute (IHAR) in Radzikov. The Institute coordinates and manages the plant genetic resources held in Poland. Plant genetic resources are managed under a national programme which is run by the IHAR; the programme is decentralized and includes three universities, six institutional departments, seven breeding stations, and the Botanical Gardens of the Academy of Sciences. The National Genetic Resources Centre (NCPGR) of the IHAR developed a centralised database system in 2008, which seeks to improve accessibility of genetic resources, processing and

data flow, and also seed collection management. In 2008, more than 90 per cent of accessions had passport data stored in the database (Bulinska-Radmonska, 2008). All passport data has been available since 2006 through the EURISCO web catalogue and most is available through the Global Biodiversity Information Facility (GBIF). Annual distributions of genetic resources go to researchers, breeders and gene banks.

Additionally, the BARKA Foundation aims to provide assistance to farmers who undertake on-farm conservation activities for local varieties.

3.2 Experiences of Polish institutions with lack of access to resources in provider countries where ABS policies are in place

No examples of institutions experiencing a lack of access to resources in provider countries have been found. That National Focal Point for Poland confirmed that there are no known cases of lack of access in provider countries.

3.3 Examples of recent benefit-sharing agreements in the Poland

No recent benefit-sharing agreements are known. However, a 2001 report to the CBD on access and benefit-sharing describes one project from that time which aims to conserve fruit tree varieties and traditional processing methods employed by local communities within Poland (Podyma *et al*, 2001).

The project is located in Landscape Park, Lower Vistula Valley, in the region of Chrystków. This region was historically an important area for apple, plum and other fruit production. Many of the old varieties had been replaced by dwarf varieties, which were more resistant to disease and frost. A programme was implemented to catalogue and identify old apple and plum varieties in the region and then to produce apple plantings in a nursery, which were then transplanted to farmers' orchards for cultivation. At the same time, a project to restore traditional methods of drying, storing and processing fruit was also implemented. Demonstrations and training for farmers, as well as information dissemination through multiple media (e.g. seminars, booklets, etc.), were components of the effort to increase cultivation of the old varieties.

The project was funded through proceeds from the sale of the young trees, as well as local activities and donations. Trees were sold at low cost and farmers could get free advice regarding tree maintenance and rejuvenation of old trees. Farmers purchase the apple trees for their commercial qualities, though the initial profits were reported to be small. This is the first such project in Poland that attempted to involve the public in active biodiversity conservation and to demonstrate that profits could be realised from maintaining biodiversity.

The National Focal Point indicated that there are no known initiatives within industry or the research sectors in Poland to comply with provider country ABS legislation or to develop any ABS-related procedures.

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5 INTERVIEWEES

Bozena Haczek, National Focal Point, Poland, Department of Nature Conservation, Ministry of the Environment, Poland (interview conducted on 15 November 2011 by telephone).

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Spain

1 INTRODUCTION

Spain is part of the Mediterranean basin, which is counted among the 25 global biodiversity hotspots. Spain is thus one of the EU countries richest in biodiversity. Spain has diverse habitats, including notably forests, marine and freshwater areas.[49] 54% of all species known in Europe can be found in Spain.[50] Spain also has a number of seed banks.[51] There is no significant indigenous population in Spain. However, there is significant knowledge concerning the use of biological resources which is considered as 'traditional knowledge'.[52] More than 2,000 species are still used traditionally in Spain, many for medicinal and food purposes.[53] Research efforts are being undertaken to recover knowledge about, for example, the use of herbal plants, and to facilitate access to such knowledge.[54] These characteristics make Spain a **provider country.**

Concerning Spain's profile as **user country**, it should be noted that in 2006 Spain had (after France) the second-highest number of biotechnological companies in the EU (van Beuzekom and Arundel, 2009). Almost half of them were involved in R&D to a significant extent (van Beuzekom and Arundel, 2009). Growth in the biotech sector is significant. A particular feature of Spanish R&D spending on biotechnology is that a relatively high share comes from the public sector (van Beuzekom and Arundel, 2009). Spain is also one of the few countries in the EU where there is considerable cultivation of genetically modified crops. Besides the biotechnology industry, other industries which depend on access to genetic

[49] Fourth National Report of Spain to the CBD, March 2009, p. 3; also see Conservation International, Biodiversity Hotspots, Mediterranean Basin, http://www.biodiversityhotspots.org/xp/hotspots/mediterranean/Pages/default.aspx

[50] Fourth National Report of Spain to the CBD, March 2009, p. 7.

[51] See the overview in the former Spanish Strategy for the Conservation and Sustainable Use of Biodiversity, Part I, p. 55, http://www.cbd.int/doc/world/es/es-nbsap-01-p1-en.pdf

[52] See for example http://conocimientostradicionales.info

[53] See http://www.cbd.int/countries/profile.shtml?country=es#thematic

[54] See for example the website of the HERBAM research project in Catalonia, http://www.herbam.net

resources, are the cosmetic and perfume industries, as well as producers of ornamental plants in Catalunya and the Canary Islands.[55]

Spain considers itself both a user and provider country.[56]

Spain signed the Protocol on 21 July 2011 and the Spanish government supports its ratification. Ratification is expected to happen before July 2012. Spain has undertaken a study for assessing the obligations contained in the Protocol and for looking at the options for implementing the Protocol.[57]

While deliberations on future legislation are still at the initial stage, future policy measures might include both revisions to existing legislation and new legislation. Legislation on access is likely to be adopted. The recent Strategic Plan for Natural Heritage and Biodiversity deals *inter alia* with access to genetic resources.[58] Funds have been allocated for ABS issues under the Strategic Plan, allowing, in principle, for the implementation of the Protocol.[59]

Concerning the temporal and substantive scope of the Protocol, Spain holds the view that the Protocol is rather clear in this regard. The scheme established under the Protocol follows the CBD and needs first to be consolidated and implemented in its present form, before further negotiations take place on the matter.[60]

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

In Spain, legislative competence is divided between the federal state and the regions (*Comunidades Autónomas*), which retain significant regulatory power. The Ministry for the Environment, the Rural and Marine Areas (*Ministerio de Medio Ambiente, y Medio Rural y Marino*, MARM) is responsible for international issues, the adoption of framework or basic legislation, and has a few other competencies in the area of biodiversity. However, competence for spatial planning lies with the regions. Altogether, the Spanish governance structure is highly de-centralised which poses considerable problems with regard to policy integration and coordination in environmental matters. Concerning ABS, this results in a

[55] See the former Spanish Strategy for the Conservation and Sustainable Use of Biodiversity, Part I, p. 45, http://www.cbd.int/doc/world/es/es-nbsap-01-p1-en.pdf

[56] Interview with Tania López-Piñeiro, 2 November 2011

[57] Interview with Tania López-Piñeiro, 2 November 2011

[58] The Strategic Plan for Natural Heritage and Biodiversity has been very recently adopted: http://www.boe.es/boe/dias/2011/09/30/pdfs/BOE-A-2011-15363.pdf

[59] Interview with Tania López-Piñeiro, 2 November 2011

[60] Interview with Tania López-Piñeiro, 2 November 2011

situation where competences are divided between different governance levels. However, the basic legal conditions are set at the federal level.

2.1.1 User-side legislative and policy measures

In terms of user legislation, Law 10/2002[61], which implements the EU bio-patent Directive in Spain, states in its preamble that when the subject matter of an invention consists of plant or animal material, or the invention uses such material, the patent application must indicate the geographic origin of the material, in case it is known. This does not affect the examination of the patent application or the validity of rights derived from patents granted.[62] This clause, however, has not been integrated into the patent law as such, and therefore has no legal validity currently.

One author refers to a study on Spanish patent law which reviewed applications for patents using biological material (Blakeney, 2005).[63] One result of the study was that the geographic origin of biological material was usually stated in applications. Furthermore, the study also found that in order to comply with the requirement to describe prior art, traditional uses of biological material were frequently mentioned in patent applications.

Spain has no other user measures in place. [64]

2.1.2 Provider-side legislative and policy measures

At the federal level, Spain has adopted several pieces of legislation of relevance to ABS.

Law 42/2007 on natural heritage and biodiversity (*Ley 42/2007 del Patrimonio Natural y la Biodiversidad*)[65] contains the basic legal framework for biodiversity conservation. Art 68 sets

[61] The full name of the law is Ley 10/2002 de 29 de abril, por la que se modifica la Ley 11/1986, de 20 de marzo, de Patentes, para la incorporación al derecho español de la directiva 98/44/CE, del Parlamento Europeo y del Consejo, de 6 de julio, relativa a la protección jurídica de las invenciones biotecnológicas. In English this translates as Law No 10/2002 of 29 April, by which Law No. 11/1986, of 20 March, is modified, in order to incorporate into Spanish law of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological invention. The law is online at http://www.oepm.es/cs/Satellite?c=Normativa_C&cid=1150364392718&classIdioma=_es_es&pagename=OEPMSite%2FNormativa_C%2FtplContenidoHTML

[62] The Spanish original is: "Cuando una invención tenga por objeto una materia biológica de origen vegetal o animal o que utilice una materia de este tipo, la descripción relativa a dicha invención deberá incluir en su caso información sobre el lugar geográfico de origen de dicha materia, cuando éste sea conocido, y ello sin perjuicio del examen de las solicitudes de patente y de la validez de los derechos que se deriven de las patentes expedidas".

[63] Unfortunately, the original study is not referenced and could not be obtained.

[64] Strategic Plan for Natural Heritage and Biodiversity has been very recently adopted: http://www.boe.es/boe/dias/2011/09/30/pdfs/BOE-A-2011-15363.pdf, p. 103119

forth rules on access to **wild genetic resources** and sharing the benefits from their utilization. The term used in this Article is "*recursos genéticos procedentes de taxones silvestres*", which translates as "genetic resources from wild taxa". It should be noted that according to the "*disposición adicional tercera*" of Ley 42/2007, the law does not apply to plant or animal genetic resources for food and agriculture. It also does explicitly not cover fish resources (see below 2.2. for these); this, however, implies that maritime genetic resources other than fish that are under Spanish sovereignty come within the purview of Ley 42/2007, in principle.

Art 68(1) states that the CBD and the ITPGRFA apply to ABS concerning these resources. Art 68(2) states that a "*Real Decreto*"[66] may stipulate that prior informed consent (PIC) and mutually agreed terms (MAT) may be required for access to wild genetic resources. However, no such *Real Decreto* has been adopted yet, meaning that currently there is no prior informed consent, mutually agreed terms or ABS requirement in Spanish law. One of the reasons why such legislation has not been adopted so far is that the Spanish government wanted to wait for the outcome of the ABS negotiations.[67]

Competence for negotiating access conditions is allocated to the *Comunidad Autónoma* on whose territory the respective genetic resources are found *in situ* or kept *ex situ.* The paragraph explicitly refers to Art 15 CBD. Art 68(3) stipulates that the *Comunidades Autónomas* may adopt additional legislation on access to resources in their territory, if this is necessary for their conservation. In such cases, the MARM has to be informed. So far no such legislation at the regional level exists, given, in particular, that no access legislation has been adopted yet at the federal state.

Traditional knowledge is addressed more in detail in Art 9 of Law 42/2007. Art 9(1) mandates the establishment of an inventory of the natural heritage and biodiversity[68] (*Inventario Español del Patrimonio Natural y de la Biodiversidad*, hereafter IEPNB). Art 9(2) stipulates that the IEPNB is to include traditional knowledge on the natural heritage and biodiversity. Art 70 of Law 42/2007 contains an obligation for authorities to preserve, maintain and support traditional knowledge and practices. Moreover, they must support the fair sharing of benefits arising out of the use of traditional knowledge. Art 70 also requires the establishment of inventories of traditional knowledge, to be integrated into the IEPNB. More detailed rules on the IEPNB are contained in *Real Decreto* 556/2011.[69] Annex I 4.b of this Decreto specifies which types of traditional knowledge are to be included in the

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[65] Available at http://noticias.juridicas.com/base_datos/Admin/l42-2007.html

[66] A „Real Decreto" in Spanish law is a regulation issued by the executive power and requiring the consent of the Council of Ministers.

[67] Interview with Tania López-Piñeiro, 2 November 2011

[68] Inventario Español del Patrimonio Natural y de la Biodiversidad

[69] Real Decreto 556/2011, de 20 de abril, para el desarrollo del Inventario Español del Patrimonio Natural y la Biodiversidad – in English: Real Decreto 556/2011, of 20 April , for the development of the Spanish inventory of the natural heritage and biodiversity, http://www.boe.es/boe/dias/2011/05/11/pdfs/BOE-A-2011-8228.pdf

IEPNB and describes the information to be recorded, which includes a narrative description of the knowledge and the evaluation of the 'conservation status' of the traditional knowledge, measured for example by the amount of people using it. So far, the inventory on traditional knowledge has not yet been established,[70] while some other parts of the IEPNB are already being filled gradually.

Concerning access to traditional knowledge, *Real Decreto* 556/2011 stipulates that the IEPNB is to be put to the use of citizens (Art 4). It also states that the IEPNB is of a public nature (Art 12). However, procedures are to be put in place to protect intellectual property rights. How these are to look like is not clear as of present. In general, the legal situation and basis concerning access to traditional knowledge are different from the one on access to genetic resources.

Concerning **plant genetic resources for food and agriculture** (PGRFA), the applicable federal law is Law 30/2006 on seed and nursery plants of plant genetic resources (*Ley 30/2006 de semillas y plantas de vivero y de recursos fitogenéticos*).[71] This law mainly regulates the registration of plant varieties in the plant variety catalogue. Its Title 4 deals with plant genetic resources. Plant genetic resources are defined in Art 44 as "any type of genetic material of plant origin with actual or potential value for agriculture and food, including fungi"[72]. Genetic material, in turn, is defined as "reproductive material or plant propagation material which contains functional hereditary units".[73] Art 46ff of Ley 30/2006 contain rules on access to PGRFA, with the exception of those PGRFA which are part of the ITPGRFA's multilateral system. As is the case for wild genetic resources, the *Comunidades Autónomas* may adopt additional legislation on access to resources in their territory, if this is necessary for their conservation. In such cases, the MARM has to be informed (Art 46(1)). Moreover, it is stipulated that the plant genetic resources may only be accessed for the purpose of research, genetic improvement or fostering their conservation and sustainable use (Art 46(2)). Access for foreign nationals and companies is only permissible if an MTA is concluded or conventions or bilateral treaties on access are in place (Art 46(3)), Art 47(1) mirrors the clause in Art 12(3)(d) ITPGRFA, stating that recipients shall not claim any intellectual property or other rights that limit the access to the plant genetic resources for food and agriculture, or their genetic parts or component, in the form received. In addition, Art 47 also stipulates several more duties for the recipients of PGRFA: They must report every two years and over a period of 20 years in total, on the research carried out with the PGRFA and any practical application resulting from this research. The reports are to be delivered to the body or entity that provided the PGRFA. In addition, when a recipient of a PGRFA commercialises a product derived from the PGRFA received, the recipient must ensure that

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[70] See http://www.marm.es/es/biodiversidad/temas/inventarios-nacionales/inventario-espanol-patrimonio-natural-biodiv/IECT.aspx (last visited 28 Oct 2011).

[71] Available at http://noticias.juridicas.com/base_datos/Admin/l30-2006.t4.html

[72] Spanish original: "*cualquier material genético, de origen vegetal, que por extensión incluye los hongos, con valor real o potencial para la agricultura y la alimentación*".

[73] In Spanish: "*material reproductivo y de propagación vegetativa, que contiene unidades funcionales de la herencia*."

the product is freely available to anyone in Spain for purposes of research and genetic improvement. However, the intellectual property rights of the recipient are to be respected in this case.

An interesting article concerning benefit sharing is contained in Art 51 of Ley 30/2006. Art 51 entitled 'farmers' rights' stresses that farmers must obtain some of the benefits deriving from the utilisation of plant genetic resources for food and agriculture. To this end, relevant authorities are required to take measures to facilitate the conservation, use and trading of seed and nursery plants of local varieties in danger of extinction that farmers conserve on their farms in limited quantities. Moreover, authorities also have to take measures to protect, conserve and develop traditional knowledge relating to PGRFA.

2.2 Other relevant national legislation

Other relevant legislation that could be of relevance for the implementation of the Protocol includes rules on marine genetic resources and scientific research in this regard.

Ley 3/2001[74] contains rules on fishing motivated by conservation objectives. It regulates access to fish resources, but it does not contain rules on the use of other ocean resources such as microorganisms. Ley 41/2010[75], which deals with marine conservation, contains rules on marine conservations areas, inter alia. It states, in its "*disposicion adicional primera*" that "marine genetic resources will be regulated by the legislation on fisheries". However, so far the fisheries legislation does not contain any specific rules on non-fish maritime resources. Thus, marine genetic resources other than fish appear to be covered by Ley 42/2007 which also applies to certain terrestrial genetic resources.

Ley 3/2001 also contains rules on research relating to fisheries and oceans. It sets forth that research on fish and oceans is to be promoted. It is not evident that any kind of permit is required for this type of research.

3 NATIONAL ABS PRACTICES

Concerning national ABS practices, information available is somewhat scarce. However, a few observations can be made relating to Codes of Conduct and similar instruments as well as on ABS practices more generally.

Codes of Conduct and similar instruments

[74] The full title is Ley 3/2001, de 26 de marzo, de Pesca Marítima del Estado ,or in English Law 3/2001 of 25 March, on state marine fishing, online http://noticias.juridicas.com/base_datos/Admin/l3-2001.html#

[75] The full title is Ley 41/2010, de 29 de diciembre, de protección del medio marino, in English: Law 41/2010, of 29 December, on the protection of the marine environment, http://noticias.juridicas.com/base_datos/Admin/l41-2010.t5.html#da1

The Spanish Association of Biotechnology Companies (ASEBIO)[76] is a member of Europabio, the European biotech association. Europabio has so called core ethical values, by which all members are bound. In these, Europabio states: "We support the principles embodied in the United Nations Convention on Biological Diversity (CBD) to protect biological diversity including adherence to the principles of access and benefit sharing."[77] This is, however, obviously a weak and legally non-binding statement. Interestingly, ASEBIO also has a so called 'ethical code' of its own. While this code contains a general commitment to biodiversity conservation, it does not refer to the CBD or ABS.[78] Similarly, none of the codes featured on the website of Farmaindustria, the Spanish Association for the Pharmaceutical Industry, relates to ABS.[79] In sum, there does not seem to be much express commitment from the Spanish private sector concerning ABS.

Equally, ensuring compliance with ABS requirements does not appear to feature high on the agenda of relevant public research institutions. For example, the National Bioethics Committee does not refer to the CBD on its website, which otherwise features quite a number of national and international legal documents relevant for biomedicine and health sciences.[80] Also, its recommendations on good scientific practice do not mention ABS.[81] By contrast, the *Agencia Estatal Consejo Superior de Investigaciones Científicas* (CSIC), which is the biggest public research institution in Spain, refers to CBD on its website as relevant piece of international legislation.[82] However, the Code of good scientific practice of this institution does not mention the CBD or any of its rules. [83]

Concerning botanical gardens, seven Spanish botanical gardens are members of the International Plant Exchange Network (IPEN),[84] representing only a small share of all botanical gardens in Spain. Gardens that wish to join IPEN must sign a code of conduct which sets out responsibilities for acquisition, maintenance and supply of living plant

[76] The name in Spanish is Asociación Española de Bioempresas

[77] http://www.europabio.org/cross-sectors/positions/europabio-core-ethical-values-cev

[78] See the Code at http://www.asebio.com/es/codigo_etico.cfm

[79] See http://www.farmaindustria.es/Farma_Public_ING/Codigo/index.htm

[80] See http://www.comitedebioetica.es/index.php

[81] Recomendaciones del Comité de Bioética de España con relación al impulso e implantación de buenas prácticas científicas en España, www.comitedebioetica.es/documentacion/docs/buenas_practicas_cientificas_cbe_2011.pdf

[82] See http://www.csic.es/web/guest/normativa

[83] Código de Buenas Prácticas Científicas del CSI, http://documenta.wi.csic.es/alfresco/downloadpublic/direct/workspace/SpacesStore/bdeab818-4f53-4de9-9637-3a9a6c3909fe/C%25c3%2593DIGO%2520DE%2520BUENAS%2520PR%25c3%2581CTICAS%2520COMPLETO.pdf

[84] See list of members at http://www.bgci.org/resources/ipen/

material and associated benefit-sharing. Under the code of conduct, gardens commit themselves to act in compliance with the CBD and the Convention on International Trade in Endangered Species (CITES) when acquiring, maintaining, and transferring living plant material.[85]

Finally, it is worth noting that the Spanish Ministry of Foreign Affairs adopted, in 2007, a Strategy for International Cooperation with Indigenous Communities.[86] It states that no funding or other support will be given to any activity that does not respect certain principles. Among these is that the prior, free and informed consent by indigenous peoples is required for every activity that affects them, their lands, territories and resources. While no explicit reference is made to the prior informed consent requirements of the CBD and the Protocol, this would seem to preclude the provision of public funding to any research projects that do not comply with prior informed consent requirements concerning access to genetic resources.

ABS agreements and biopiracy cases

A review of several documents[87] and standard internet searches did not reveal the existence of any ABS agreements. Concerning access to genetic resources in Spain, this is not surprising, as Spanish legislation currently does not contain any PIC, MAT or ABS requirements. Nonetheless, the responsible ministry has sometimes been contacted with access requests, and in this context, has gathered some information on a voluntary basis. Accordingly, most requests came from outside Spain, and mostly from research institutions rather than the commercial sector.[88]

Concerning the use of genetic resources outside of Spain, a 2006 report on 36 biopiracy cases in Africa lists two potential cases of biopiracy both involving Pharmamar, a Spanish company that mainly focuses on marine research (McGown, 2006). However, these cases appear to have received a limited amount of public attention.[89] Generally, in the run-up to

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[85] The code of conduct is available at http://www.bgci.org/files/ABS/IPEN/IPEN%20Code%20of%20Conduct.doc

[86] Estrategia de la Cooperación Española con los Pueblos Indígenas, http://www.aecid.es/galerias/programas/Vita/descargas/estrategia_pueblos_indigenas.pdf, an English summary is available at http://www.aecid.es/galerias/programas/Vita/descargas/indigenas_resumen_ing.pdf

[87] Among the resources reviewed were Intergovernmental committee on intellectual property and genetic resources, traditional knowledge and folklore, Analysis of potential cases of biopiracy, 9th session, Geneva, April 24 to 28, 2006, WIPO/GRTKF/IC/9/10, Robinson 2010, the WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements at http://www.wipo.int/tk/en/databases/contracts/list.html as well as the websites www.grain.org and www.etc.org. Also, Tania López-Piñeiro was not aware of any published ABS agreements.

[88] Interview with Tania López-Piñeiro, 2 November 2011.

[89] A google search using the terms "biopiracy" and "Spain" (or alternatively the Spanish equivalents) did not produce any search results. Pharmamar is, however, mentioned in the context of biopiracy related to genetic resources in several publications, see for example Manzi and Mayz (2003).

adoption of the Protocol, Spanish companies were mainly concerned with legal clarity and certainty, as they did not want to appear as 'bio-pirates.' [90]

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5 INTERVIEWEES

Tania López-Piñeiro, Head of Strategies and Conservation Plans Unit, Ministerio de Medio Ambiente y Medio Rural y Marino, interview conducted by phone on 2 November 2011

[90] Interview with Tania López-Piñeiro, 2 November 2011.

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: The Netherlands

1 INTRODUCTION

The Netherlands is a major user country, as it has jurisdiction over a large number of users of genetic resources, especially in the seed sector and animal breeding sector. Because of the great importance of these two sectors and the small size of the country, these sectors are strongly dependent of international activities and international transfer of genetic resources. Besides being a user country, the Netherlands can also be regarded as a significant provider of genetic resources in the form of high quality crop varieties and animal breeds.

The Netherlands is a major player of the international biodiversity trade: it dominates the world export trade of live plants (41% of the world's total export value) and ranks third, after the United States and France, in the value of agricultural exports. It is also the fifth largest importer of live plants (6.5% of the total import value). The highly developed Dutch plant breeding industry strongly stimulates this trading. All of the top ten international vegetable seed companies have their main office or an important research department based in the Netherlands (Louwaars *et al.,* 2009). With an export value of over 2 billion euros, the sector plays a major role in the country's economy. It also provides 10,000 jobs and it is fuelling a high-quality academic infrastructure in the field of plant breeding and genetics. Breeding activities are mainly carried out by the private sector, whereas public research institutions play a major role in the development of breeding and genomics research (Ministry of Agriculture, Nature and Food Quality, 2005).

Activities *in situ* conservation of genetic resources in the Netherlands is very marginal and very little policy has been formulated. The conservation of traditional genetic material is however encouraged. Home gardens, national parks and nature reserves maintain traditional plant varieties, even though very few of them are still exploited commercially. The conservation of rare Dutch animal breeds has been encouraged by the government by support for the Foundation for Rare Domestic Animal Breeds (Ministry of Agriculture, Nature and Food Quality, 2002; 2005).

Ex situ management, on the other hand, has largely been developed, by both the Government and the private sector. The largest public genebank, the Centre for Genetic Resources of the Netherlands (CGN), manages a collection of over 24,000 gene samples of plant materials, and over 300,000 samples of animal breeds. The Fungal Biodiversity Centre for micro-biological material (CBS) is another large-scale institution with an international role, holding over 50,000 strains. Other public entities,), including botanic gardens, NGOs

and private collections, also hold genetic resource collections on a smaller scale. The National Plant Collections co-ordinates the Dutch botanic gardens and makes and performs genetic transactions with the research community and other botanic gardens (Ministry of Agriculture, Nature and Food Quality, 2002; 2005; van de Wouw and Visser, 2011).

Together with 12 other Member States and the European Union, the Netherlands has signed the Nagoya Protocol (hereafter, 'the Protocol') on 23 June 2011. This early signing reflects the political importance of the Protocol for the Netherlands. The big commercial interests do play a major role in this respect. So far no major initiatives have been taken to implement the Protocol but an inventory of current regulations and practices on ABS regarding plant genetic resources in the Netherlands has been carried out by CGN in 2011 (van de Wouw and Visser, 2011) and a project group has been established to set up an implementation route in parallel with the European Commission's planning. Various relevant environmental policies are now developed within the European Union. Therefore, the Netherlands will decide on national implementation of the Protocol once proposals that can be expected from the European Commission and their consequences have been clarified. Given these developments, national implementation of the Protocol will be presented to Dutch Parliament only after that (van de Wouw and Visser, 2011).

Generally, the public authorities in the Netherlands are in favour of a 'light version' implementation of the Protocol whereby implementation should occur as much as possible through existing structures and measures. For the Netherlands it is very important to maintain free exchange of genetic resources, to minimize the obstacles for users to access genetic resources, to minimize the administrative burdens (both for public authorities and users) and to have large discretion at the national level to adapt ABS policies to national circumstances and different use purposes.

Two official documents form the actual policy base for genetic resource conservation and use (plant, animal and microbial) in the Netherlands: The 'Sources of existence' document, adopted by the Dutch Parliament in 2002 (Government of The Netherlands, 2002), and the 'Biodiversity works, for nature, for people, for ever' document, released by the Dutch government in 2008 (Ministry of Agriculture, Nature and Food Quality, 2008).

2 NATIONAL LEGISLATION AND POLICIES

In accordance with COP 5 Decision V/26 of the CBD related to the establishment of a national focal point, the Netherlands appointed CGN, in the person of Bert Visser, as the national focal point on ABS. A website was created by the national focal point to provide information on the application of ABS in the Netherlands and beyond.[91] The Netherlands also established a competent national authority, currently in the person of Léontine Crisson from the Ministry of Economic Affairs, Agriculture and Innovation. The competent national authority is in principle responsible for granting access and issuing written evidence that access requirements have been met and for advising on applicable procedures and requirements for obtaining the prior informed consent (PIC) and establishing the mutually

[91] http://www.absfocalpoint.wur.nl/

agreed terms (MAT). However, as the Netherlands does not require PIC and therefore no permits have been issued so far, the competent national authority is currently not active in carrying out these tasks (van de Wouw and Visser, 2011).

2.1 National legislative and policy measures which directly address ABS

2.1.1 User-side legislative and policy measures

Specific ABS user legislation does not exist in the Netherlands. The 2002 'Sources of Existence' document serves as the framework of Dutch ABS policy-making. Following the definition of genetic resources given by the CBD, the document covers microbial, plant and animal genetic resources. Human genetic material is excluded. According to this document, the priorities of the Dutch government are based upon the Convention on Biological Diversity (CBD) and the government will fully comply with the obligations related to the Convention. Hence, it directly takes over basic principles from the CBD for the exchange of genetic resources and the achievement of the third objective of the CBD: (1) national and international cooperation focused on a fair distribution of the profits resulting from the use of these resources should be reinforced; (2) the exchange of genetic resources should be based on prior informed consent between the supplier and the receiving party; (3) the exchange should not threaten the sustainable use of resources; (4) the benefit sharing should help relieve poverty; (5) local and indigenous knowledge is to be taken into consideration when reaching mutually agreed terms (Government of The Netherlands, 2002).

In its policy programme 'Biodiversity works, for nature, for people, for ever' the government lists the creation of an international agreement on a fair ABS regime as one of its priorities in international cooperation (Ministry of Agriculture, Nature and Food Quality, 2008). In 2000, the government also released a policy document entitled 'Nature for People, People for Nature'. It underlined the importance of a fair north-south distribution of the benefits of the utilisation of biodiversity in the fight against poverty (Government of The Netherlands, 2000).

The Convention of Biological Diversity was tacitly approved by Dutch Parliament in 1994, whereas the Dutch legislature explicitly endorsed the FAO International Treaty of Plant Genetic Resources for Food and Agriculture (IT-PGRFA) in 2005. Both instruments entered into force for the Netherlands in the years of their approval. No additional legislative measures were deemed necessary by the Dutch government for the implementation of either instruments (van de Wouw and Visser, 2011). The access to Dutch ex-situ collections, which form part of the public domain, was regulated by the Ministry of Agriculture, Nature and Food Quality in August 2006. For access to the plant genetic resources managed by CGN, the IT-PGRFA's standard Material Transfer Agreement (sMTA) is used. Resources from the botanic gardens are distributed with the internationally agreed IPEN MTA, based on the provisions of the CBD, and their access is limited to internal use and research purposes (CGN, 2011). Types of uses not covered by the international agreements are not regulated by specific policy measures (van de Wouw and Visser, 2011).

In 2005, the Directorate-General for International Cooperation (DGIS) of the Netherlands Ministry of Foreign Affairs joined forces with the German Agency for Technical Cooperation (GTZ, now GIZ), to organize a regional ABS capacity development workshop for African Countries. This multi-stakeholder workshop was held in October 2005 in Addis Ababa, Ethiopia. Their collaboration established the multi-donor Dutch-German ABS Capacity-Building Initiative for Africa in 2006. It offers strategic Africa-wide multi-stakeholder workshops, as well as thematically specific or regionally focused ABS workshops and trainings. The Initiative now involves several other donors; since 2010 the Netherlands was no longer in a position to contribute to it.

The Wageningen UR Centre for Development Innovation (CDI) runs an international programme of short courses, including courses on genetic resources management and genetic resources policies. CDI and CGN co-organise yearly courses in Wageningen and abroad, lately in Ethiopia and in India.

2.1.2 Provider-side legislative and policy measures

The Netherlands has a no-PIC policy. This means that prior informed consent for exporting Dutch genetic resources is not required. It should be noted, however, that this no-PIC policy has not been laid down in law as such. In its 2002 'Sources of existence' policy document, however, the Dutch government explicitly states that it does not deem it necessary to secure its national sovereignty regarding access and use of its own *in-situ* genetic resources (van de Wouw and Visser, 2011). This policy was decided for mainly on the premise that sustainable use is an important incentive for conservation.

As a result of this policy of free availability of plant genetic resources, collections of valuable genetic resources are easily accessible and plant genetic resources are actively distributed in and outside the Netherlands. For farm animal breeds, genetic resources are the property of the cattle farmers or breeding organizations. They have full authority over the access to their resources and over the level of protection of their breeding populations. In practice, the rights to the genetic material are transferred to the buyers of animal breeds (Ministry of Agriculture, Nature and Food Quality, 2002).

It should be noted however that this general policy of not requiring prior informed consent for getting access to plant genetic resources does not prejudice other existing legislation such as legislation in the field of nature protection.

2.2 Other relevant national legislation

The Netherlands has not yet identified any specific legislative measures that could contribute to and/or will be affected by the implementation of the Protocol. Which legislative measures will contribute or be affected depends to a large extent on whether or not the European Commission will initiate implementing legislation, and the content of such legislation. In this respect it is good to know that for the Netherlands it is a very important principle to maintain free exchange of genetic resources, to minimize the obstacles for users

to access genetic resources, to minimize the administrative burdens (both for public authorities and users) and to have large discretion at the national level to adapt ABS policies to national circumstances and different use purposes.

3 ABS PRACTICES IN THE NETHERLANDS

3.1 Dutch research institutions' practices and policies on ABS

The Centre for Genetic Resources, The Netherlands (CGN) conducts, on behalf of the Dutch government, statutory research tasks associated with the genetic diversity and identity of species that are important for agriculture, food and forestry. CGN maintains collections of crops, domestic animals, and trees and shrubs. CGN has traditionally adhered to a policy of unrestricted availability of germplasm held in its genebank. In the interest of keeping this material available for future research and utilization, CGN has undertaken not to claim legal ownership over the germplasm held in its genebank, or to seek any intellectual property rights over that germplasm or related information.

As part of its activities CGN regularly organises missions to collect genetic resources from all over the world. These collection missions are usually governed by Memorandums of Understanding (MoU). Since 2006, MoUs use the standard Material Transfer Agreement (sMTA) of the International Treaty for Plant Genetic Resources for Food and Agriculture (IT-PGRFA) as a basis for collecting material. In 2008, missions have been organised to Uzbekistan and Tajikistan to collect landraces of spinach (*Spinacia oleracea*) and its wild crossable relative *S. turkestanica*. The legal basis of the expedition was formed by the MoU signed between CGN and the national ABS authorities of Uzbekistan and Tajikistan. In the nineties of the previous century the CGN had already set up missions to Uzbekistan (1997 and 1999) and Kyrgyzstan (1999) to collect several crops. More recently, a mission was set up to collect three crop wild relatives (CWR) of leek in Greece (2009), and of other wild relatives of spinach in Armenia, Azerbeidzjan and Georgia (2011).

3.2 Dutch company practices and policies on ABS

Specific examples of corporate policies concerning ABS in the Netherlands have not been found. Plantum, the Dutch association for the plant reproduction material sector, does however underline that several Dutch plant-breeding companies have started to integrate attention to ABS measures in their company policies.

3.3 Experiences of Dutch stakeholders with accessing resources in provider countries

As mentioned above, the CGN has funded and organised several collection missions in third countries. However, in some cases the CGN did not manage to set up or successfully conclude collection missions because of the unwillingness of authorities to have certain genetic material collected and transferred abroad.

Dutch companies have had similar experiences. For instance several Dutch seed companies failed to set up a project with a Latin-American country through which a major collection would be secured, researched and made available, due to the inability of the provider country to formally approve the international transfer of the material and to formally make the material available to third parties.

The interviewees also pointed out that efforts need to be made to make sure you are dealing with the right official bodies in a provider country. In the Teff case (described in more detail below) for instance the Dutch company Health and Performance Food International (HPFI) initially negotiated an ABS agreement with the Ethiopian Agricultural Research Organization (EARO), without knowing that the Institute for Biodiversity Conservation (IBC) in Ethiopia had been designated by Ethiopian legislation as Competent National Authority for ABS and therefore was to be approached for concluding an ABS agreement. As a result the contract had to be renegotiated (Secretariat of the Convention on Biological Diversity, 2008).

3.4 Other lessons learned

It is much more difficult for the Dutch authorities to reach out to and inform public institutions such as academic research institutes (as opposed to major seed companies and cattle breeding companies) that ABS touches upon their research activities and that as a result there is a need to take into account ABS principles when exchanging genetic material with other researchers.

3.5 Examples of ABS agreements in the Netherlands

Most ABS agreements in the Netherlands relate to genetic resources for food and agriculture and have been concluded through the standard Material Transfer Agreement (sMTA) in the context of the specialised international ABS regime established by the IT-PGRFA. Botanic gardens, on their part, use a Material Transfer Agreement (MTA) developed by IPEN, the international network of botanic gardens, though botanic gardens which are IPEN member are not required to sign an MTA. The scope of this regime is rather limited as it only applies to exchange of material for non-commercial purposes. If commercial use is sought at a later date the country of origin's PIC is required (van de Wouw and Visser, 2011). The *Centraal Bureau voor Schimmelcultures* (CBS) Fungal Biodiversity Centre – an institute of the Royal Netherlands Academy of Arts and Sciences (KNAW) and situated in Utrecht, which maintains a world-renowned collection of living filamentous fungi, yeasts and bacteria – also uses a standard MTA for the exchange of material.

ABS agreements concluded beyond these regimes are rather scarce. This results from the uncertainty of developing countries about what will happen once their genetic material passes their national borders, about which authorities are competent to deal with ABS, about how to draft an ABS agreement, etc. The example below is therefore to be considered as exceptional.

The Teff case

In 2004 the Institute for Biodiversity Conservation (IBC) in Ethiopia, the Ethiopian Agricultural Research Organization (EARO) and the small Netherlands-based company Health and Performance Food International (HPFI) concluded an ABS agreement for the breeding and development of tef (*Eragrostis tef*). Tef is one of the most significant cereal crop species in Ethiopia and Eritrea and is very important in the national diet, where it is commonly made into *injera*, a flat, spongy and slightly sour bread. Tef is also grown for livestock forage. Tef is increasingly desired in Western markets, because of several characteristics one of which is being gluten-free. HPFI was highly interested in tef, as it develops tef products for Western markets such as bread, sports bars and beer (Secretariat of the Convention on Biological Diversity, 2008).

It took several and protracted rounds of negotiations to conclude the final agreement. This resulted partly from the low levels of awareness as to the role and responsibilities of the Competent National Authority and even its identity. Neither HPFI nor EARO initially knew that IBC had been designated by Ethiopian legislation as Competent National Authority for ABS. Another cause for the delays in concluding an agreement can be related to differences in culture and mentality, especially in relation to the involvement of governments in ABS agreements according to the negotiator of the HPFI. Whereas the Ethiopian government wanted to talk to the Dutch government rather than to the Dutch company concerned, the Dutch company did not want to involve the Dutch government in the negotiations.

The scope of the agreement is limited to the provision by IBC (on behalf of Ethiopia) to HFPI of tef for the purpose of developing food and beverage products. The use of tef for other purposes such as chemical or pharmaceutical applications is not allowed without the consent from the IBC and access to the traditional knowledge of Ethiopian communities related to tef is not permitted without written agreement. IBC, in turn, cannot grant access to tef genetic resources made available to HFPI to other parties for the purposes listed in the annex without the consent of HFPI. The agreement includes among others a commitment by HFPI to pay IBC a lump sum of profits arising from the use of tef genetic resources, to pay royalties to IBC of 30% of net profit from the sale of seeds of tef varieties, a license fee linked to the amount of tef grown by HFPI, and contributions by HFPI of 5% net profit to a fund established to improve the living conditions of local farming communities and for developing tef business in Ethiopia. The agreement also sets out a commitment by HFPI to create joint ventures with Ethiopian companies to establish tef businesses in Ethiopia (Secretariat of the Convention on Biological Diversity, 2008).

The implementation of the agreement, however, has bumped into several obstacles including a decision of the Ethiopian government to ban tef exports and, more recently, HFPI going bankrupt. Irregularities on the transfer of rights acquired by HFPI to other companies have been reported, and this issue is still under investigation.

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Koen van Ginneken, Programme Legal instrumentation Nature and Area Planning, Ministry of Economic Affairs, Agriculture and Innovation, 2 November 2011, The Hague.

Bert Visser, ABS focal point, Centre for Genetic Resources, 2 November 2011, The Hague.

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: United Kingdom

1 INTRODUCTION

The UK is primarily a user of genetic resources. There are many sectors across the UK that use genetic resources obtained overseas, both for commercial and non-commercial purposes. These include pharmaceuticals, cosmetics, plant breeding (horticulture and agriculture), natural and traditional medicines, the wildlife trade, culture collections, zoos, aquaria, botanical gardens and universities. From the outset of the negotiations that led to the signature of the CBD in 1992, the pharmaceutical and agribusiness sectors in the UK have been identified as the largest and most important users of genetic resources.

The UK does not have a great deal of *in situ* biodiversity, but some UK genetic resources have been used in scientific research and by industry. For example, a recently announced cancer treatment, based on the chemical colchicine, was derived from the Autumn Crocus (*Colchicum autumnale*), a native British flower (Battison, 2011). Marine resources may also be important in the future, such as any extremophiles found in the economic zones surrounding the UK Overseas Territories (e.g. South Georgia and the South Sandwich Islands). Moreover, landraces and cultivars are maintained by a significant number of growers and amateur gardeners. Extensive landrace diversity exists for cereals, forage crops and fruit and vegetable species (Defra, 2010a). There are also a significant number of crop wild relatives in the UK and more than 200 native livestock breeds (NSC, 2011). The Overseas Territories have more than 340 endemic species, including significant bird and marine resources (Defra, 2009).

Most of the UK's provider role is likely to be brokered through *ex situ* collections, however. For example, institutions such as the Natural History Museum and the Royal Botanic Gardens, Kew contain some of the world's largest collections of living and preserved genetic resources. These two institutions alone perform tens of thousands of specimen transactions each year. This includes collecting biological materials from provider countries and intermediaries, and supplying materials to third parties in the UK and overseas. There is neither specified role for indigenous and local communities nor pertaining to traditional knowledge in the UK.

The UK Government signed the Nagoya Protocol on 23 June 2011 (*hereafter*, 'the Protocol') and is committed to its implementation. At EU-level, the UK Government has confirmed through Council Conclusions the need for timely implementation and ratification. In the recently released Natural Environment White Paper 'The Natural Choice' (Defra, 2011), the UK Government emphasised that implementing the Protocol can ensure that developing

countries receive a share of the profits from commercialising genetic resources (e.g. from pharmaceuticals and cosmetics), and will also help to provide access to those resources for UK companies.

To date, the effective coverage of ABS issues in the national legal systems in the UK is generally covered by well-established laws of property, trespass, statutory protection of species and site protection. This was considered to be adequate for CBD requirements according to a 2005 review of the experience of implementing ABS arrangements under the CBD. The review indicated, however, that "due to the changing nature of common law and those statutory laws, the body of applicable ABS in the UK should be reviewed in the future" (Latorre, 2005).

Defra recently commissioned a study by an external evaluator to assess the affected sectors and determine potential options for the UK to implement the Protocol. Government is interested in considering the full range of implementation options, from regulation to more 'light touch' voluntary agreements and provision of information to stakeholders. Resources available to Government to implement the Protocol are limited; any measures put in place will need to take this into account.

2 NATIONAL LEGISLATION AND POLICIES

2.1 National legislative and policy measures which directly address ABS

COP 5 Decision V/26 requests that all signatories to the CBD establish a national focal point and one or more competent authorities to take responsibility for ABS arrangements or provide such information within its jurisdiction. The UK subsequently established a focal point for this purpose, under the Research Policy and International Division, Science Directorate of the Department for Environment and Rural Affairs (Defra). A website was also developed to provide information on the CBD and ABS, in particular.[92] The website has been updated to reflect the adoption of the Nagoya Protocol. The UK has not, however, established a competent national authority on access to genetic resources (Defra, 2010b).

2.1.1 User-side legislative and policy measures

The UK does not have ABS user legislation in place. A guidance document is available from the Defra website, which explains what steps the UK has taken with respect to access and benefit sharing vis-à-vis the CBD, and provides definitions of genetic resources, traditional knowledge, access and benefit sharing.

The definition of genetic resources is taken directly from Art 2 of the CBD. UK guidance indicates that genetic resources include both living and preserved materials, and recognises Decision II/11 of the CBD Conference of the Parties, which reaffirmed that human genetic resources are not included in the CBD framework (Defra, 2010b). The guidance also notes that national legislation in some countries may extend the obligation to obtain prior

[92] Defra website, 'What we are doing internationally - Access to genetic resources' http://www.defra.gov.uk/environment/natural/biodiversity/internationally/access-genetic-resources/, page last modified 2 April 2011 [page accessed 26 October 2011].

informed consent (PIC) and to share benefits beyond those derived from genetic resources, to include associated traditional knowledge and the derivatives of genetic resources. The UK does not have its own policy or other guidance with respect to traditional knowledge or derivatives of genetic resources.

UK guidance also explains that benefit-sharing is not defined under the CBD, but that national laws in other countries may require that benefits are shared according to mutually agreed terms, following the agreement of prior informed consent. The guidance document states that the parties to any such agreement "can be as imaginative and ingenious as they are able" in defining benefit sharing and agreeing mechanisms to do so, as long as the requirements of relevant access laws and any other contractual commitments are met (Defra, 2010b). A list of potential monetary and non-monetary benefits that such agreements may include is provided as well.

The UK does not have any measures in place to ensure that genetic resources used within in its jurisdiction have been accessed in accordance with prior informed consent or that mutually agreed term has been established where required by provider countries. There are no policies regarding traditional knowledge or non-compliance.

No formalised or regular mechanisms have been established by public authorities to monitor R&D activities with respect to the use of genetic resources within its jurisdiction. A study was undertaken in 2005, however, which reviewed the experiences and extent of ABS implementation by UK stakeholders under the CBD (Latorre, 2005). The study represents Defra's first effort to work more closely with stakeholders on ABS issues and was intended to identify the most important issues and needs of the various stakeholder groups. The review findings were intended to inform Defra's national policy development, including on any future ABS regime under the CBD, and to implement the International Treaty on Plant Genetic Resources for Food and Agriculture. Defra has recently commissioned a new study to assess the potential impacts and options for implementing the Nagoya Protocol in the UK, which will include a survey of stakeholders as well. The findings from this study are expected to inform Defra's participation in the second meeting of the Intergovernmental Committee of the Nagoya Protocol in April 2012.

2.1.2 Provider-side legislative and policy measures

The UK does not have ABS provider legislation in place. UK guidance indicates that anyone seeking to access UK genetic resources must obtain permission from the owner of those resources, whether the land owner or the owner of any collection of resources (i.e. for *in situ* and *ex situ* resources) (Defra, 2010c).

2.2 Other relevant national legislation

The UK has developed a guidance document that outlines relevant areas of UK law that govern access to genetic resources (Defra, 2010c). Relevant areas of UK law pertain to land and intellectual property, as well as health and safety rules and regulations, and can vary by jurisdiction amongst the countries of the United Kingdom (England, Scotland, Wales and Northern Ireland), and its Crown Dependencies and Overseas Territories.

In general, permission from the owner of UK genetic resources is required to enable access to the resources. Variations in the rules surrounding ownership and access may occur where access is subject to:

- Countryside and Rights of Way Act 2000 (Part I);
- Commons Act 2006;
- Commons Registration Act 1965;
- National Parks and Access to the Countryside Act 1949;
- Wildlife and Countryside Act 1981;
- Contractual agreements with third parties (e.g. local authorities); and
- Practice and custom (e.g. countryside held by the National Trust or woodland held by the Woodland Trust).

Regarding *in situ* collection, ownership of genetic resources is largely determined by who owns the land on which they are found, except for:

- Wild animals (other than game or fish), which are regulated by Game and Poaching laws;
- Protected species (which may be subject to the Wildlife and Countryside Act 1981 (WCA) or the Conservation Regulations 1994); and
- Protected sites containing genetic resources (which may be subject to the rules governing a Site of Special Scientific Interest (SSSI)).

Where intellectual property rights apply to genetic resources, the user must agree access with the intellectual property rights owner under the rules governing the type of intellectual property involved.

Some health and safety legislation in the UK may affect access to genetic resources, particularly where access is related to potential health and safety risks from work activities. In some cases, interaction with certain substances may require notification of a UK Competent Authority. Health and safety legislation which directly influences access to genetic resources includes:

- Health and Safety at Work Act 1974 (HSWA);
- Management of Health and Safety at Work Regulations 1999 (MHSWR);
- Control of Substances Hazardous to Health Regulations 2002 (COSHH);
- Reporting of Incidents, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR);
- Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009;
- Advisory Committee on Dangerous Pathogens (ACDP);
- Legislative controls over the safety of GMOs used in containment; and,
- Genetically Modified Organisms (Contained Use) Regulations 2000.

3 NATIONAL ABS PRACTICES

UK research institutions and company practices and policies on ABS

The UK has a number of research institutions and companies that have adopted procedures and developed policies and guidelines regarding ABS. Some of these could be considered as examples of best practice for implementing the Protocol, providing model contracts, clauses and procedures that could be replicated in other organisations.

Royal Botanic Gardens, Kew

Kew has been a leader in developing a sectoral response in the UK, and internationally, on ABS for botanical gardens/collections. Kew's policies have been developed since 1997, when the Convention & Policy Section at Kew (funded by the UK Department for International Development) launched a pilot project for botanic gardens. This involved representatives of 28 botanic gardens from 21 countries and included four workshops. The aim was to develop harmonized policies/guidelines for botanic gardens on access to genetic resources and benefit-sharing. A set of principles on access to genetic resources and benefit-sharing for participating institutions were developed and botanic gardens and other similar organisations are invited to endorse the non-legally binding principles and to develop their own institutional policy to set out how the Principles will be implemented (CBD, 2002).

Within Kew, the Overseas Fieldwork Committee is responsible for ensuring that permits are obtained from provider countries. Each Kew collector must fill out a form, verifying that a permit has been obtained, three months in advance of the expedition; travel clearance is not made available unless the form has been completed. These procedures have been in place since 2005-06. Kew has also begun using ABS agreements to ensure prior informed consent. There's also a Kew intranet site for staff, containing guidance and information regarding ABS and traditional knowledge, as well as the requirements for obtaining a permit.

Natural History Museum

The Natural History Museum (NHM) has also developed a system to ensure that specimens are accessed with the appropriate permissions and used as per terms of the access agreement. This system takes a risk-based approach informed by the likelihood of exploitation by third parties. The primary objective is to generate and maintain trust with provider countries and demonstrate that there is a robust process in place. The NHM has a clear policy on prior informed consent and mutually agreed terms (MAT) for staff, which was in place before the CBD (although it has changed since the CBD). The NHM apply the policy to items given to the museum (in addition to items it obtains directly from other sources). A permit should be collected from the appropriate authority (often very difficult), and then staff should submit agreement to a team in NHM for approval prior to signing anything. The steps to be followed when planning a collection trip include:

- Complete documentation outlining purpose(s) of the trip;
- Documentation filed by the collection manager; and
- Documentation filed by the central registrar.

Every lot submitted to the NHM is given a number, which is uploaded to a central database. The PIC and MAT associated with the lot is then attached to this number. There are currently no policies at NHM on traditional knowledge. Most of the 'benefits' generated by the NHM, which are / can be shared with provider countries, are non-monetary. Benefits include: identification of species, training, production of documentation and guidance, and joint publications.

PlantNetwork

The Plant Collections Network of Britain and Ireland (PlantNetwork, formerly PlantNet) is a national network of botanic gardens, arboreta and other documented plant collections for Britain and Ireland. PlantNetwork aims to promote plant collection use and education for public benefit in Britain and Northern Ireland. PlantNetwork provides information on its website about the CBD, as well as guidance on best practice regarding the steps that should be taken to ensure that access and benefit sharing have been agreed. Model Material Transfer Agreement (MTA) text is also available on the site (PlantNetwork, 2010).

GlaxoSmithKline

GlaxoSmithKline (GSK) is an international research-based pharmaceutical and healthcare company based in the UK. GSK is currently working on its own and in conjunction with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA) and international chamber of commerce (ICC) to develop positions on Protocol implementation. Their work with the two pharmaceutical associations is part of a pharmaceutical industry-specific effort, while the ICC work is cross-sector. A pharmaceutical and cross-sector position is expected to emerge regarding how the industry would like to see the Protocol implemented, and particularly regarding the role of checkpoints.

GSK has already prepared position papers regarding Protocol implementation and specifically on proposals regarding disclosure requirements through patent applications (GSK, 2011a and 2011b). GSK supports the Protocol overall, but suggests that implementation should involve national governments determining the conditions under which access to genetic resources should be given, and for the parties concerned to mutually agree the benefits that will be shared. GSK does not support proposals to include a disclosure requirement in patent applications because they argue that the patent system was not designed to regulate or enforce rules relating to conduct, and that a disclosure requirement would create significant legal uncertainties for researchers and those who wish to develop commercial products.

Experiences of UK institutions with lack of access to resources in provider countries where ABS policies are in place

Multiple difficulties exist in provider countries in terms of ABS. Many of the problems in provider countries have been developing for 20 years, though over the past five years, much of the new legislation on ABS has been put in place.

In countries that set up centralised ABS systems, it has become difficult for UK organisations to arrange agreements (e.g. Brazil and South Africa). Some countries, such as Malaysia, have

banned access altogether, eliminating a source of genetic resources for UK organisations. Other countries require strict terms and conditions; for example, China requires that all specimens are repatriated after a specified period. This creates problems for organisations where a large number of samples are collected and/or where samples are transmitted to third parties. In India, it has become so difficult to obtain access that it can be impossible to be certain that specimens are accessed legally, so collection in India is generally avoided as a result. Finally, the Philippines Executive Order had very stringent requirements, which effectively stopped R&D in this country; a replacement was to be implemented, but this has not happened yet.

Examples of recent benefit-sharing agreements in the UK

Eden Project

The Eden Project has been working with the Seychelles government and other conservation organisations since 2000 on projects to promote ecological restoration and sustainable livelihoods on the islands (www.edenproject.com). The Eden Project has since developed a new ornamental hybrid using the endangered *Impatiens gordonii* from the Seychelles and crossing it with a more common type (Hannah, 2011). The new hybrid is called Impatiens 'Ray of Hope' and is being bred by the Eden Project and sold in the UK in order to raise funds and awareness for rare and endangered plant conservation (BGCI, no date). The prior informed consent was obtained from the Seychelles Ministry of Environment through the botanical garden in Mahé; half of any profits from retail sales of the new variety are given back to the Seychelles to support plant conservation for rare and endangered species.

Wollemi Pine

Several botanic gardens, including the Royal Botanic Gardens, Kew, have partnered with the Australian government and Wollemi Pine International Pty Ltd to commercialise the Wollemi Pine. The Pine was discovered in 1994 near Sydney, Australia and is one of the world's oldest and rarest plants (BGCI, no date). There are currently thought to be fewer than 100 adult trees existing in the wild; research is now focused on ensuring the conservation of the Wollemi Pine. The Pine is being grown and sold to the public as a way to generate funds for conservation of wild plants in Australia.

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ANNEX 2: COUNTRY REPORTS NON-EU COUNTRIES

- Australia
- Brazil
- India
- The Philippines
- Switzerland
- Uganda

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Australia

1 INTRODUCTION

As a developed megadiverse country, Australia is both a provider and user country for genetic resources and stands to gain considerable economic, social and environmental benefits from their utilisation (NCA, 2002). It controls approximately 10% of the world's natural genetic and biochemical resources, most of which have not yet been evaluated for commercial potential (a significant portion of the country's biota still has to be described). Australia's research community includes 450 biotechnology companies, many of which are research-intensive SMEs and spin-outs from universities, other publicly funded research institutes and non-profit research organisations. By 30 June 2011, the sector's market capitalisation was estimated at AUS $23.4 billion.[93]

Australia has large tracts of indigenous-owned land, covered by different types of associated rights regulated under the Native Title Act 1993. An Indigenous Advisory Committee is consulted on general environmental matters. There is high interest in the indigenous and local communities and traditional knowledge aspects of the Protocol.

Australia has not yet signed the Protocol but technical consultations at competent national authority level have been completed and the decision has now shifted to the political phase. It contributed actively to the development and adoption of the CBD Bonn Guidelines, with which its domestic policy framework, also adopted in 2002, is closely aligned.

2 NATIONAL LEGISLATION AND POLICIES

2.1 Legislative and policy measures which directly address ABS

Australia has a federal system of government, divided between national (Commonwealth) government, six sovereign States and two self-governing Territories. Legislation is based on the common law system derived from the United Kingdom.

Each government manages access to biological resources under its jurisdiction under its own laws. Ownership rights to native biological resources depend on whether they are found in

[93] Australian Department of Innovation, Industry Science and Research, Portfolio Factsheets September 2011 http://www.innovation.gov.au/AboutUs/KeyPublications/Documents/InnovationPortfolioFactSheets.pdf, accessed 14 November 2011.

Commonwealth, State or Territory government lands or waters, indigenous lands, freehold or leasehold lands. Commonwealth jurisdiction covers defence lands, certain national parks, Australia's external territories and 10 million km^2 of ocean resources.

A policy goal under the National Strategy for the Conservation of Australia's Biological Diversity (1996) is to "ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia" (Objective 2.8).

At legislative level, the framework Environment Protection and Biodiversity Conservation Act 1999 (the EPBC Act) establishes a basis to issue regulations to manage access to and use of genetic resources in Commonwealth areas (sec.301). Options for implementation were considered by the Voumard Inquiry 1999-2000, based on consultations across governments and with industry, scientific researchers, indigenous and local communities and civil society. The rationale included encouraging domestic and foreign biodiscovery investment into Australia, taking advantage of its robust system of commercial and intellectual property law, stable public administration and strong scientific and research base offering collaborative opportunities. In parallel, enhanced access to genetic resources was addressed through Australia's Biotechnology Strategy (2000).

This process culminated in the adoption of Part 8A, Environment Protection and Biodiversity Conservation Regulations 2000 (the EPBC Regulations), operational since 2005. Under Australia's Constitution (sec.9), national regulations override state and territory law in the event of any conflict.

In 2002, the 14 Commonwealth, State and Territory Ministers constituting the Natural Resource Management Ministerial Council endorsed the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (NCA, 2002). This non-binding framework endorses the Bonn Guidelines and was intended to guide action by governments to develop or review ABS measures. It sets out general principles for each jurisdiction's legislative, administrative or policy frameworks, including to *"introduce terms and conditions of access to Australian resources that Australia would be prepared to meet if introduced by other countries."*

The NCA's objectives have only had limited success (only Northern Territory and Queensland have adopted ABS legislation: Victoria and Tasmania have some recent measures for this purpose). As each jurisdiction has different rules for accessing biological resources, "this is a potential source of confusion for permit applicants and land managers. It also creates an unnecessary need for multiple permits where bioprospecting ventures occur across jurisdictional boundaries" (DEWHA, 2009).

The competent national authority recognises the ongoing challenge to build a consistent approach at national level, but notes that a) some States and Territories have been waiting for the Protocol's finalisation and b) that traditional knowledge issues have to be addressed at national level.

In 2009, the Government established the National Biodiscovery Forum to facilitate exchange

of views between researchers and science, industry and environmental policy-makers. The second National Biodiscovery Forum (August 2011) had the theme 'From research to reality - translating biodiversity research outcomes through biotechnology' with a special focus on marine biodiscovery.

2.1.1 Provider-side legislative and policy measures

The objectives of Australia's ABS regime cover the CBD's three objectives, responsibilities to indigenous and local communities under Art 8(j) and 10(c) CBD, and the need to promote certainty and reduce administrative costs (8A.01, EPBC Regulations).

A permit is required for any access to "*biological resources*[94] *of native species for research and development of any genetic resources, or biochemical compounds, comprising or contained in the biological resource"* in Commonwealth areas. The competent national authority for issuing permits is the Department of Sustainability, Environment, Water, Population and Communities (SEWPAC).

Exemptions from this permit requirement include indigenous persons' use of biological resources as well as "taking of public resources" for non-research purposes, including fishing for commerce or recreation, taking wild animals or plants for food, collective plant reproductive material for propagation and commercial forestry (Regulation 8A.03). The competent national authority considers this exemption regime has proved fairly straightforward: most agricultural research is focused on non-native genetic resources so falls outside the scope of the Regulations. The fisheries interface is slightly more complex as the Commonwealth has competence for marine molecular/genetic research c.f. harvesting of marine resources in certain coastal waters is a fisheries department competence.

Case by case exemptions may also be made for: *ex situ* collections of biological resources (including future additions) held by a public department or agency where administered consistent with the purpose of the EPBC Regulations; or where use of the resources is required to be controlled under any international agreement to which Australia is a party (e.g. the International Treaty on Plant Genetic Resources for Food and Agriculture) (regulation 8A.05).

The application process distinguishes between research purposes but not between national/foreign applicants.

Applicants for **non-commercial scientific research permits** (no fee) do not need to negotiate a benefit-sharing agreement and need only obtain written permission from the access provider. They must also make a Statutory Declaration confirming non-commercial intent and undertake to negotiate a benefit-sharing agreement with the access provider should the purpose of the research change to a commercial one. They must report on their results,

[94] Defined as "genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity" by sec.528, EPBC Act.

offer a duplicate of each sample to an Australian public institution that is a taxonomic repository and seek permission before transferring the material to third parties. There are no explicit traditional knowledge requirements.

Permits for commercial or potentially commercial uses require the applicant to enter into a benefit-sharing agreement with the resource provider. An AUS $50 permit fee applies. Prior informed consent (PIC) is required from the indigenous owner or native title holder where access is to genetic resources on indigenous people's land. A benefit-sharing agreement must provide for 'reasonable' benefit-sharing arrangements, including protection for and valuing of indigenous people's knowledge to be used. Regulations 8A.8 and 10 set out detailed requirements and information to be considered prior to the grant of a permit, including: use of indigenous people's knowledge, including details of its source (e.g. whether it was obtained from scientific or other public documents, the access provider or another group of indigenous persons); benefits to be provided or agreed commitments given in return for the use of such knowledge; a copy of the written agreement/the terms of any oral agreement regarding use of such knowledge; the details of the applicant's proposals to benefit biodiversity conservation in the area if access is granted; and details of the benefits that the access provider will receive for having granted access. The knowledge itself does not have to be revealed.

There are no minimum benefits sharing requirements: parties to the contract agree benefits on a case-by-case basis. However, SEWPAC has published two model contracts to reduce transaction costs associated with developing arrangements and provide for reporting: a) where the Commonwealth is the access provider and b) where others (e.g. indigenous people) are the access provider. Schedule 4, Model Agreement, sets out indicative benefits, including contributions to conservation and scientific knowledge, technology transfer and revenue generated by the commercialisation of intellectual property related to the genetic resources if relevant.

Generic conditions for issue of a permit require collections of biological resources to be undertaken in accordance with the principles of ecologically sustainable development, including the precautionary principle, and for assessment where the environmental impact of the proposed access is likely to be "more than negligible" (8A.16, EPBC Regulations).

Transparency is ensured through the Genetic Resources Information Database (GRID: sec.515A, EPBC Act) which provides a low-cost mechanism of 'virtual' certificates of origin and evidence of legal provenance (Burton 2009). GRID supports the permit register required under Regulation 8A.1 (http://www.environment.gov.au/grid/public/perrep.jsp) and sets out full details of all permits, including the access party, conditions and details of samples collected. As it is not always possible for researchers to provide a detailed description of biological resources prior to access (particularly where the biodiversity is poorly known, not taxonomically described or because of the nature of the collection methodology), permit holders are required to provide updated lists as this information becomes known. Applicants may request that information is treated as confidential but no requests have been made to date.

Eight ABS contracts have now been completed with organisations engaged in commercial research (four with Australian public Institutions, three with foreign research organisations). A further contract with an Australian research institution is under consideration. The mutually agreed terms (MAT) for benefit-sharing closely followed the model contracts provided by SEWPAC.

The EPBC Regulations provide a mechanism to accredit existing administrative or regulatory regimes for permit issuing purposes aligned with the national ABS policy framework in order to minimise duplication. Accreditation is now in place for the Great Barrier Reef Marine Park Authority, Australian National Botanic Gardens, Australian Institute of Marine Sciences and Australian Antarctic Division. To date, SEWPAC has used these accreditation powers restrictively but it will issue revised accreditation criteria in mid-November 2011 and then intends to promote early accreditation to avoid legislative complexity.

By 26 October 2011, 116 permits had been issued through the Protected Areas Policy and Biodiscovery Section, SEWPAC, under Part 8A, EPBC Regulations: nearly all were for non-commercial purposes. When access permits issued under accredited regimes are included, the total rises to over 500. Most related to protected areas or marine waters under Commonwealth control (where the main challenge is coordinating managers from different sectors and building awareness).

Permit variations, transfers and penalties for breach of conditions are governed by Regulation 17, EPBC Regulations. The current penalty for non-authorised access in Commonwealth areas is 50 penalty units (fine of AUS $5500). Very few cases of non-compliance have been recorded, and the number of permit applications is rising.

Monitoring arrangements are under development. All permits have a reporting requirement and a condition that the accessed resources should not transferred to a third person without permission. The competent national authority envisages that commercial permit requirements should also encourage placing samples, at the end of research, into collections or museums (e.g. the Australian Institute for Marine Science requires all samples to be assessed for the BioResource Library).

With regard to **traditional knowledge**, the main challenge is to strike an appropriate balance between indigenous people's prerogatives for self-determination (avoiding State intrusion) and ensuring appropriate legislative safeguards consistent with the Protocol. Indigenous-owned land in areas leased by the Commonwealth (e.g. national parks) is jointly managed. Consultative mechanisms are in place, as determined by joint management boards and the management plan for each park. Although PIC is operational, the competent national authority indicates that there is little experience of accessing traditional knowledge, given the difficulty of developing a framework to give scientists legal certainty and overcome distrust.

A possible option under consideration would involve developing a Standard Protocol for traditional knowledge, using the existing model benefit-sharing contracts as a starting point. This could facilitate demonstration of the prior informed consent through a checklist of elements to be addressed (adequate time for discussions, availability of independent legal

advice etc.). This type of mechanism would support government oversight of due process, but the competent national authority would not be privy to the traditional knowledge content covered by the agreement. This type of format could be coordinated with the indigenous peoples' section of Australia's National Biodiversity Fund which supports development of traditional knowledge recording and protocols.

A dedicated website (http://www.environment.gov.au/biodiversity/science/access/index.html) provides legislative information and lists the competent national authority for each jurisdiction and key operational contacts to facilitate the work of researchers and industry.

At subnational level, the two dedicated ABS laws are Queensland's *Biodiscovery Act 2004* and the Northern Territory's *Biological Resources Act 2006*. The latter establishes a two-tier regime for genetic resources access on private land: at a contractual level, PIC and MAT must be agreed with the private landholder but the Territory government requires a permit for all resource collection to avoid significant environmental damage. The Northern Territory Natural Resource Management Board has also developed Guidelines for Indigenous Ecological Knowledge Management which also cover archiving and repatriation (Holcombe, 2009).

2.1.2 User-side legislative and policy measures

Australia's existing framework has been developed from a provider perspective i.e. domestic access. Following the adoption of the Protocol, the competent national authority is currently focusing on the most appropriate user measures which are the main gap under current arrangements.

Whereas access can be regulated at subnational level (linked to State and Territory jurisdictions), it is envisaged that user legislation will be developed and implemented at national level to avoid additional administrative burdens for States and Territories.

Various options are being considered, aiming to make use of existing institutional structures and processes to promote simplicity and avoid delay. Although incremental costs are envisaged (increased permit numbers), the fact that Australia has already streamlined its national framework is expected to minimise new administrative burdens.

Australia does not envisage using the national Patent Office (although it does not want to exclude possible models related to the World Intellectual Property Organization) as such models would take too long to be developed.

One approach considered well-suited to the Australian context would be to use existing public research institutions as checkpoints (rather than the competent national authority which is exclusively concerned with native genetic resources). Most scientific research in Australia already has a public funding component, mostly through the Australian Research Council grants (administered by the Commonwealth) or the Health and Medical Research

Council funding agency. Both have good understanding of ABS issues. This means that contractual links with researchers are or could easily be put in place.

It is envisaged that the future legislative framework would introduce a cover-all offence of using foreign genetic resources without PIC or MAT, and authorise the designated checkpoint to oversee compliance with foreign country user legislation. This would be facilitated by international certificates of compliance, to be verified by the research body and passed to the national government if necessary. Australian research stakeholders require the future legislation to minimise barriers by providing practical mechanisms to demonstrate compliance in other countries.

The competent national authority stresses the need for effective awareness-building targeted at education and research institutions and a progressive behavioural shift. Australian universities are considered keen to set high standards for biodiscovery, particularly where traditional knowledge is concerned. Once the Protocol ratification process is under way, Australia envisages developing a code of conduct setting out standards for how genetic resources research is carried out and sourced. Stronger university buy-in might build on the precedent of ethics committees and review panels, with access to scientific publications acting as a driver for best practice by researchers.

2.2 Summary of studies evaluating ABS legislation

A positive academic evaluation of the effectiveness of Australia's ABS framework was published four years after the EPBC Regulations became operational (Burton, 2009). This predates the Protocol but assessed the regime's compliance with the Bonn Guidelines and drew on direct contacts with the competent national authority.

Burton's study considers that the GRID – a low-cost database based on open-source software - contributes significantly to legal certainty, compliance and verification by enabling 'due diligence' testing before investment in research. It is an evolving mechanism that progressively lists the identity of samples collected, giving them a unique identity, and now contains details of thousands of samples. By providing a platform for open verification, it reduces the risk of accusations of misappropriation or biopiracy and supports domestic and foreign researchers in protecting the intellectual property in their discoveries in all potential markets. Because GRID spans the full research time-frame, it should provide a deterrent to misplaced patent challenges.

The study also supported the requirement that non-commercial researchers undertake to conclude a benefit-sharing agreement if the purpose of research changes, as most work starts as non-commercial biodiversity research. This recognises that accidental or serendipitous discovery is a continuous feature of science and addresses the risk of simplified non-commercial procedures being used to circumvent the purpose of the legislation.

Another positive feature is the power to exempt *ex situ* scientific collections that operate in accordance with international/sectoral voluntary schemes for CBD compliance or otherwise

meet the Regulations' objectives. This means they do not have to deal with the regulatory and procedural burdens of 2 CBD compliance systems and can maintain their existing collaborative systems with similar institutions, while demonstrating to third parties they meet accreditation requirements under Australian national law. Burton recommends that the adoption of institutional accreditation to international standards should be further considered in the light of Australian practical experience.

At government level, an independent review of the EPBC Act 1999 was published on 21 December 2009. The 'Hawke Review' (DEWHA, 2009) was generally positive with regard to the current ABS regime but made several concrete recommendations:[95]

- move Part 8A Regulations into the EPBC Act to increase community awareness, continue rationisalisation and accessibility of the Act's compliance and enforcement provisions and increase the penalty provisions for non-compliance with access regulations;
- require benefit-sharing agreements to refer to 'equitable' sharing of benefits instead of 'reasonable';[96]
- require informed consent where Indigenous knowledge is accessed or used for non-commercial purposes on Commonwealth land;[97]
- amend use of 'taking' in the context of *ex situ* collections to clarify that persons who "receive or hold" biological resources from Commonwealth ex-situ collections are subject to the requirements of the provisions;[98]
- reinvigorate the Nationally Consistent Approach to reduce legal uncertainty and avoid multiple permit applications for bioprospecting across jurisdictional boundaries.[99]

Although no final decision has been reached, the competent national authority indicates that the Regulations will likely be incorporated into the revised Act. The policy setting for administrative user measures may be achieved through a series of small but significant amendments to the legislation, combined with memoranda of understanding between government bodies, strengthening of existing contractual obligations and stronger buy-in from universities and research institutes.

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[95] See generally Recommendation 22, DEWHA 2009 at p.138.

[96] See §5.109, based on a submission by the NSW Young Lawyers Environmental Law Committee that the use of 'reasonable' provided for less than Australia's obligations under the CBD as it does not create any concrete obligation for an access applicant to directly provide a portion of the profits from the use of traditional knowledge to knowledge holders.

[97] See §5.126. The current regulations only cover traditional knowledge in the context of commercial permit applications.

[98] See § 5.110.

[99] See § 5.113-4.

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Northern Territory website with focal points, legislation applicable to different areas and links: http://www.environment.gov.au/biodiversity/science/access/contacts/nt/index.html

Queensland *(2004) Biodiscovery Act*
http://www.legislation.qld.gov.au/legisltn/acts/2004/04ac019.pdf

Queensland website with focal points, legislation applicable to different areas and links:
http://www.environment.gov.au/biodiversity/science/access/contacts/qld/index.html

Voumard Inquiry (2000) Public Inquiry into access to biological resources in Commonwealth areas http://www.environment.gov.au/biodiversity/publications/inquiry/index.html

7 STAKEHOLDERS CONSULTED

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European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Brazil

1. INTRODUCTION

Brazil is one of the world's 17 megadiverse countries; about 70% of the world's catalogued animal and plant species are found there. Brazil has an estimated 15-20% of the world's biodiversity, and probably the greatest number of endemic species on a global scale.[100] Despite harboring approximately 18% of the global plant diversity, Brazil's agriculture and food security depend on the introduction of genetic resources from other countries.[101] Nevertheless, several Brazilian native species are important for human consumption at the regional and local scale. These include cassava, pineapple, peanuts, cocoa, cashew, cupuassu, passion fruit, Brazil nut, guarana, jabuticaba. Additionally, native forage species support a good part of the national livestock sector and, more recently, agrobusiness companies have become more interested in native medicinal and ornamental plants.[102] Finally, a significant amount of germplasm is held in ex-situ collections.[103]

In Brazil, there are more than 200 indigenous peoples and 180 languages; altogether this is a population of 600,000 or 0.2 % of the Brazilian population, making Brazil also a culturally mega-diverse country.[104] 1,000 communities of *Quilombolas,* who are descendents of run-away slaves from African, have been officially identified. The respective population is estimated at around 2 million people.[105] Artisan fisherfolk, nut gatherers and rubber tappers from other types of traditional communities, with a population of about 4.5 million people, according to the Ministry of the Environment. Such communities have considerable knowledge relating to plant and animal natural resources, and how to manage them.

This implies also a high agricultural diversity. Examples are the indigenous Kaiabi people who use more than 140 crop varieties, or the traditional community of the *seringueiros* (rubber-tapers) in which 17 varieties of mandioca, 14 of banana and nine of beans are

[100] See http://www.cbd.int/countries/profile.shtml?country=br

[101] Ministry of Agriculture 2009, p.8

[102] Ministry of the Environment 2010, p. 43

[103] Ministry of Agriculture 2009

[104] Santilli 2009, p. 190

[105] See http://www.palmares.gov.br

used.[106] This diversity of cultivated plants allows adaptation to different environmental conditions, leading to the relative stability of local agriculture systems and satisfying local demand for food and medicinal products as well as other plant products for self-consumption and commercialization.[107]

In the framework of the National Biodiversity Strategy Project, a synthesis on biodiversity-related TK in Brazil was compiled, based on a review of publications during the last 20 years on the knowledge and use of biodiversity by traditional peoples in Brazil. However, of 206 indigenous nations in Brazil, only 106 had their traditional knowledge studied. Several projects are being implemented in relation to traditional knowledge such as "Zero Hunger and Sustainable Development in Indigenous Communities", "Ethnic Identity and Cultural Heritage of Indigenous Peoples", and the "Brazilian Indigenous Peoples Program". There is also a "Brazilian Program for Valuing and Protecting Traditional Knowledge Associated to Biodiversity", which involves communities possessing traditional knowledge in the implementation of legislation on access and benefit-sharing, through the creation of a network for information dissemination and for processing complaints.[108] Brazil is also carrying out specific training programs on ABS among local communities, inter alia.[109]

Altogether, Brazil is a **provider country.**

Brazil was a central actor in the ABS negotiations; the fact that the EU and Brazil agreed on central elements of the Nagoya Protocol was instrumental in bringing about the Protocol's adoption. Brazil was among the first states to sign the Nagoya Protocol (2 February 2011), but has not yet ratified it.

There are ongoing efforts on revising the current ABS system (see below). In August 2011, a conference was held in Brasília, where the government and business representatives discussed the implementation of the 20 Aichi targets, defined at the COP-10/CDB.[110] National goals and subgoals were defined, as and a strategic plans on how to execute the global goals at the national level until 2020 was adopted.

2. NATIONAL LEGISLATION AND POLICIES

2.1 Legislative and policy measures which directly address ABS

Brazil is a provider country, and hence has provider, but no user measures in place.

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[106] Santilli 2006

[107] Ministry of the Environment 2010, p. 212

[108] See http://www.cbd.int/countries/profile.shtml?country=br#thematic

[109] Ministry of the Environment 2010, p. 203

[110] Empresários e e governo trabalharão juntos para adaptar metas globais de proteção da biodiversidade ao contexto nacional, 5 August 2011, http://www.mebbrasil.org.br/default.aspx?pag=noticias&id=39

2.1.1 Characteristics of provider legislation and policies

The central piece of legislation implementing the CBD in Brazil is Provisional Measure (PM) 2.186-16/2001. It regulates access to GRs, to associated knowledge (ATK), the sharing of benefits derived from their use, and the transfer of technology for the conservation and use of biological diversity (Article 1). Biological and biochemical resources are not addressed; PM 2.186-16/2001 explicitly states that the human genetic heritage is not covered (Article 3). ATK is defined in Article 7/IV PM 2.186-16 as knowledge or individual or collective practice, associated to GR, of a native Brazilian or local community. PM 2.186-16/2001 applies to both wild and domesticated GRs, and makes no distinction between the two regarding ABS. Thus there is no specific regime for plant genetic resources for food and agriculture (PGRFA), even though Brazil has ratified the ITPGRFA.

Provisional Measure 2.186-16/2001 contains two main elements: authorization of access to GR and ATK, and the benefit-sharing.

Rules on access

The Genetic Patrimony Management Council (CGEN)[111], the Brazilian Institute of Environment and Natural Resources (IBAMA) and the National Council for Scientific and Technological Development (CNPq) all have specific tasks concerning ABS on genetic resources.[112]

Access, according to a technical orientation issued by the CGEN, is different from collecting biological material. Access is defined as the 'the activity carried out with GRs with the objective of isolating, identifying or using information of genetic origin or molecules and substances arising from the metabolism of living beings and of extracts obtained from such organisms'.

The access authorizations and additional normative acts are issued primarily by the CGEN. The CGEN is composed of 19 ministries and federal agencies and coordinated by the Ministry of the Environment; since 2003, representatives of biotechnology companies, researchers in scientific institutions or indigenous and traditional communities have been attending the monthly CGEN meetings; they have the right to speak, but cannot vote.

If access is considered to have only strictly scientific purposes, authorizations are issued by two institutions with faster procedures, the Brazilian Institute of Environment and Natural Resources (IBAMA), and the National Council for Scientific and Technological Development (CNPq).

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111 The CGEN has been created and defined by Decree 3945 of September 28, 2001, see www.mma.gov.br/cgen

112 But none of them is mentioned on the website of CDB as "Access and Benefit-sharing Competent National Authorities", see http://www.cbd.int/doc/lists/nfp-abs-cna.pdf

Access to GR and ATK can only be permitted once the previous consent by indigenous peoples (when access occurs in indigenous territories or ATK is accessed), of an environmental agency (when access occurs in a protected area) or of the owner of private land has been given. When indigenous people do not agree, the CGEN may not authorize access.[113] When access takes place in waters under Brazilian jurisdiction, the maritime authority must give its consent, or even of the National Defence Council, if an 'area that is indispensable to national security' is involved.

Foreign institutions or individuals wishing to access genetic resources must cooperate with a Brazilian institution.[114] No fee for access permits is foreseen. The recipient of an access permit is required to present annual reports to the CGEN. The permit may be suspended and sanctions may be imposed if the permit is mis-used (Article 14.1 and Article 30 PM 2.186-16). Decree 5459 of 7 June 2005 regulates infringements of the rules of the Provisional Measure and contains remedies for illegal activities involving the genetic heritage and associated traditional knowledge.

Rules on benefit-sharing

When access is with the aim of commercial use, a BS contract must be signed between the providers and the users of the GR or the ATK; the BS contracts requires approval from the CGEN (Article 29 PM 2.186-16). These contracts may provide for different benefits, including payment of royalties, profit sharing, technology transfer, no-cost licensing of products and processes, and training (Article 25 PM 2.186-16). The PM also sets forth certain mandatory elements for BS agreements, e.g. period of duration and intellectual property. For the cases where genetic resources from federal public areas are used, it is set forth[115] that the benefits will be dedicated to specified public funds, notably the Fundo Nacional do Meio Ambiente[116] and the Fundo Nacional de Desenvolvimento Científico e Tecnológico.

According to the Ministry of Environment, CGEN, by 2010, had approved 25 benefit-sharing contracts.[117] From 2002-2009, 44 scientific research proposals involving scientific knowledge were approved.[118]

Traditional knowledge

[113] Santilli 2009, p. 189

[114] ICTSD 2010, p. 2; New Zealand Ministry for Economic Development 2011, p. 14.

[115] See Decreto Nº 6.915, of 29 July 2009

[116] The Fundo Nacional do Meio Ambiente funds environmental projects, see http://www.mma.gov.br/sitio/index.php?ido=conteudo.monta&idEstrutura=1&idConteudo=3419&idMenu=3036

[117] However, on p. 212, it is stated only one contracts had been approved. It is unclear, where the difference in numbers comes from.

[118] Ministry of the Environment 2010, p. 213.

Several relevant legal norms relate to traditional knowledge and its holders. Most importantly, the Brazilian Constitution (Article 231) recognizes the social organization, customs, languages, beliefs and traditions of indigenous peoples and the *Quilombola* communities and gives them the right to the exclusive use of the natural resources in their traditional lands. Furthermore, the Constitution gives indigenous peoples, their communities and organizations the standing to defend their rights and interests in courts (Article 232 of the Constitution). The Public Prosecution is given a role in safeguarding these rights: it may initiate civil investigations and suits to protect, inter alia, the environment and other diffuse and collective interests, and to defend in court the rights and interests of the indigenous populations (Article 129/III and V of the Constitution). Diffuse and collective interests include rights regarding traditional knowledge related to genetic resources.[119] However, the need remains to develop specific legislation establishing a system for the protection of the knowledge, innovations and practices, taking into account their specific characteristics. Such instruments are still in the early stages of discussion with indigenous and traditional peoples.

Generally, there are mechanisms in place to allow the participation of traditional knowledge holders in decision-making processes, for example in the Genetic Patrimony Management Council (CGEN), the National Biodiversity Commission, and the National Environmental Council. Indigenous communities and local communities that create, develop, detain or conserve TK associated to the genetic patrimony according to Article 9 of the Provisional Measure 2.186-16/2001 have the guaranteed right to

- Indication of the origin of the TK in every single publication, utilization, exploration and divulgation;
- Impede non-authorized third-parties from
    - using, testing, researching or exploring TK;
    - disseminating, transmitting or re-transmitting data or information that integrate or constitute TK
- Receive benefits from the economic use by third parties, directly or indirectly, of associated traditional knowledge to which they hold rights

In access negotiations, communities must be clearly informed in an accessible language about the proposed research activities (purpose, methodology, duration, geographical area, knowledge to be accessed, budget, and potential impacts), and on the rights and responsibilities of each party. They have the right to refuse the access to their knowledge during the process of consent.[120]

IPR

[119] Kishi 2009, p. 317/318

[120] ICTSD 2010, p. 4

The central article setting forth a link between IPR and ABS is Article 31 of PM 2.186-16.121. For its implementation, Resolução Nº 207/09 has been adopted. Accordingly, every patent application built on genetic resources has to declare whether access was in compliance with the relevant laws; applicants must provide the number and date of the relevant authorization. A study carried out in 2006 showed that until that date fewer than 10 per cent of the patent applications filed at the National Institute of Industrial Property (INPI) identified the origin of the genetic material or of the ATK, and that no patent application filed at the INPI had attached an authorization of access issued by the CGEN.[122] Art. 30 of PM 2.186-16.123 allows as one possible sanction for the non-compliance with the Brazilian ABS legislation the suspension or cancelling of related patents.

ATK, by its nature, cannot be protected through patents in Brazil.[124]

It is also worth noting, that the Brazilian Law No. 9.456, of 25 April 1997 on Plant Variety Protection[125] recognises farmers' rights in that it allows, in Article 10, everyone to store and plant seeds for his own use on his premises as well as to use or sell as food or raw material the product of his planting, except for the purposes of reproduction. Moreover, small farmers are allowed to multiply seed, for donation or exchange with other small rural producers, in the framework of state-authorized programs. The law also permits in general, to use protected plant varieties for research purposes.

2.1.2 Characteristics of user legislation and policies (to the extent that it is relevant for country concerned)

There is no user legislation in place.[126]

2.2 Summary of studies evaluating ABS legislation

Generally, the hope that Brazil might considerably benefit from its cultural and biological diversity have not been fully met.[127]

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121 Article 31 reads "... grants of industrial property rights made by the competent bodies to a process or product obtained from sample components of genetic heritage is contingent on the observance of this Provisional Act, and the applicant must inform the origin of genetic material and associated traditional knowledge, where appropriate."

122 Santilli 2009, p. 194

123 Article 31 reads "... grants of industrial property rights made by the competent bodies to a process or product obtained from sample components of genetic heritage is contingent on the observance of this Provisional Act, and the applicant must inform the origin of genetic material and associated traditional knowledge, where appropriate."

124 Kishi 2009, p. 318/319

125 English translation online at http://www.wipo.int/wipolex/en/text.jsp?file_id=125403

126 All measures listed at http://www.cbd.int/abs/measures/group.shtml?code=br are provider measures.

One of the perceived weaknesses of the system is that companies and scientists are discouraged to access GR and ATK because of high transactions costs, legal uncertainties, the risks of public blame of bio-piracy and time consuming procedure. Obtaining a permit lasts about three years.[128] Researchers have complained, for example, about the requirement to obtain the consent of relevant communities for their research, arguing that they will not always know where a genetic resource is found at the beginning of their research.[129] Moreover, enforcement in Brazil appears to have been quite strict, with the competent authorities allegedly imposing substantial fines since November 2010 on cosmetics, pharmaceutical, and other companies suspected of violating ABS legislation.[130] In 2010, the Ministry for the Environment announced that the rules on ABS needed to be revised to facilitate research and development of industrial products from biodiversity.[131]

Another issue is the law's focus on bilateral BS contracts. This is seen as one of its most serious weaknesses, given that in many situations knowledge on the characteristics, properties and uses of biological resources is held, produced and/or shared by various traditional peoples.[132] According to a report by ICTSD, in the new law, which the federal government is currently preparing, bilateral contracts between users and providers of GR are no longer foreseen in cases where users are from Brazil. When users of GR are based in Brazil, they would have to contribute to a public BS fund a fixed percentage rate of benefits deriving from commercial sale or licensed patents. Bilateral contracts would only have to be negotiated cases when users of GR are foreign institutions; in these cases the BS agreement would be negotiated with CGEN and benefits would flow into the public BS fund. This fund would finance activities aimed at the conservation and sustainable use of biodiversity.[133]

Finally, as the Ministry of the Environment points out, there is a lack of implementing legislation for some of the ABS rules, leading to a significant number of pending cases.[134]

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[127] See Kleba 2009, p. 119

[128] Brasil tenta estabelecer medidas para preservar a biodiversidade, http://www.valor.com.br/brasil/1013660/brasil-tenta-estabelecer-medidas-para-preservar-biodiversidade

[129] Azevedo 2005, p. 4

[130] Mitchell 2011

[131] http://www.brasil.gov.br/cop10-english/overview/what-s-at-stake-at-cop-10/genetic-resources-2013-access-and-benefit-sharing-abs/br_model1?set_language=en

[132] Santilli 2009, p. 190; Kishi 2009; Kleba 2009, p. 120 ff.; ICTSD 2010, p.2/3

[133] ICTSD 2010, p. 2/3

[134] Ministry of the Environment 2010, p. 212f.

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European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: India

1 INTRODUCTION

India is one of 17 'megadiverse' countries on the planet and its network of protected areas covers around 4.7% of the country's total land area.[135] India is a key centre of crop diversity with around 45,500 plant species, 375 closely related wild varieties and 6,500 varieties used in indigenous healthcare (Government of India, 2008). Traditional knowledge and beliefs are of great importance to India's cultural heritage as well as for the conservation of an important number of its plant and animal species. India has over 19,000 community established 'sacred groves' to which indigenous communities have spiritual and cultural connections. These groves contain a large number of medicinal and wild plants about which traditional knowledge and beliefs are kept. This traditional knowledge exists both in coded (medicinal texts) and non-coded (oral and undocumented) form.[136] Its plant diversity, coupled with a rich base of traditional knowledge related to the use of these natural resources, makes India a provider of genetic resources. It is estimated that more than 6,000 plant species, forming about 40% of the plant diversity of the country are used in India's codified and folk healthcare traditions with around 70% of the population using plants for health care (Ved and Goraya, 2007). Although India's trade in medicinal plants and related products is not necessarily well documented,[137] the country certainly profits from its biodiversity and related knowledge: domestic trade of the Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) industry is around Rs. 80-90 billion (1.2 – 1.3 billion EUR) with exports in the range of Rs. 10 billion (146 million EUR) per annum.[138] As India continues to develop its industry, interest in international cooperation regarding access to genetic resources in other countries may well be growing in importance.

Indigenous groups (scheduled tribes) in India number over 700 and make up around 8.2% of the population (Government of India, 2011). They are recognised in India's Scheduled Tribe Recognition of Forest Rights Act (2006) which recognises community rights to traditional

[135] CBD India National Country Profile, Accessed at; http://www.cbd.int/countries/profile.shtml?country=in on 05/11/11

[136] Ibid.

[137] Agriculture & Industry Survey, Accessed at: http://www.agricultureinformation.com/mag/2007/06/india-lacks-credible-data-on-medicinal-plants/ on 14/11/11

[138] National Medicinal Plants Board, Accessed at: http://nmpb.nic.in/index.php on 14/11/11

knowledge of forest biodiversity and community rights to intellectual property and traditional knowledge related to this biodiversity. Nevertheless, these communities have few legal rights over natural resources which are to a large extent nationalised (Mitra and Gupta, 2009; Pant, 2009).

India is an active party of the CBD and has been a strong supporter of the ABS process at the international level, acting as chair of the group of LMMCs (Likeminded Megadiverse Countries). It was an early signatory of the Protocol on May 11th, 2011. India will furthermore host the 11th CBD COP as well as the Second Meeting of the Open-ended Ad Hoc Intergovernmental Committee for the Protocol on Access and Benefit-sharing (Intergovernmental Committee) in April 2012.

The chairman of the Indian Expert Committee on ABS, noted in interview that although planned, ratification of the Protocol has not yet taken place, as it must first pass through a number of administrative channels.[139] Nevertheless, as mentioned above, India has engaged positively with the CBD and the ABS process, therefore reflecting the observation by the CBD Secretariat that "signature also creates an obligation, in the period between signature and ratification, acceptance or approval, to refrain in good faith from acts that would defeat the object and purpose of the Protocol."(CBD Secretariat, 2011).

The 2002 National Biodiversity Act provides a framework for implementation of the CBD and the Protocol. However, despite the legal status of this framework, adequate awareness and understanding of its provisions on ABS in general has yet to spread, particularly at the state and local levels where it matters most.[140] Thus there remains room for improvement in the practical implementation of the Protocol.

3 NATIONAL LEGISLATION AND POLICIES

3.1 Legislative and policy measures which directly address ABS

As mentioned above, India is mainly a provider country; it does not as yet have user policies or legislation in place to implement ABS provisions.

Overall legislative framework

India has several legislative acts which regulate access to genetic resources and the benefits arising from their use. The Indian Biological Diversity Act 2002 (hereafter referred to as the Biodiversity Act) provides the key framework for the implementation of the CBD.

India ratified the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) on 10 June 2002 and has provided for farmers' rights to participate in the fair and equitable sharing of the benefits arising from the use of plant genetic resources for food and agriculture through the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act of

[139] Interview with Dr. R.S. Rana

[140] Interviews with Dr. R.S. Rana and with Jebra Muchahary

2002. This constitutes a *sui generis* regime of protection for plant variety rights. However, unlike the international Treaty, the Indian Act does not explicitly provide for farmers' rights to participate in decision-making regarding the benefit-sharing.

The Patents (Amendment) Act of 2005 regulates the Indian patent system. The Patents Act has specific provisions that allow indigenous knowledge to be recognised as prior art[141] and is thus an important pillar in the Indian legislative framework for ABS. Whilst the Biodiversity Act and the Patents (Amendment) Act refer primarily to the use of biological resources, the PPVFR Act refers above all to the use of genetic resources. None refers explicitly to the use of biochemical resources, although the definition of biological resources under the Biodiversity Authority includes "plants, animals and micro-organisms or parts thereof, their genetic material and by-products [...] with actual or potential value." (Section 2(c))

One further relevant piece of legislation with respect to traditional knowledge is the Scheduled Tribe Recognition of Forest Rights Act (2006). According to Art 3(1)(k) of this Act, forest dwelling Scheduled Tribes and other traditional forest dwellers have the "right of access to biodiversity and community rights to intellectual property and traditional knowledge related to biodiversity and cultural diversity". This report will focus primarily on the Biodiversity Act however, as the primary legislative act for regulating access to biological resources and the sharing of benefits arising from their use.

Access to genetic resources: general rules

The Indian Biodiversity Act established a three-tier system to control access to biological resources. The National Biodiversity Authority acts as the competent national authority for all access requests from **foreign** nationals (including applicants who are not Indian citizens or are non-resident Indians), research organisations or companies, as well as for regulating the export of research results carried out by foreign nationals within India. The Act also grants the National Biodiversity Authority competence to act on behalf of the Central Government to "take any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource which is derived from India." (Section 18 (4)). Thus, the Indian state can take action against parties who have not adhered to India's rules for Prior Informed Consent and Mutually Agreed Terms. Indeed, India has fought high profile and high cost IPR cases against a patent granted by the European Patent office for the use of neem as an anti-fungicide (Sheridan, 2005) and a patent granted by the US patent office for known traditional use of turmeric (Brody, 2010). However, following these experiences, India is now tending towards challenging patents through the less resource intensive method of pre-grant opposition. In the last two years, India has brought about the cancellation or withdrawal of 36 applications to patent traditionally known medicinal formulations, primarily through use of its Traditional Knowledge Digital Library which collects and stores information on prior art (Gupta, 2011).

[141] In most systems of patent law, 'prior art' refers to information publically available in any form before a given date that could affect a patent's claim of originality. If an invention has been described in prior art, a patent on that invention is not valid.

At the second level of the system established by the Biodiversity Act is the State Biodiversity Board, to whom **Indian** nationals must direct their applications for access to resources (Section 23). Indian citizens do not need to apply for any approval for access to bioresources for research purposes. Finally, at the third level are Biodiversity Management Committees, established to promote conservation and sustainable resource use as well as to document local knowledge relating to biodiversity (Section 41(1)). These local committees must facilitate documentation of traditional knowledge through the compiling of Peoples Biodiversity Registers. Biodiversity Management Committees are also authorised to levy charges by way of collection fees from any person collecting bioresources for commercial purpose from areas falling within their territorial jurisdiction [Section 41 (3)] to be accrued in Local Biodiversity Funds. The National and State Authorities are required to consult with the relevant local Biodiversity Management Committees when taking any decision relating to the use of biological resources and knowledge associated with such resources (Section 41(2)).

The Biodiversity Act stipulates that international applicants must 'apply' to be granted 'approval' by the National Biodiversity Authority (Section 19). By contrast, citizens or organisations registered in India intending to "obtain biological resources for commercial utilisation, or bio-survey and bio-utilisation for commercial utilisation" (Section 7) do not have to apply for approval. Instead, Indian nationals shall give 'prior intimation' in 'such form as may be prescribed by the State Government to the State Biodiversity Board.' (Section 24(1)). The use of the term 'prior intimation' rather than prior informed consent suggests that persons or organisations registered in India are legally at liberty to carry out the activities mentioned in Section 7, whether consent is granted by the State Biodiversity Board or not (Gopalakrishnan, 2007). In theory, this prior intimation can still be called into question: "On receipt of an intimation under sub-section (1), the State Biodiversity Board may, in consultation with the local bodies concerned and after making such enquiries as it may deem fit, by order, prohibit or restrict any such activity if it is of opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing benefits arising out of such activity" (Section 24(2)). However, in practice, it means that the holders of biological resources and associated knowledge are not entitled to be informed or to give prior informed consent.

In its only concrete acknowledgement of traditional practices, the Biodiversity Act does exempt "local people and communities of the area, including growers and cultivators of biodiversity, and *vaids* and *hakims*[142] who have been practising indigenous medicine" in Section 7 from the requirements to give notice to the State Biodiversity Board before their use of biological resources.

A further exemption is granted to collaborative research projects, even where these involve foreign institutions or individuals. As stipulated in Section 5 of the National Biodiversity Act, collaborative research projects between Indian organisations and public sector organisations of third countries do not require authorisation from the National Biodiversity Authority as long as the project has been approved by the Central Government and

[142] Healers and practitioners of traditional medicine.

complies with their policy guidelines on the matter.[143] The export of PGRs in the category of collaborative research is decided on by the PGR Export Facilitation Committee which submits its recommendation to the Department of Agricultural Research and Education and the Chairman of the NBA for final approval.[144]

All in all, this system has several weaknesses regarding implementation. As mentioned above, both the National and State authorities are required by the Biodiversity Act to 'consult' with the local Biodiversity Management Committees (Section 41 (2)). The result of this consultation however is not legally binding. If the local Committee does not agree with the decision, there is no right for recourse. Furthermore it may be difficult to establish whether the relevant stakeholders – i.e. those with whom the knowledge of a biological resource or its uses reside – are consulted in the first instance. This can be exacerbated by land development such as dam-building and forestry which may involve the resettlement of communities away from resources about which they have traditional knowledge (Gadgil, 2000).

ABS rules for foreigners

In order to access biological resources and associated knowledge for research or commercial utilisation, foreign applicants must complete a form and make a payment of 10,000 rupees (146 EUR) to the National Biodiversity Authority. Specific information about the nature of access sought and the biological material and associated knowledge to be accessed must be outlined. This information includes, among other, the geographical location of the proposed collection, a description of the associated traditional knowledge, including its nature (i.e. oral or documented), and any identified individual or community holding the traditional knowledge. Furthermore, information must be provided on any commercial gains being derived and expected to be derived from the resource, an estimation of benefits that would flow to India or its communities arising out of the use of accessed biological resources and traditional knowledge as well as benefits that may accrue to the applicant or their country.

The Biodiversity Act stipulates that while granting approvals for access to biological resources, applications for patents, or any other intellectual property protection National Biodiversity Authority shall,

"ensure that the terms and conditions subject to which approval is granted secure equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefits claimers." (Section 21 (1)).

[143] The 'Guidelines for International Collaboration Research Projects Involving Transfer or Exchange of Biological Resources or Information relating thereto between institutions including government sponsored institutions and such institutions in other countries'/'Central Government's Guidelines in Respect of Biodiversity' were published in the Official Gazette of India 08/11/06 in Hindi language.

[144] National Bureau of Plant Genetic Resources, Accessed at: http://www.nbpgr.ernet.in/faq.htm on 7/11/11

Mutually agreed terms must therefore be established before genetic resources can be accessed.

In terms of the benefits to be shared, the Biodiversity Act states only that these must be 'equitable'. Section 22 (2) outlines the methods through which benefit-sharing can take place, namely: granting joint ownership of IPR to the National Biodiversity Authority or identified benefit claimers; technology transfer; location of R&D facilities in locations that will improve living standards for benefit claimers and involvement of local communities in these R&D processes. Finally, Section 22 (2) mentions two forms of direct financial payments: establishment of a venture capital fund to aid the benefit claimers; and the payment of monetary compensation and other non-monetary benefits to benefit claimers. This monetary compensation may be directed by the National Authority to be placed in the National Biodiversity Fund (Section 22 (3)).

Section 20 of The National Biological Diversity Rules, 2004 sets out criteria for benefit sharing, as established in Section 21 of the Biodiversity Act.[145] Section 20 of the Rules states that "the Authority shall by notification in the Official Gazette formulate the guidelines" and "describe the benefit sharing formula' which 'shall be determined on a case-by-case basis", the quantum of which shall be mutually agreed upon by applicants and the National Authority "in consultation with the local bodies and benefit claimers". At the time of writing, the Authority has yet to publish guidelines or a benefit sharing formula. However, a working template for the sharing of monetary benefits has been developed by the Expert Committee on Access and Benefit Sharing and is being used for general guidance until official guidelines for this purpose are duly notified. A summary of this template is found in Table 1 below.

[145] Biological Diversity Rules, 2004 http://www.nbaindia.org/rules.htm

Table 1

Category Commercial use	Benefits from direct commercial use	Benefits from commercial use after licensing to a licensee (third party)
The Applicant commercialises the process/product	The applicant shall pay royalty @ up to 3% of the highest ex-factory sale price of the product sold or used for captive consumption (in such cases, the price would be determined on the basis of the price which the product would get if sold in the market).	The applicant pays a mutually agreed upfront amount until the product/ innovation enters into commercial production.
The Applicant licenses the process/product to a licensee	The Applicant shall pay up to 5% of the license fee received from the Licensee as one-time benefit sharing at this stage. The Applicant shall also provide a copy of the contract, entered into, to the Authority.	Upon commercialization, the applicant shall further pay, in addition to the payment made earlier, up to 4% royalty on the amount received by him as his royalty-charges from the licensee on an annual basis.
The Applicant collects the bioresource from its natural populations, with prior approval of the concerned SBB/BMC/State Wildlife Board, and exports it under DGFT permit.	The Applicant shall pay 5% of the total FOB value of the bioresource under export to the Authority.	

***Source*:** Rana, 2010

Form I which must be completed by foreign applicants also requests a "proposed mechanism and arrangements for benefit sharing".[146] In this way, it is the National Authority, rather than the local communities where the resources are located, which will have the final say about the level and type of benefit sharing. Indeed, the Rules go on to state that the quantum of these benefits 'may be decided in due regard to the defined parameters of access, the extent of use, the sustainability aspect, impact and expected outcome levels, including measures ensuring conservation and sustainable use of biological diversity.' However, as the National Authority 'may' do this, there is a lack of clarity as to how these decisions are taken.

The Biological Diversity Rules also state that "the Authority shall stipulate the time frame for assessing benefit sharing on short, medium, and long term benefits" depending on the case, and that "the Authority shall stipulate that benefits shall ensure conservation and sustainable use of biological diversity." Furthermore, "while granting approval for access or for transfer of research results or applying for patent and IPR or for third party transfer of the accessed biological resource and associated knowledge (the Authority) may (also) impose terms and conditions for ensuring equitable sharing of the benefits arising out of the use of accessed biological material and associated knowledge." Thus, the National Biodiversity Authority has ultimate authority over the type and quantum of benefits to be distributed. Although access is granted in consultation with local Biodiversity Management Committees, the National Authority is not obliged to consult with the Committees with regard to the benefits they shall receive. Furthermore, there is also room for rising costs and confusion in relation to benefit-sharing due to the fact that the local Committees may also levy charges from those who access resources within their territorial jurisdiction (Section 41 (3)).

Traditional knowledge

Traditional knowledge relating to the use of biological resources is only briefly addressed in the preamble of the Biodiversity Act which refers to 'local people' or groups and 'local

[146] Form I to be found at: http://www.nbaindia.org/download.htm

knowledge'. It states that the Central Government shall "endeavour to respect and protect the knowledge of local people relating to biological diversity as recommended by the National Biodiversity Authority through such measures, which may include the registration of such knowledge" (Section 36 (5)). The Indian government has developed an innovative tool in the form of the Traditional Knowledge Digital Library (TKDL). This is an online-resource which documents information on traditional knowledge related to medicinal plants and their uses. As it helps to establish prior art for patent searches, the TKDL may help to direct the flow of benefits arising from the use of these resources to the source community. However, despite access and non-disclosure agreements between the international patent offices and the Indian government, there is no guarantee that the knowledge in the TKDL will truly be respected and protected.

Furthermore, an important debate exists as to whether the registration of this knowledge in a database may be incompatible with the nature of traditional knowledge systems related to biological resources (Githae, 2009; Robinson, 2010). The Biodiversity Act does in most instances refer to access to biological resources and 'knowledge associated thereto', however, there is no specific mention of which local groups this knowledge might belong to, the systems traditionally used for preserving such information, and how these might be protected. The national and state Authorities must consult with the local management committees, which may have close links to the holders of traditional knowledge. However, there is little legal reassurance that these holders will have control over eventual access decisions taken by the national Authority and indeed any assurance that they will receive the resulting benefits from the use of the resources and knowledge they hold.

Monitoring

The Biodiversity Act makes no mention of monitoring. The Biological Diversity Rules note that "The Authority shall take steps to widely publicise the approvals granted, through print or electronic media and shall periodically monitor compliance of conditions on which the approval was accorded." (Section 14(10)). The Authority shall also "monitor the flow of benefits as determined under sub rule (4) in a manner determined by it." (Section 20(10)). No further concrete guidelines on monitoring could be found. However, the National Biodiversity Authority Annual Report 2009-10 plans for the design and implementation of the Indian Biodiversity Information System, to include online submission/ processing and monitoring of applications, agreements and funds flow as recommended by the expert committee formed for the purpose.

IPR legislation

India has one of the most far-reaching links between ABS and patent legislation worldwide. Although it primarily relates to access rather than benefit sharing, the Indian Patents (Amendment) Act (2002 and 2005 iterations) establishes a framework in which both oral and written traditional knowledge are recognised, thus helping to establish prior art in relation to biological resources and associated knowledge. Any patent application must disclose the source and geographical origin of the biological material used in the invention (Section (8) (a) Patents (Amendment Act, 2002). Patents can be denied or revoked if they do not disclose or wrongly mention the source of geographical origin or if the invention is "anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere."(Section (18) (a), Patents (Amendment Act,

2002). The Patents (Amendment) Act (2002 and 2005 iterations) also explicitly excludes "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component(s)." (Section 4(p), Patents (Amendment Act, 2002).

The PPVFR Act also contains a number of interesting rules. The PPVFR Act was established to provide for plant breeders rights over new varieties. However, it also stresses the rights of farmers, and allows them to save, breed, use, exchange, share or sell the plant varieties, which they developed, improved and maintained over many generations.[147]

The Act also allows for claims of benefit sharing concerning the variety registered. Upon receipt of the certificate of registration, claimants are invited to submit requests for benefit sharing (Section 26). The claimants may only be citizens of India or an organization established in the country and are above all expected to be farming or tribal communities who have contributed to the genetic diversity used by the breeder. The PPVFR Authority shall then explicitly indicate in its order the amount of the benefit sharing, if any, for which the claimant shall be entitled. This amount shall take into consideration the extent and nature of the use of genetic material and its commercial utility and demand in the market of the variety, and is to be deposited in the National Gene Fund (Section 26). The Fund is to be used for benefit sharing and compensation to individuals, organisations, and local communities. It will also be used for supporting conservation and sustainable use of genetic resources, including in situ and ex situ collection and for strengthening the capabilities of the *panchayat*[148] in carrying out such conservation and sustainable use (Section 45).The PPVFR Act is thus a retro-active way of allocating benefits and as such is not based on prior informed consent or mutually agreed terms. It also relies upon potential claimants of benefits being aware of a variety being registered. Although the registration is made public, it is not clear that implicated indigenous communities or farmers will have easy access to this information.

3.2 Summary of studies evaluating ABS legislation

Despite the existence of a legislative framework with provisions for ABS in India, there is a lack of examples that illustrate its implementation. Most studies cite a few well-publicised cases such as the ABS relating to the genetic resources and traditional knowledge held by the Kani tribe in Kerala. Although this example did take place before the introduction of the Biodiversity Act, it continues to be used as a key example. Dutfield (2000) and Bijoy (2007) for example, describe how access to a sub-species of *Trichopus zeylanicus* was granted to the Tropical Botanic Research Institute, Kerala to produce a herbal compound known as 'Jeevani'. This access and development was to be in return for their sharing the licence fee and royalty payments with the Kani. However, the state's failure to recognise the tribe's territorial and resource rights hindered progress in benefit-sharing and the funds took more than three years to reach the tribe. Furthermore, the tendency described in Robinson (2010)

[148] Local government body operating at the village level.

towards ex-situ development of genetic resources in government or private sector facilities may disconnect inventions from their origin, further complicating the allocation of benefits.

A study produced by UNEP/WIPO (2004) includes a case study, also on the Kani. It concludes that there is a need for multi-stakeholder frameworks which should include all relevant parties and should discuss access, value addition[149] and benefit sharing. This may include indigenous groups and, where these groups do not hold rights to the land they occupy, should also include those holding territorial rights such as the Forest Department. Involvement of key community stakeholders such as traditional healers can also assist as a tool to ensure the communities' acceptance of benefit sharing arrangements. Furthermore, the study points out that the process of ABS had important effects on the empowerment of the community. The UNEP/WIPO study also suggests that the scope of protectable subject matter (and therefore the benefits to be shared) could have been much wider if international patents had been filed to protect the formulation of Jeevani outside of India, if product patents were available for pharmaceutical products and if trademarks had been registered. Finally, the study notes that although effective protection of intellectual property is necessary for generating benefits, it is not a sufficient condition for benefit sharing. It points out that additional measures are needed to supplement the role of intellectual property rights in benefit sharing of biological resources and traditional knowledge.

An article from Prathapan and Rajan (2011) finds that attempts of nationalisation and restricted access to biodiversity for commercial benefit from the global South are unlikely to be successful due to innate weaknesses and contradictions. Furthermore the authors argue that hardly any ABS models provide a sustainable source of supplementary income for rural communities. Prathapan and Rajan note that, despite imposing severe restrictions on access to biodiversity, India's gains in sharing commercial benefits of biodiversity among its stakeholders are minimal, citing both the example of the Kani (pre-Biodversity Act) and one of the first ABS arrangements facilitated by the National Biodiversity Authority, concluded with Pepsico for the cultivation of marine alga, *Kappaphycus alvarezii.* The article finds the interest in benefit-sharing from the global South to be the wrong shortcut to economic development and food security, and should not substitute national innovation and industrialisation.

An undated Technical Report from a 2004-5 Gene Campaign project examines customary laws and practices for protecting traditional knowledge on biodiversity as well as the treatment these laws and practices are given in the contemporary Indian legal system. The study notes that to fulfil its obligations under the CBD, India has tried to regulate access to genetic resources and associated knowledge by incorporating certain provisions in its legislations through an interface between the Patents Act 1970 (amended up to 2005) and the Biological Diversity Act, 2002, e.g. the disclosure of origin of source and related knowledge used in inventions, as well as the requirement to provide evidence of benefit sharing and prior informed consent (PIC). Due to this ad-hoc development of Indian

[149] Value added products are explicitly excluded from the definition of biological resources under the 2002 National Biodiversity Act, mainly to allay industry's fears that the export of these products may be hampered. (See http://www.nbaindia.org/faq.htm).

legislation, Gene Campaign sees a need for increased harmonisation. A useful article by S. Bala Ravi (2006) deals with this need for harmonization, assessing key issues relating to ABS under the current Indian legislative framework. It analyses the PPVFR Act and the Biodiversity Act and concludes that they present both apparent and real discrepancies or conflicts in their ABS provisions.

R.S. Rana also provides detailed overview of international agreements relating to ABS (CBD and Protocol, ITPGRFA and WTO-TRIPS) and their implications and relationship with the Indian national Biodiversity Act. Key issues pointed out are the lack of adequate awareness at all levels, the lack of case studies showing examples of ABS models as well as a need for adequate monitoring mechanisms to ensure compliance of ABS agreements. Above all, Rana's article calls for recognition of national ABS legislation at the international level. This could take place through bilateral and regional agreements as well as under the proposed International Regime on Access & Benefit Sharing following the Protocol's entry into force.

Lastly, a point raised by Rana which is often raised in relation to the Indian ABS system is the lack of clarity with regard to what 'fair and equitable' benefit sharing entails and the level of benefit sharing that is expected. It is crucial that this is established in a clear way, i.e. through the drafting of the guidelines as provided for in the 2004 Biological Diversity Rules. A lack of clarity may not only slow down the process of benefit-sharing, but may also deter private companies to invest in R&D if the total costs of compensation are unknown (Demanague, 2005).

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5 INTERVIEWS

Dr. R.S. Rana, Chairman of the Expert Committee on Access and Benefit Sharing set up by the National Biodiversity Authority, 3 November 2011.

Mr. Jebra Ram Muchahary, President of the Indian Confederation of Indigenous and Tribal Peoples (ICITP), 10 November 2011.

European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Philippines

1 INTRODUCTION

The Philippines is one of the ten most megadiverse countries in the world and is at or near the top in terms of biodiversity per unit area. It has over 7000 islands and the fifth longest coastline in the world. It was the first country in the world to develop a stand-alone ABS regulatory framework, only 18 months after the CBD's entry into force. Executive Order No.247 on *Prospecting of biological and genetic resources, byproducts and derivates* (1995) followed extensive consultations, including with indigenous peoples. This has been replaced by the legislative framework described below.

The country has a large number of indigenous ethnic groups: in the 1990s, there were more than 100 highland tribal groups constituting approximately 3% of the population. The National Commission on Indigenous Peoples (NCIP) is mandated to protect and promote the interest and well-being of Indigenous Cultural Communities/Indigenous Peoples (ICCs/IPs) with due regard to their beliefs, customs, traditions and institutions. It is the primary government agency that formulates and implements policies and programmes for the recognition, promotion and protection of the rights and well-being of IPs with due regard to their ancestral domains and lands, self-governance and empowerment, social justice and human rights, and cultural integrity.

At the regional level, the Philippines plays a lead role within ASEAN (Association of Southeast Asian Nations) to support development of ABS frameworks within the 10 member states. It is providing a government contribution to the two-year UNEP/GEF programme, *Building capacity for regionally harmonized national processes for implementing CBD provisions on access to genetic resources*, and hosted the *Regional Workshop on ABS: Understanding the Nagoya Protocol* (25-26 October 2011, Manila, Philippines). The project's main focus is national-level review and assessment of existing ABS policies and institutions but these assessments will be regionally leveraged to build capacity and assist in the development/revision of ABS policies in line with the Protocol.

2 NATIONAL LEGISLATION AND POLICIES

2.1 Legislative and policy measures which directly address ABS

The regulatory framework is now laid down by the Wildlife Act 2001, which covers ABS within the context of biodiversity as a whole, and implementing Rules and Regulations issued in 2004.

The Bioprospecting Guidelines 2005 explain the legislative requirements in detail: they aim to streamline the access procedure and facilitate compliance by legitimate resource users; provide guidance on prior informed consent (PIC) and benefit-sharing; and establish a cost-effective, efficient, transparent and standardized system for monitoring compliance with the prior informed consent, collection quotas, fair and equitable benefit-sharing and transfer of materials to third party recipients. They also specify the relationship between ABS regulations and e.g. CITES and seed/plant variety rules.

2.1.1 Provider-side legislative and policy measures

The regime's **scope** is determined by the definition of 'bioprospecting', namely "the research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom solely for commercial purposes" (sec.5, Act). There is no reference to biochemical resources. The 2004 Rules and Regulations define additional terms:

Biological resources: "genetic resources, organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential use or value for humanity, including but not limited to, all biological specimens such as plants, seeds, tissues and other propagation materials, animals, live or preserved, whether whole or in part";

Genetic material: "any material of plant, animal, containing functional units of heredity";

Genetic resources: "genetic material of actual or potential value" (Rule 5.1.bb, ss and tt).

Exempted uses of biological resources include traditional and subsistence use, commercial consumption for direct use (logging, fishing), scientific research on wildlife (for academic or taxonomic purposes) or on agrobiodiversity, and *ex situ* collections currently accessed under international agreements to which the Philippines is a party. Access to any other *ex situ* collections sourced from the Philippines is subject to the permit/access rules in the legislation. The Guidelines generally require collectors to undertake to comply with their provisions if the resources are subsequently used in bioprospecting (GL 3.1).

The Act's definition only covers research for commercial purposes. However, the subsequent transfer of resources collected from non-commercial research and the use of research findings for commercial purposes must comply with the Guidelines i.e. no spin-off technology may be developed from the results of the scientific work (GL 3.2).

With regard to **access,** bioprospecting activities by any resource user, including government agencies, are subject to permit, irrespective of land ownership. The 'Bioprospecting Undertaking' (BU) is concluded with the competent national authorities (Protected Areas and Wildlife Bureau, Department of Environment and Natural Resources (PAWB/DENR)) or the Bureau of Fisheries and Aquatic Resources**,** Department of Agriculture (BFAR/DA). For bioprospecting in the Province of Palawan, the Palawan Council for Sustainable Development (PCSD) representative must be a co-signatory.

A BU may only be made with a foreign resource user if a local collaborator has been engaged to participate in the bioprospecting activity. The competent national authority may recommend qualified Filipino scientists as research collaborators in the process of product development or technology transfer (GL 19).

Prior informed consent must be obtained from the resource provider, defined to include the local community, indigenous peoples, protected area management boards or private land owner from where the biological resources were collected (Chapter V). This is evidenced via the *Prior Informed Consent Certificate* (Annex IV). The Competent national authority must provide assistance to prospective users and separately, to providers evaluating proposals for the prior informed consent to effectively negotiate benefit-sharing. Parties and other stakeholders may use the *Checklist of Process and Content Indicators* (Annex V) to monitor whether benefit-sharing agreements are fair and equitable.

Specific procedures based on 'Free Prior Informed Consent' (FPIC) apply for **indigenous peoples**. The Guidelines supplement the provisions of the Indigenous Peoples Rights Act 1997 (IPRA, RA 8371) which provide that "access to biological and genetic resources and to indigenous knowledge related to the conservation, utilization and enhancement of these resources shall be allowed within ancestral lands and domains of the ICCs/IPs only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community". The National Commission on Indigenous Peoples (NCIP) has lead responsibility for assisting communities to document FPIC and negotiate benefits. Indigenous and local communities consent must be evidenced through the *Compliance to Proper Procurement of Prior Informed Consent* form (Annex VI) which requires a summary of the proposal to have been written in a language or dialect understandable to the indigenous and local communities. The mutually agreed terms (MAT) must be evidenced through a signed *Certificate of Acceptance* of the benefits in the BU, translated into local language (Annex VII). Access to biological resources does not imply automatic access to associated traditional knowledge: access to traditional knowledge must be explicitly set out in the FPIC application and reflected in the certificate.

Implementing agencies at national or regional level make an initial evaluation of the application. Once the resource user supplies all necessary information, including the PIC certificate and a summary of the agreed terms of benefit-sharing (i.e. MAT), the final evaluation is made within 15 days by a technical expert committee within DENR or DA. This must consider the standard minimum terms and conditions (Annex I) and compliance with the Annex V indicators. Indigenous and local communities' representative bodies sit on these committees for applications that concern ancestral domains/lands. The regulatory

framework provides for inter-agency coordination for applications covering species under multiple jurisdictions: a joint evaluation is conducted and only one BU is signed.

Signature of the BU, if approved, normally takes place within a month of the committee's recommendation. Each BU must contain the negotiated terms of benefit-sharing, standard terms and conditions relating to compliance (Annex I) and the quota of allowable species/specimens to be collected (Annex III). The maximum length of the collection period is 3 years, renewable based on mutually agreed terms. The relevant agencies must provide for a common depositary of relevant information, which is publicly accessible subject to "reasonable confidentiality limitations".

A series of fees are charged under the access regime:

application filing fee: 500 pesos to each implementing agency (GL 11.1);

rehabilitation/performance bond (surety) equivalent to 25% of the project cost as reflected in the research budget (a precondition to begin sampling) (GL 12.1);

'bioprospecting fee'. The minimum per BU is US$3000. This can be reduced or increased to up to three times the minimum, based on criteria in §15.2 (related to wildlife impact, rarity or rate of reproduction; above-average commercial potential; use of the resarch for pest/disease vector control; or bioprospecting involving traditional knowledge);

Filipino resource users without foreign collaborators pay 10% of the assessed bioprospecting fee, whilst Filipino students carrying out academic research pay 3%. In both cases, the balance (90%/97%) must be paid if the user subsequently enters into collaboration or agreements with commercial investors;

bioprospecting fees are paid via the implementing agencies into the Wildlife Management Fund or the Protected Area Fund, where applicable, or equally divided between relevant agencies.

Guidelines for benefit-sharing agreements are provided in Chapter VI. Minimum requirements for monetary benefits (GL 16) are as follows:

royalties: a minimum 2% of total global gross sales of the product made or derived from the collected samples must be paid annually for as long as the product is sold in the market. The user must present an audited annual gross sales report to the signatory agencies as basis for computation of the royalty (if not the product seller, s/he is responsible for securing the sales records from the seller for submission to the signatory agencies). 75% of these royalties are paid to the providers and 25% to the national government (via the competent national authority);

up-front payments: the user shall pay US$1,000 per collection site annually to the providers for the duration of the collection period, to be considered as advances from royalties. Pro-rata reductions apply for Filipino resource users and students, with no foreign collaborators or investors;

all payments are non-reimbursable even if no profit is eventually realized from the bioprospecting activity;

procedures for equitable sharing between multiple provider groups are set out in GL 20. Monetary benefits for local communities are overseen by the 'Sangguniang Pambarangay' solely for biodiversity conservation or environmental protection, including alternative or supplemental livelihood opportunities for community members. Funds for indigenous peoples must be used consistent with the Ancestral Domain Sustainable Development and Protection Plan or their disposition determined by the NCIP.

Non-monetary benefits may be negotiated in addition to the above, including equipment for biodiversity inventory and monitoring and /or resource conservation; technology transfer; formal training including educational facilities; infrastructure directly related to the management of the area; health care; and other capacity building and support for in-situ conservation and development activities. In addition, the Standard Terms and Conditions (Annex I) require the deposit of a complete set of all voucher specimens with the National Museum of the Philippines and a complete set of all living specimens in mutually agreed and duly designated depositories.

Where collected materials are transferred to third party recipients, the resource user must issue a *Certificate of Compliance: Material Transfer to Third Party Recipients Bioprospecting Undertaking* (Annex II) that all provisions in the Material Transfer Agreement covered by the BU have been complied with. The recipient of the materials must also attest to the Certification.

Compliance monitoring is required under the BU through annual progress reports, covering the status of the prior informed consent procurement, progress on collection of samples, progress on benefit-sharing negotiations and payment of benefits (GL 23). Proof of user compliance is delivered through three standardised forms: *Certification of compliance to the proper procurement of PIC* (Annex VI); *Certification of acceptance by resource providers of the monetary and/or non-monetary benefits provided in the BU* (Annex VII); and *Certification of compliance to collection quota as prescribed in the BU* (Annex VIII). All certifications must be signed by the provider, attested by the DENR/DA/PCSD regional representative and appended to the annual progress report.

Overseas monitoring of Philippines-sourced resources is covered by GL 26. The competent national authority must notify the Department of Foreign Affairs (DFA) and the Department of Science and Technology (DOST) about BUs with foreign entities and may seek their assistance in monitoring inventions and commercialisation abroad. The DFA, through its Embassies and Missions abroad, is encouraged to report any BU breaches to the competent national authority and make representations with foreign authorities on:

preventing biological resources from entering countries without a BU;

requiring disclosure of country of origin (CO) and presentation of BU in patent applications;

facilitating enforcement of claims against collectors or commercialising entities.

2.1.2 User-side legislative and policy measures

The Wildlife Act, 2004 Rules and Regulations and 2005 Bioprospecting Guidelines do not address compliance by Filipino resource users conducting bioprospecting activities overseas.

2.2 Summary of studies evaluating ABS legislation

The regime first put in place by the Executive Order 247 of 1995 was extremely restrictive in its approach to access and faced particular implementation difficulties related to scope and prior informed consent (Benavidez, 2004). It created a procedure that turned out to be very long, exhaustive and costly resulting in delay, uncertainty and high transaction costs for the users. The consequence was that basic research and bioprospection projects were frustrated (Medaglia, 2004; Santons and Sampaio, 1998).

In the first seven years of implementation, only two out of 33 research agreements were approved (CISDL, 2005). Concretely, only one out of eight applications for commercial research and only one out of 17 for academic research were approved by 2004 (Medaglia, 2004). As a result, government, researchers and providers have not received any major benefits. The 2005 Bioprospecting Guidelines are a big step forward towards establishing an effective ABS regime. Whether the Philippines will effectively succeed in achieving this, depends crucially of the way it will implement the new legislative framework (Richerzhagen, 2010).

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European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Switzerland

1 INTRODUCTION

Switzerland has about 230 different basic habitats. It also has one of the highest species diversities within Europe, with approximately 19,000 species of plants and fungi recorded and an estimated 40,000 animal species to be found in the country (Federal Office for the Environment, 2010). There are no indigenous or local communities in Switzerland.[150]

Switzerland has a well-developed private sector and research landscape potentially interested in the use of genetic resources. According to an OECD report, Switzerland in 2006 occupied the 10th position concerning the number of biotechnology firms and the 8th position concerning private sector biotechnology R&D spending globally (van Beuzekom, Brigitte, Arundel, 2009). This is remarkable given that Switzerland is a small country with only about 7.6 mio inhabitants in 2008.[151] Switzerland is also the seat of companies such as Novartis, one of the biggest pharmaceutical companies at the global scale, and Weleda, a major company producing natural cosmetics and pharmaceuticals.[152] In sum, Switzerland is predominantly a user country (Kraus and Rüssli, 2009).

Switzerland signed the Protocol in May 2011 and initiated the ratification process.[153] A national conference on ABS was held in April 2011. A 2009 study written for the Federal Office for the Environment contains a comprehensive overview of existing user measures and further options, for example with regard to checkpoints (Kraus and Rüssli, 2009).

2 NATIONAL LEGISLATION AND POLICIES

2.1 Legislative and policy measures which directly address ABS

[150] See http://www.cbd.int/countries/profile.shtml?country=ch#status

[151] See Suisse Federal Statistical Office, http://www.bfs.admin.ch/bfs/portal/en/index/international/laenderportraets/schweiz/blank/kennzahlen.html

[152] According to its 2010 company report, Weleda had a turnover of about € 300 million in 2010.

[153] See http://www.sib.admin.ch/de/nagoya-protokoll/umsetzung-in-der-schweiz/index.html

In line with its characteristic as a user country, Switzerland has no provider legislation in place. However, is has taken quite a number of legislative and other measures concerning the use of genetic resources from other countries.

2.1.1 Provider-side legislative and policy measures

Switzerland has no provider legislation with CBD relevance in place. While there is some legislation restricting access to biological resources, these are motivated by a concern for nature conservation. Access to *ex situ* genetic resources for food and agriculture which fall within the scope of the ITPGRFA Multilateral ABS System is based on the standard Material Transfer Agreement (sMTA) of the ITPGRFA (Federal Office for the Environment, 2010).

2.1.2 User-side legislative and policy measures

In terms of binding legislation, Switzerland currently only has Art 49(a) of the patent law in place. This article, introduced in 2008, contains an obligation to disclose the source of genetic resources and traditional knowledge used in an invention when a patent application is filed, provided the invention is directly based on these resources. Normally, the source will be the country of origin; however, a seed bank or the ITPGRFA Multilateral System are also sources within the meaning of this article (Kraus and Rüssli, 2009).

According to Kraus and Rüssli (2009), the following measures may be taken in case of non-compliance with the disclosure requirement:

"If a patent applicant does not provide the information relating to the indication of source, the Swiss Federal Institute of Intellectual Property will set a deadline for the applicant in order to provide the lacking information. If the information is still not provided at the end of that deadline, the patents will not be granted. Art 81a of the patent law foresees that anyone who willfully provides false information under Art 49a is liable to a fine of up to 100,000 Swiss francs. The courts may also order the publication of the judgment."

Besides this legal norm, several non-legal measures have been adopted.

The Swiss Academy of Sciences (SCNAT) has developed a set of recommendations, summarized in a document entitled 'Access and Benefit Sharing – Good practice for academic research on genetic resources'.[154] Compliance with the guidelines is voluntary; however, the SCNAT offers researchers support in complying with the recommendations. Compliance with ABS requirements is not incorporated as a requirement for obtaining research funding in binding legislation.

[154] Available at abs.scnat.ch/downloads/ABS_Brochure.pdf

All major Suisse botanical gardens are members of the International Plant Exchange Network (IPEN)[155]. For becoming members, they must adhere to the IPEN code, which includes a commitment to comply with the rules of the CBD.[156]

Generally, Switzerland appears to be quite active in promoting ABS in other countries, and at multilateral level. For example, it has published a thematic report on ABS to the CBD.[157] Switzerland also supported the International Institute for Sustainable Development (IISD) in developing the ABS management tool, a best practice standard and a handbook designed to assist companies, researchers, local and indigenous communities, and governments to comply with the Bonn Guidelines and the CBD's ABS requirements.[158]

2.2 Summary of studies evaluating ABS legislation

There is no comprehensive ABS legislation in place yet in Switzerland; for fulfilling eventual obligations arising out of the Protocol, Switzerland would have to take further measures, e.g. regarding checkpoints. The study by Kraus and Rüssli (2009) investigates several options in this regard. Besides extending the information to be provided by applicants in patent proceedings, these include incorporating measures related to genetic resources into the following sets of rules:

- *The authorization regime for pharmaceuticals*: The Swiss Agency for Therapeutic Products could serve as a checkpoint. The federal regulation governing the production of pharmaceuticals could be amended to include rules on ABS.

- *The approval system for agricultural products and food*: In this context, the Federal Office of Public Health, in the case of food, and the Federal Office for Agriculture, in the case of agricultural means of production could act as checkpoints). However, a marketing approval is only required for some types of food, e.g. genetically modified food.

- *Import regulations for living plants, animals, animal products and foods of animal origin*: Different authorities are responsible for the enforcement of import regulations, including the customs authorities and the border veterinarian service. Import of genetic resources into Switzerland could be made to require a certificate of origin. However, Kraus and Rüssli (2009) note that custom authorities operate on a sample basis. Inspecting all genetic resources at the border is not feasible, as sometimes they come as part of natural products. Also, the 'import' of traditional

[155] See http://www.cbd.int/countries/profile.shtml?country=ch#status

[156] See the Code at http://www.botgart.uni-bonn.de/ipen/criteria.html

[157] Swiss Agency for the Environment, Forests and Landscape (SAEFL), Thematic report on benefit- sharing, 2001, http://www.cbd.int/doc/world/ch/ch-nr-abs-en.pdf

[158] See http://www.iisd.org/abs/

knowledge or research results obtained elsewhere is not amenable to border inspection. Thus Kraus and Rüssli see only a limited role for border inspection in ensuring compliance with ABS rules.

- *Rules for research funding:* Voluntary measures to encourage researchers to comply with ABS rules are proposed; the inclusion of a binding rule which would link "the finance of research projects including genetic resources by the Confederation [i.e. Switzerland] to the respect of CBD as regard access and benefit sharing" (Kraus and Rüssli, 2009) is also mentioned as a possibility. Such rules could be adopted at the federal or cantonal, i.e. regional, level.

Another option considered is using the existing system for the registration of plant varieties as checkpoints.

Generally, Kraus and Rüssli (2009) highlight the problem of avoiding a double burden for individual products, e.g. a product that is patented should not be again subject to disclosure requirements during marketing authorization procedures.

ABS practices and biopiracy

Swiss companies and research institutions have in the past repeatedly been accused of misappropriation of genetic resources, with some of those cases also involving patent claims by Suisse actors. Among the publicized incidents were bioprospection activities carried out by the University of Lausanne in Zimbabwe[159] and various cases involving the Suisse pharmaceutical company Novartis.[160]

On the other hand, there are also good practice examples, such as the Suisse company Weleda being a member of the Union for Ethical Biotrade. The members of this organization are committed to a joint standard. The standard is currently under revision, but includes a commitment to complying with access and benefit-sharing legislation and guidelines on fair benefit-sharing;[161] members are subject to verification of compliance with the standard by external organizations, of which many are based in developing countries.

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[160] Among these the so called Novartis-Bioamazonia case which has sometime been described as a decisive factor behind the adoption of the current Brazilian ABS system, see on this case Peña-Neira, *et al*, 2002.

[161] The draft version of the standard is available at http://www.ethicalbiotrade.org/revisionprocess/index.html

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European Commission
Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

Country report: Uganda

1 INTRODUCTION

Uganda is a provider country with exceptional diversity and varied habitats, because of its position in the zone of overlap between the East African savannah and the West African rain forests. It is ranked as one of the ten megadiverse countries in the world with particularly high diversity of mammalian species. Uganda includes part of the Albertine Rift Area of Regional Endemism (a Peistocene forest refugium). Conservation of biological diversity has been largely *in situ*, focused on species and ecosystem levels in protected areas, with limited attempts at *ex situ* conservation.

The environment and natural resources sector provides the basis for Uganda's economic and social development (UNU-IAS, 2008). Cultural institutions historically played a leading role in management of biological and genetic resources although this diminished with the creation of a central government, and still potentially play a key role in managing various aspects of access to genetic resources. Traditional knowledge is mainly practical, in the fields of agriculture, fisheries, health, horticulture and forestry. Some indigenous knowledge systems have been incorporated into national development plans. Traditional healing systems are being integrated into modern healthcare delivery services.

Uganda has not yet signed the Nagoya Protocol. In March 2011, the government submitted a capacity needs assessment for the Protocol implementation to the CBD Secretariat (GoU, 2011).

2 NATIONAL LEGISLATION AND POLICIES

2.1 Legislative and policy measures which directly address ABS

The framework National Environment Act 1995 (Ch 153) empowered the National Environment Management Authority to issue guidelines and prescribe measures for the sustainable management and utilisation of Uganda's genetic resources for the benefit of the people of Uganda (sec.44).

The National Environment Regulations (Access to Genetic Resources and Benefit Sharing) 2005 were first issued as guidelines in 2001 and then given formal effect in 2005. They were designed to fulfil ABS requirements under the CBD as well as the Bonn Guidelines 2002.

In July 2007, the government issued Guidelines for Accessing Genetic Resources in Uganda (GoU, 2007) "to provide for simple arrangements and procedures including measures for accessing biological and genetic resources of Uganda, their products and derivatives for scientific research, commercial and any other purposes connected therewith and to ensure equitable sharing of the benefits accruing therefrom". The Guidelines envisage the need to train local stakeholders in their application.

2.1.1 Provider-side legislative and policy measures

The 2005 Regulations (a) prescribe the procedures for access to genetic resources for scientific research, commercial purposes, bioprospecting, conservation or industrial application; (b) provide for the sharing of benefits derived from genetic resources; and (c) promote the sustainable management and utilisation of genetic resources, contributing to conservation of Uganda's biological resources.

With regard to **scope**, the Regulations define biological resources to include "genetic resources, organisms or parts of organisms, populations or other biotic component of ecosystems with actual or potential value for humanity". "Genetic resources" means "genetic material of actual or potential use or value, and includes their derivative products and intangible components." A "derivative product" means "an unimproved or unmodified biologically active chemical compound associated with targeted biological or genetic material formed by the metabolic processes of the organism, modified and used in a technological application, and includes molecules, combinations or mixtures of natural molecules including raw extracts of living or dead organisms and soil matter, DNA or ribonucleic acid (RNA) or chemical compounds, modified, created or synthesised from genetic material originally obtained in accordance with these Regulations" (Reg.2).

This definition covers naturally occurring or naturalised resources, including genetic resources bred for or intended for commercial purposes within Uganda or for export, whether in *in situ* or *ex situ* conditions.

The Regulations do not apply to the exchange of genetic resources by a local community among themselves and for their own consumption, or where certified to be purely for food or other consumptive purposes as prescribed by the relevant laws; the transit of genetic resources through Uganda; access to genetic resources derived from plant breeders as defined by the laws relating to plant breeding and protection of plant varieties; human genetic resources. They also exempt approved research activities intended for educational purposes by Ugandan institutions recognized by the competent national authority and which do not result in access to genetic resources for commercial purposes or exports to other countries. If the use is changed to commercial, the procedure for obtaining an Access Permit under the Regulations must then be followed. For the above categories, a licence may be granted for the use or export of genetic resources under any other laws, provided full consideration is given to the provisions of these Regulations.

The **competent authority** is the Uganda National Council for Science and Technology. UNCST was established in 1990 within the Ministry of Finance, Planning and Economic

Development. Under the Regulations, it is mandated to:

- assist in rationalising the use of foreign science and technology;
- coordinate ABS-related activities across institutions and sectors;
- act as a clearing house for information on research and development in scientific institutions, other enterprises and on the potential application of their results;
- protect intellectual property through appropriate patent laws and operate a national patent office;
- coordinate Lead Agency activities related to access to genetic resources and support the negotiation of the prior informed consent (PIC) and the mutually agreed terms (MAT), ensuring that Ugandans benefit from sufficient benefit-sharing provisions;
- operate the access permit system consistent with the Regulations and establish a procedure for accessing relevant information;
- monitor the use of genetic resources in and transferred outside Uganda, including supervision of compliance with contractual conditions, and establish monitoring and evaluation mechanisms for this purpose;
- ensure that Uganda keeps representative samples and specimen of genetic resources collected under the Regulations and approve the depository.

Access to genetic resources (AGR) is prohibited without an Access Permit from UNCST. The Regulations establish a complex sequenced procedure: its application has been clarified in the 2007 Guidelines which include flow-chart diagrams and annex standardised forms.

First, the applicant pays the UNCST a fee of 50,000 Ugandan shillings to obtain the prior informed consent application form (Annex 1, Guidelines). It then applies directly to the resource owner for the prior informed consent. The right to grant - and charge for - prior informed consent follows tenure (cultural communities on ancestral domains/lands; local communities; Uganda Wildlife Authority/National Forestry Authority for protected areas; private land owners). Access to *in situ* resources on community land, including consultations through the local or indigenous cultural structures, is covered in Guideline 3.3.2.

Prior informed consent is mandatory for access to **indigenous knowledge**: holders must be actively included in negotiation of benefits on the basis of full disclosure of potential benefits and risks arising from resource use. Benefit sharing arrangements must not negatively interfere with traditional knowledge systems and practices of indigenous peoples and local communities. The UNCST must maintain a national reference file where indigenous and local communities and any other interested parties may deposit records of knowledge associated with genetic resources. Indigenous and local communities have exclusive rights over their traditional knowledge and only they may surrender it to the UNCST.

Intellectual property rights with respect to traditional knowledge-related products or processes must not be recognised if access took place in breach of the Regulations/Guidelines. Indigenous and local communities are guaranteed the right to have the origin of traditional knowledge access mentioned in all publications, uses, exploitation and disclosures; prevent unauthorised third parties from using or carrying out tests, research or investigations relating to traditional knowledge or disclosing, broadcasting or re-

broadcasting data or information that incorporate or constitute associated traditional knowledge; and to derive profit from economic exploitation by third parties of associated traditional knowledge in which the community owns rights as provided in for under Ugandan laws and international legislation (Guideline 3.5).

Second, the applicant negotiates an **Accessory Agreement** (Annex 3) with the resource owner, which should clarify respective roles, rights and responsibilities in writing. If there are multiple owners for a particular genetic resource, all owners should be signatories; if genetic resources are accessed from several areas, each owner with tenure enters into a separate agreement with the applicant.

The Guidelines (3.1.1) set out a checklist for owners to consider before signing such Agreements. These include whether the owner had adequate knowledge of the Regulations and was able to engage in reasonable negotiations with the applicant on benefit-sharing; was given adequate time to consider the application, consult with relevant people and negotiate the MTA; for communal areas, whether the views of the Local Council were sought; and whether the owner was aware of the value of the resources being accessed. Once the Accessory Agreement is signed, the resource owner may grant prior informed consent (Annex 2) in return for a fee of 120,000 Ugandan shillings (Reg.12). The applicant must also carry out an environmental impact assessment if access to the resource will potentially result in significant environmental impact (EIA Regulations 1998).

Third, the applicant enters into a time-limited **Material Transfer Agreement** (MTA) with the Lead Agency responsible for managing the genetic resources concerned. Where responsibilites are shared (e.g. fisheries resources in wildlife protected areas, forest reserves overlapping with national parks), the Lead Agency with the legal mandate over a particular resource must carry out its functions in consultation with the other agency with an overlapping mandate.

The MTA (Annex 4) sets out the terms under which genetic resources can be transferred from one party to another and is intended to enable the government to keep track of material accessed and hold records of material collected from Uganda in any given period of time. It must provide for “reasonable benefit-sharing arrangements, including protection for, recognition of and valuing of any indigenous people’s knowledge to be used” and contain a long list of mandatory information. This includes a description of ownership of any commercialisation/publication rights, use of traditional knowledge (specifying source, but not content), the benefits to be shared and details of expected technology transfer (Guidelines 3.1.3). Future use of genetic resources must be negotiated in the MTA from the start of the process. Parties to the transaction are encouraged to seek support from a mediator when negotiating.

A negotiable fee is payable by the applicant to the Lead Agency upon signature of an MTA (Reg.14(2)), after which the Lead Agency refers the application to the UNCST for final determination. The MTA only takes effect if the permit is actually issued. If the MTA is not renewed on expiry, possession of genetic material originating from Uganda reverts to the government.

Lastly, the applicant submits the completed application to the UNCST, indicating whether the genetic resources are to be exported. This must contain written prior informed consent, an Accessory Agreement, an EIA certificate where required, a negotiated and signed MTA (plus receipts of payment of required fees) and a "detailed project highlighting the nature of the genetic resources to be accessed, including species of interest, location, quantity, activities, duration, purpose" and any other information required by the UNCST (Guideline 3.1.4). Based on the Lead Agency's recommendation, UNCST issues or refuses the permit. If the permit is granted (Annex 5), a further fee of 300,000 Ugandan shillings is payable to the UNCST (Reg.19) and access is then authorised.

The Regulations integrate the genetic resources permit system with Uganda's CITES legislation. Where genetic resources are to be exported, the applicant must obtain an Export Permit from the CITES Management Authority (in addition to requirements under the Regulations).

Access to *ex situ* resources is handled directly by UNCST, including for genetic resources overseas where Uganda is the country of origin. It is required to keep an inventory of relevant conservation centres. MTAs in accordance with the Regulations should be entered into between such centres and the relevant third parties in or outside Uganda.

Regulation 20 provides for the **sharing of all benefits** accruing from the collection, modification and use of genetic resources based on the principle of fairness and equity on mutually agreed terms. The Guidelines set out an indicative list of direct and indirect benefits (i.e. monetary and non-monetary) to be negotiated on a case by case basis. Guideline 5.3 sets out an indicative structure for benefit-sharing between commercial product developers and government agencies and/or other resource owners and users.

Resource owners may charge the applicant additional fees for the AGR actually accessed, guided by market forces and with advice from Lead Agencies (Guideline 5.2). Such charges must have been agreed and included in the MTA. If the materials concerned "obtain unforeseen commercial value after conclusion of the agreement", the applicant must declare this value to UNCST so that benefits can be renegotiated and the MTA revised accordingly.

The UNCST is mandated to collect and store all information regarding access to genetic resources: Lead Agencies have equivalent duties within their areas of competence and must give copies to the UNCST. Access permit applications may include a request for confidential treatment of information given to the UNCST or the Lead Agencies, stating the reasons. Confidentiality of information does not apply where it is considered necessary for the public good or environmental protection and does not go beyond three years.

As of 2006, there was no national policy on IPR although the National Science and Technology Policy 2001 provides for its formulation (UNU-IAS, 2008). The 2007 ABS Guidelines indicate that the Patents Act 1991 is relevant to ABS for genetic resources when an applicant wishes to register or claim ownership of the proprietary interests in genetic resources accessed and obtained from Uganda.

The Lead Agencies are required to implement a **monitoring system** to track and keep record on the genetic resources accessed in Uganda and the extent of benefit sharing achieved. Permit holders must submit regular status reports on research and development relating to the genetic resources accessed under the permit. The information and experience gained will form the basis for review and updating the Guidelines after the first five years of implementation.

2.1.2 User-side legislative and policy measures

Uganda's existing legislation does not address compliance by Ugandan resource users conducting bioprospecting activities overseas.

2.2 Summary of studies evaluating ABS legislation

A 2005 study, conducted by external consultants and updated by the competent national authority in 2006, was published following peer review in 2008 (UNU-IAS, 2008). A separate case study was carried out from a plant genetic resources perspective (Lewis-Lettington and Munyi, 2006). Both were completed before the 2007 Guidelines were finalised. The Guidelines took the case study's conclusions into account and also drew on the ABS legislative frameworks in Australia and Brazil.

The UNU-IAS 2008 study found that Uganda's ABS Regulations were the most comprehensive instrument in the four countries analysed in the study (the others were Botswana, Ghana and Zambia). Some ABS arrangements have been made between Ugandan and external collaborating universities and the UNCST and others between national scientific research institutions and UNCST. However, although some private firms were engaged in biotechnology activities with a medical or agro-genetic focus, there was a need to attract the private sector to participate more in ABS.

Policy and legal reforms were needed to strengthen collaboration mechanisms among the various institutions, provide incentives for team building and coordination, and harmonise the IPR policy with existing policies and legislation and improve its implementation. The decentralisation policy needed review in respect of local government capacity to manage ABS. At operational level, capacity was weak for handling ABS legal issues related to access and community rights as well as future litigation. Makerere University had recognised the need to bridge the legal capacity gap amongst institutions and private practitioners and created an undergraduate environmental law course that could include ABS elements.

The study's examples focused more on access to biological resources as commodities, especially in protected areas, than on bioprospecting for genetic resources. They identified the need to build indigenous and local communities capacities for effective ABS negotiation and management and saw Uganda's innovative resource management approaches, based on community conservation and collaborative forest management, as possible building blocks for equitable benefit-sharing.

Other constraints included low public awareness and training on the value of genetic resources and low levels of monitoring and research, resulting in insufficient information for decision-making. The study highlighted the lack of a national system for information management and exchange to capture relevant data from different sectors and institutions carrying out ABS-related research. Several institutes have elaborate ABS-relevant data banks targeting management of information related to Uganda's genetic resources but there is a need for personnel and standards to capture relevant data. There is no operational Clearing-House mechanism or resources to coordinate information acquisition, which limits development of national capabilities through exchanging and disseminating information on experiences and lessons learned in implementing the Bonn Guidelines.

The study indicated that limited general information exists regarding the impacts of IPRs on biodiversity conservation and sustainable use but that Uganda has not been spared biopiracy (direct and indirect misappropriation of biological and genetic resources and traditional knowledge). Existing laws were not an effective deterrent, especially for local communities and traditional knowledge on herbal medicines, and the Patent Act 1991 did not provide adequate protection for genetic resources.

The government's capacity needs assessment for the Protocol implementation (GoU, 2011) focuses on training to enable both indigenous and local communities and government officials to negotiate and enforce Accessory Agreements/MTAs, participate effectively in collaborative research, estimate benefits precisely and negotiate PIC and MATs on a fair and equitable basis. Specific needs relate to: valuation of genetic and biological resources and their associated derivatives; valuation and documentation of traditional knowledge and traditional innovations; negotiation of ABS legal contracts; arbitration and conflict resolution; management of a multilateral fund for transboundary genetic resources and associated traditional knowledge; information sharing and the ABS-Clearing House; bio-prospecting/associated research methods and relevant equipment; taxonomic studies relevant to bioprospecting and product development, conservation and sustainable use of biological resources and genetic resources inventorying/ documentation; tracking and monitoring of genetic resources and their derivatives; Intellectual Property Right issues relevant to innovations and inventions resulting from genetic resources and associated derivatives.

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ANNEX 3: SECTORAL SHEETS

This section includes sectoral sheets for:

- Pharmaceutical Industry
- Culture collections
- Botanic gardens
- Plant Breeding/Seed sector
- Biocontrol
- Horticulture
- Academic Research
- Cosmetics Industry
- Animal Breeding Industry
- (Industrial) Biotechnology
- Food and Beverage Industry

THE PHARMACEUTICAL INDUSTRY – SECTORAL SHEET

1. The sector and ABS

The pharmaceutical sector is important for ABS because a significant share of the global market has been derived from genetic resources. Newman and Cragg (2012) indicate that 26% of all new approved drugs over the last 30 years are either natural products[162] or have been derived from a natural product (as to the latter, these are usually a semisynthetic modification). For anticancer drugs the percentage is higher: in the period 1981-2010 34% of all new approved anticancer drugs were natural products, natural product botanicals or drugs directly derived from natural products. After a decade of declined interest in natural products (from the mid-1990s to the mid-2000s), interest in natural products has renewed again (see section 3 for more details).

2. Size and characteristics of the sector

Definition/description of the sector

The pharmaceutical industry comprises public and private organizations involved in the discovery, development, and manufacture of drugs and medications. Drug development relies on the collaboration and effort of highly trained scientists at universities and private companies. While many drugs, such as quinine and morphine, are extracted from plant substances, others are discovered and synthesized by techniques including combinatorial chemistry and recombinant DNA technology. Identifying new drug targets[163], attaining regulatory approval, and refining drug discovery processes are among the challenges that the pharmaceutical industry faces in the continual advancement of control and elimination of disease.

Global market and development prospects

The global market for pharmaceuticals amounted to $808 billion in total sales in 2009. Currently, the global pharmaceutical market is dominated by the US, which accounts for about 28% of global sales in 2009, followed by the EU accounting for roughly 15%, and Japan accounting for 12%. Together, these three regions represent nearly 55% of the global market. China is currently the world's third largest market for pharmaceutical sales. Much of the growth in recent years has come from the so-called "pharmerging" markets, that is, emerging markets targeted by pharmaceutical companies. These markets include Argentina, Brazil, China, Egypt, India, Indonesia, Mexico, Poland, Romania, Russia, South Africa and Turkey (IMAP, 2011).

Spending on medicines amounted to $856 billion and will reach almost $1,100 billion in 2015, reflecting a slowing growth rate of 3-6% within the period 2010-2015 compared to 6.2% annual growth over the past five years. The US share of global spending will decline

[162] A natural product is a chemical substance found in nature (i.e. produced by a living organism) that has distinctive pharmacological effects.

[163] Drug targets are molecular structures (e.g. proteins) which are the cause of, or are involved in, a disease or condition and can be accessed using drugs (IMAP, 2011).

from 41% in 2005 to 31% in 2015, whereas the share of spending from the EU5, that is, the top five European countries (Germany, France, Italy, Spain and the United Kingdom), will decline from 20% to 13% in the same period. The 17 "pharmerging" markets, led by China, will be responsible for 28% of total spending by 2015, up from only 12% in 2005. The next five years spending on generic medicines will steeply rise to 39% of spending in 2015, whereas spending was only 20% in 2005 (IMS Health, 2011).

The pharmaceutical sector is gradually restructuring: some very large companies with big sales/marketing organizations and capital and knowledge for late-stage clinical developments are systematically acquiring small biotechnology companies with interesting candidate products (see also below). On the one hand you have big pharmaceutical companies which need to be big because of uncertainties in the drug development process. On the other, you have the smaller biotechnology companies, most of which do not have the capital or market access to commercialize a product (IMAP, 2011).

Biotechnology-based pharmaceuticals account for an increasing share of the market. Biotechnology research tools and techniques are central characteristics of pharmaceutical R&D today (Jorgensen *et al*, 2009; sCBD, 2008; Class, 2004). "Biotech medicines are estimated to account for approximately 20% of all marketed medicines and represent 50% of all medicines in the pipeline" (Europabio, 2011). In order to compensate for unproductive R&D programs in large companies, targeted acquisitions of small biotechnology firms to gain access to a specific product or technology and licensing deals are becoming increasingly important (sCBD, 2008). Accordingly, 91% of industry executives believe pharma-biotech mergers will increase in the next 10 years, and 69% also believe there will likely be increased consolidation between companies within the biotechnology sector (IMAP, 2011). Pharmaceutical companies have also progressively increased collaboration with the academic sector (pers. comm., 2012).

Table 1: Top 15 global corporations in the pharmaceutical sector in 2004-2008

	2008 rank (US$)	2008 Sales (US$ MN)	2007 Sales (US$ MN)	2006 Sales (US$ MN)	2005 Sales (US$ MN)	2004 Sales (US$ MN)
Global Market	0	$ 724,465	$ 673,043	$ 612,013	$ 572,659	$ 530,909
PFIZER	1	$ 43,363	$ 44,651	$ 45,622	$ 45,869	$ 49,401
GLAXOSMITHKLINE	2	$ 36,506	$ 37,951	$ 37,516	$ 35,256	$ 33,231
NOVARTIS	3	$ 36,172	$ 34,409	$ 31,560	$ 29,616	$ 26,404
SANOFI-AVENTIS	4	$ 35,642	$ 33,819	$ 31,460	$ 30,953	$ 28,446
ASTRAZENECA	5	$ 32,516	$ 30,107	$ 27,540	$ 24,741	$ 22,526
ROCHE	6	$ 30,336	$ 27,578	$ 23,354	$ 20,105	$ 16,787
JOHNSON & JOHNSON	7	$ 29,425	$ 29,092	$ 27,730	$ 27,190	$ 26,919
MERCK & CO	8	$ 26,191	$ 27,294	$ 25,174	$ 23,872	$ 24,334
ABBOTT	9	$ 19,466	$ 17,587	$ 16,065	$ 14,849	$ 13,310
LILLY	10	$ 19,140	$ 17,386	$ 15,388	$ 14,232	$ 13,042
AMGEN	11	$ 15,794	$ 16,536	$ 16,270	$ 13,435	$ 10,944
WYETH	12	$ 15,682	$ 15,965	$ 14,695	$ 14,469	$ 14,019
TEVA	13	$ 15,274	$ 13,547	$ 12,001	$ 10,053	$ 8,675
BAYER	14	$ 15,660	$ 14,178	$ 12,553	$ 11,828	$ 11,019
TAKEDA	15	$ 13,819	$ 12,778	$ 11,880	$ 11,370	$ 10,707

Source: IMS

EU market (size of the market and importance for the EU economy)

The pharmaceutical industry makes an important contribution to Europe's and the world's well-being. It is a strategic sector due to its economic as well as its public health dimension. As already mentioned above, the EU accounted for roughly 15% of the global market for pharmaceuticals in total sales in 2009 (IMAP, 2011). As to spending on medicines, the share of the EU5 (Germany, France, Italy, Spain and the United Kingdom) was 20% in 2005 and is expected to decline to 13% by 2015 (IMS Health, 2011). The research-based pharmaceutical industry (amounts to approximately 3.5% of total EU manufacturing value-added. The industry in Europe (EU27 + Norway + Switzerland) directly employs 640,000 people/units; indirect employment is three to four times more than this figure; R&D employment in 2010 was estimated at 115,000 people/units. Production in 2010 was estimated at €190,000 million (EFPIA, 2011).

The biotechnology industry in Europe comprises about 1,600 companies and generated about €7.8 billion in revenues in 2005. Biotechnology companies focusing on healthcare rose from 37 in 1996 to 143 in 2005. Biotechnology medicines represent 78% of EU biotechnology products. Biotechnology medicines hold a 9% share of the EU pharmaceutical market and growth rates in biopharmaceuticals are twice as high as growth rates in non-biotechnology products (Europabio, 2011).

Economic relevance of utilization of genetic resources for the sector in Europe

it is estimated that it takes 10-15 years and costs $1.3 billion to develop a new drug (Laird and Wynberg, 2012; PhRMA, 2009). The research-based pharmaceutical industry amounts to 18.9% of total worldwide business R&D expenditure. In 2010 an estimated €27 million was invested in pharmaceutical R&D in Europe (EFPIA, 2011). Nevertheless, R&D productivity of the big pharmaceutical companies declined by 20% in the period 2001-2007 (IMAP, 2011). It should be noted however that natural products research is only one segment of pharmaceutical R&D. In addition, the probability that any genetic resource sample will lead to a commercial product is very low. It is estimated that one in 10,000 samples makes it into a commercial pharmaceutical product (PhRMA, 2005; Laird and Wynberg, 2008). The information in paragraph 3 might give an indication of the relevance of natural products in drug discovery at global level.

Any EU companies that are market leaders?

Of the top 15 global companies (listed in table 1), seven companies have their headquarters in Europe: Novartis AG (Switzerland, 38.8% of its 2010 revenue originating from Europe), Roche Holding AG (Switzerland, 32.5% of revenue from the EU/EMA[164]), Bayer AG (Germany), GlaxoSmithKline PLC (UK, 32.6% of revenue from Europe), Sanofi-Aventis SA (France, 34.8% from Europe), AstraZeneca PLC (UK, 27.9% from Western Europe) and Boehringer Ingelheim Gmbh (Germany, 31.3% from Europe) (IMAP, 2011).

Within Europe, major pharmaceutical companies are headquartered in Germany, France and Switzerland. The top 50 pharmaceutical and biotechnology companies listed in IMAP's "Pharma & Biotech Industry Global Report 2011", also features companies with headquarters in Belgium (UCB SA), Denmark (Novo Nordisk A/S and H Lundbeck A/S),

[164] EMA is the European Medicines Agency which carries out scientific evaluations of medicines for human and veterinary use.

Ireland (Shire PLC and Warner Chilcott PLC) and Italy (Menarini Group) (IMAP, 2011).

Relevance of SMEs

The pharmaceutical industry is dominated by large multinational companies, though SMEs (especially biotechnology companies) do also play a major role, especially in the early stages of the user chain (see **Error! Reference source not found.**). On the one hand there are large pharmaceutical companies which need to be big because of uncertainties in the drug development process. On the other hand, there are smaller biotechnology companies, most of which do not have the capital or market access to commercialize a product (IMAP, 2011). A large proportion of companies working in healthcare biotechnology are research-intensive SMEs (Degen *et al*, 2011; Croplife, pers. comm., 2012). Many of these SMEs are micro-enterprises consisting of 10 or fewer employees (Degen *et al*, 2011). Currently, some very large companies with big sales/marketing organizations and the capital and knowledge for late-stage clinical developments are systematically acquiring small biotechnology companies with interesting candidate products. Licensing deals with small biotech companies are also becoming increasingly important (IMAP, 2011).

Circa 681 SMEs are registered at the EMA SME office as operating in the pharmaceutical sector in Europe.[165]

3. Types and role of genetic resources in the sector

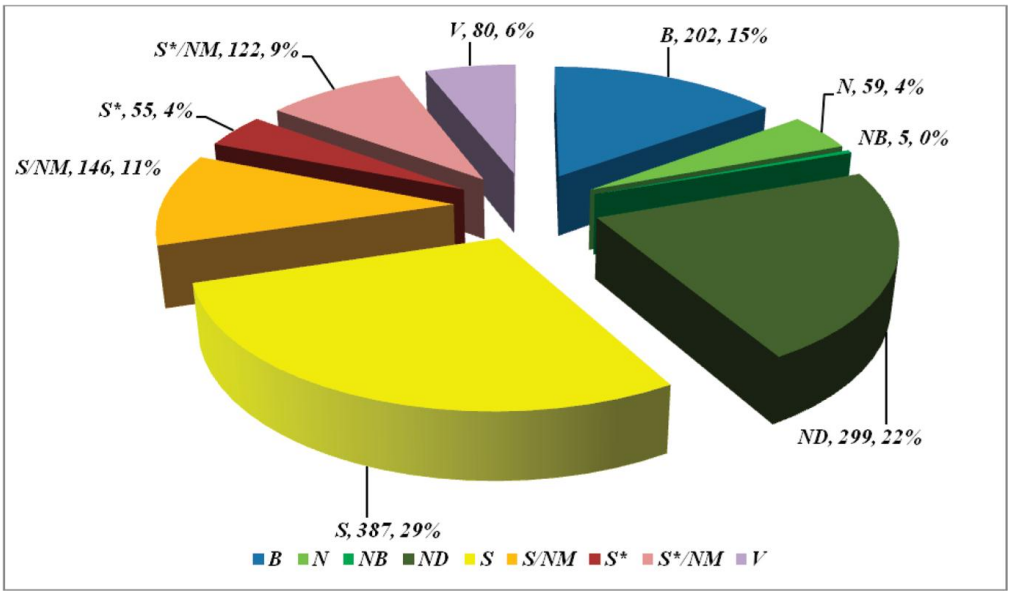
Introduction

A significant share of the global market in the past has been derived from genetic resources (ten Brink, 2011). For instance, Newman and Cragg (2012) indicate that 26% of all new approved drugs over the last 30 years are either natural products[166] or have been derived from a natural product (as to the latter, these are usually a semisynthetic modification) (see figure 1). For anticancer drugs the percentage is even higher: in the period 1981-2010 34% of all new approved anticancer drugs were natural products, natural product 'botanicals' or drugs directly derived from natural products (see figure 2). These figures do not include any of the natural product-inspired classifications (S*, S*NM and S/NM), which refer to drugs that have not been directly derived from natural products but whereby nature provided for inspiration during the synthesis process (see below for explanation of the abbreviations). Even when not taking into account these classifications, one can conclude that natural products continue to play a dominant role in the discovery of leads for drug development (sCBD, 2008; Newman and Cragg, 2007 and 2012).

[165] http://fmapps.emea.europa.eu/SME/reg_companies.php

[166] A natural product is a chemical substance found in nature (i.e. produced by a living organism) that has distinctive pharmacological effects.

Figure 1: all new approved drugs 1981-2010 by source



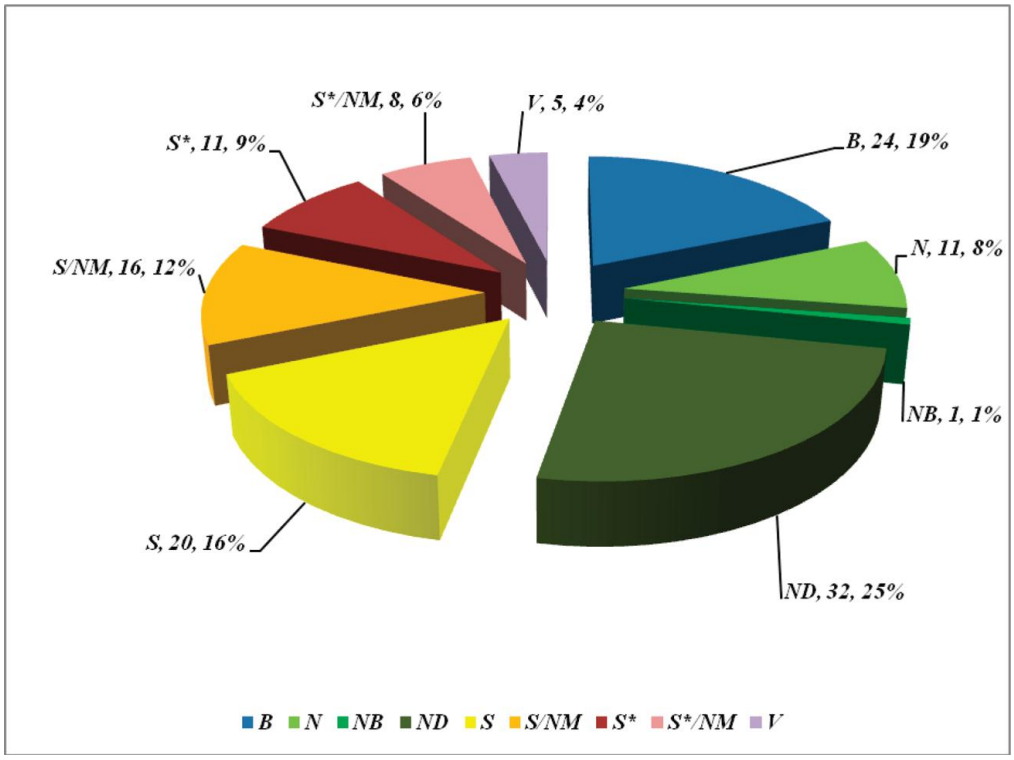
Source: Newman and Cragg (2012)

The categories used by Newman and Cragg (2012) are as follows:

- N = natural product
- NB = natural product 'botanical' (newly created category, in general these have been recently approved)
- ND = derived from a natural product and is usually a semisynthetic modification
- B = biological; usually a large peptide or protein either isolated from an organism/cell or produced by biotechnological means in a surrogate host
- S = totally synthetic drug, often found by random screening/modification
- S* = made by total synthesis, but the pharmacophore is/was from a natural product
- V = vaccine
- NM = natural product mimic (subcategory)

It should be noted that the attraction within the industry of using natural products for pharmaceutical research had decreased in the period from the mid-1990s to the mid-2000s (EFPIA, 2007). Many of the big pharmaceutical companies that had active natural products programs in the 1990s, have closed their programs (see below) (Petersen, 2007). Novartis is one of the few big companies that is still engaged in so-called 'traditional natural product research' (pers. comm., 6 February 2012).

Figure 2: all new approved anticancer drugs 1981-2010 by source



Source: Newman and Cragg (2012)

Nonetheless, technology breakthroughs, an increased understanding of genes involved in secondary metabolite biosynthesis and advances in synthetic chemistry have resulted in a renewed interest in genetic resources as sources of chemical diversity and lead generation after more than a decade of declined interest (Koehn and Carter, 2005; Newman and Cragg, 2007; sCBD, 2008). These same developments also imply that most of the research can be done in laboratories or on a computer looking at the genomes of already known organisms. Therefore demand for access to 'new' natural products is different in nature than before (sCBD, 2008).

Within the relatively small sector of natural product research, there is an increasing interest in micro-organisms. Marine organisms have also received more attention in the last 10 years. The US National Cancer Institute for instance is focusing its collections on marine organisms, as they are more promising than plants for anti-cancer agents. This is because marine organisms live in extremely hostile environments, and in some kind of perpetual state of 'chemical warfare' that produces potent toxins, and a number of novel compounds that work in a way similar to existing anti-cancer agents have been found (Newman and Cragg, 2012; sCBD, 2008).

Product examples

Examples of anti-cancer medicines based on naturally derived molecules are Paclitaxel (Taxol) from the roots of the bush *Taxus brevifolia*, Vincristina (Oncovin) from the leaves of *Catharantus roseus ocellatus* and Doxorubicina (Adriamicina) from the bacterium *Streptomyces peucetius* (EFPIA, 2007).

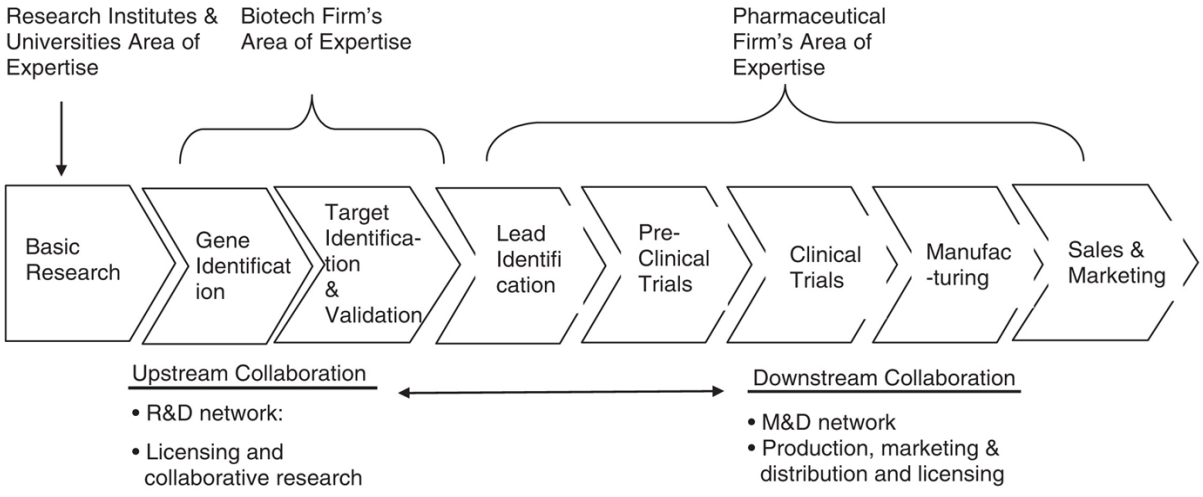
Sector-specific collections or databases of genetic resources

Pharmaceutical companies, especially those who are still doing natural products research, mostly have their own collections of plant, animal and/or microbial genetic resources. Pharmamar for instance, a Spanish biopharmaceutical company whose mission is to advance cancer care through marine-derived medicines, has built up a library of 200,000 extracts from 100,000 different marine organisms (marine invertebrates and micro-organisms) available for drug screening.[167]

Also universities and research institutes do have collections of (non-human) genetic resources which are fully oriented towards healthcare (e.g. the Institute for Tropical Medicine in Antwerp/Belgium and the Pasteur Institute in France).

Furthermore, many pharmaceutical companies have big chemical libraries amounting to thousand or hundreds of thousands of compounds which they use for high throughput screening. A certain percentage might be natural compounds or compounds derived from natural compounds (pers. comm., 6 February 2012). No data was found on the number/percentage of such compounds stored in chemical libraries of pharmaceutical companies. In addition to their own libraries, pharmaceutical companies may source external libraries of compounds which also may contain genetic resources or compounds which have been derived from genetic resources/natural compounds (EFPIA, 2007).

Figure 3: User chain in the pharmaceutical industry



Source: Advances in Strategic Management

Relevance of basic/applied research 'utilizing genetic resources' for (innovation in) the sector

Natural products research covers only a small part of the pharmaceutical industry spending on R&D, and currently only four large pharmaceutical companies maintain natural products programs of any size, with the capacity to do all facets of natural product drug discovery (Novartis, Wyeth, Merck and Sanofi-Aventis). A number of Japanese companies continue

[167] www.pharmamar.com

natural products programs, but the majority of these undertake collections primarily of microorganisms from Japan (Petersen, 2007; sCBD, 2008). Nevertheless, natural products research plays a major role in the discovery of leads for drug development and hence in innovation in the pharmaceutical sector. Most natural products research (especially the research that is involving bioprospecting) is done in academic and government research institutes or smaller discovery companies (sCBD, 2008). Big pharmaceutical companies which engage in natural products research usually collaborate with this type of players.

To improve knowledge sharing and to cut costs, pharmaceutical companies are highly interested in collaborating with academic laboratories. Partly funded by the government, academia invests effort in basic research to identify potential new targets for drugs (e.g. membrane or intracellular receptors and their signaling pathways) and biomarkers to monitor the effect of a drug. Furthermore, academia can contribute by optimizing technology to accelerate drug development. In addition, academic laboratories are highly stimulated to collaborate with pharmaceutical companies. In the EU FP7 Health program for instance, projects are only selected for funding if a certain percentage of the EU budget goes to SMEs. Furthermore, in project application forms from national governmental agencies, academic researchers have to describe how they will valorise the results of the project. Other initiatives to stimulate interaction between academia and industry include platforms such as the Innovative Medicines Initiative (IMI), a European public-private initiative that supports collaborative research projects and builds networks of industrial and academic experts to boost pharmaceutical innovation in Europe (Smits, pers. comm., 2012).

Basic/academic research may also indirectly contribute to a commercial innovation through publicly available publications/data. This was for instance the case with a green fluorescent protein. This bioluminescent protein was extracted and purified from the hydromedusan Aequorea Victoria by Osamu Shimomura (Shimomura, 1962). Later, the primary structure of the protein was unravelled and published, also at an academic lab (Prasher *et al*, 1992). Now, it is highly used as a marker for gene expression, also by pharmaceutical companies in order to study drug effects (Chalfie *et al*, 1994).

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
Patents play a major role in protecting innovation in the pharmaceutical sector. While only a small number of new chemical entities are approved annually, thousands of patents are applied for to protect variants of existing products, processes of manufacture or, where admitted, second indications of known pharmaceutical products.[168] Patents for pharmaceuticals is especially important compared with other industries as the actual manufacturing process is often easy to replicate and can be done with a fraction of the investment required for laboratory research and clinical testing. Therefore patent exclusivity is the only effective way to protect and receive a return on that investment (Thusleem *et al*, 2008). Patents are usually obtained by the time lead compounds have entered the stage of

[168] In 2011, pharmaceuticals operators based in Europe filed 5,759 applications before the European Patent Office (EPO), representing 4% of the overall number of European patent applications before the EPO. Those figures represent a strong decline compared to the previous year (6,879 applications, representing 4.5% of the overall number of European patent applications). (http://www.epo.org/about-us/statistics/patent-applications.html)

lead optimisation, even though many uncertainties with respect to commercial return remain. But without patenting at this stage, the company would have no commercial basis take the molecule(s) into further development (EFPIA, 2007).

Relevance of traditional knowledge associated with genetic resources

The role of traditional knowledge in pharmaceutical discovery has been relatively small in recent decades and is likely to become even smaller. Several reasons are being put forward for this trend: the emphasis of the pharmaceutical drug development on disease categories that do not feature prominently in traditional medicine; the decreased role of plants in discovery; the increasing role of microorganisms in discovery; and, the fact that new research approaches do not easily integrate the type of information available through traditional knowledge (sCBD, 2008).

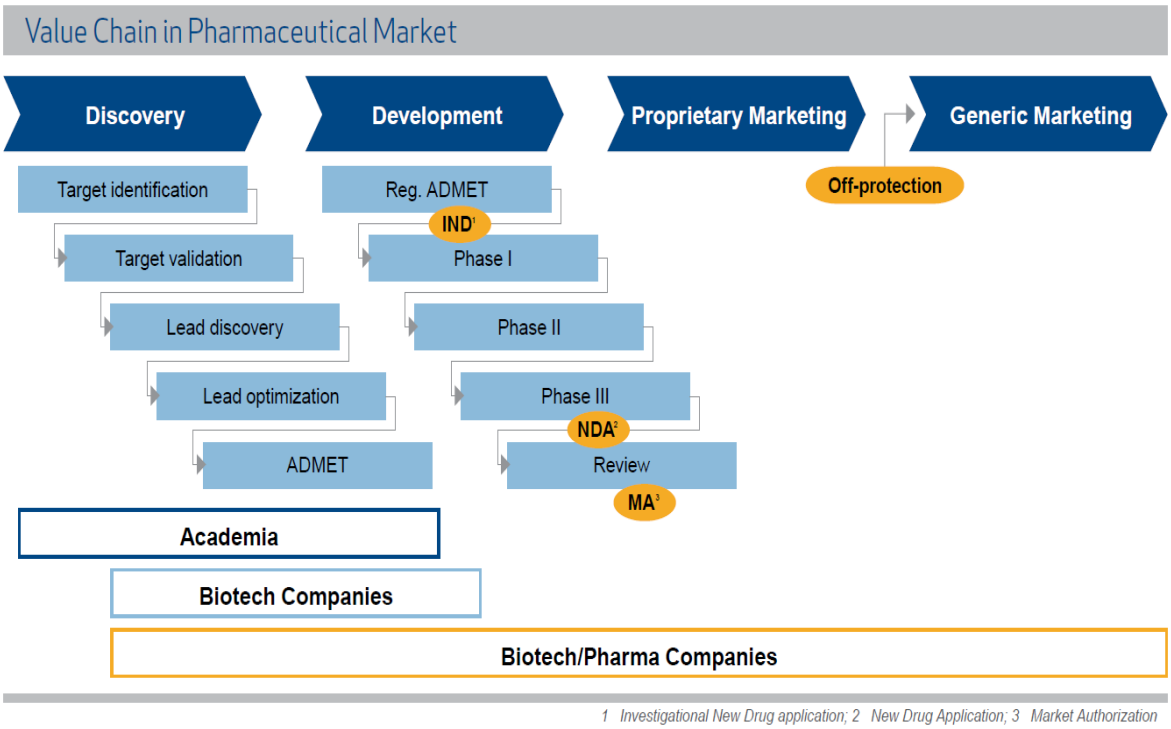
4. Sourcing of genetic materials

Introduction

In the pharmaceutical sector often many intermediaries are involved along the different steps within the user chain. A company in the pharmaceutical sector might outsource several activities or buy and/or sell certain intermediate products. In fact service providers can be found for each stage or function in the process (discovery, development, manufacturing and sales). The user chain in the pharmaceutical sector is therefore complex and continuously reshaped (see figure 3 and 4) (IMAP, 2012).

R&D in the pharmaceutical sector can be split into *discovery* and *development.* Discovery is the process by which a lead is found, including the collection of materials for screening; development encompasses chemical improvements to a drug molecule and animal and clinical studies (sCBD, 2008; Laird and ten Kate, 1999). According to Laird and ten Kate (1999) it takes about 10 to 15 years for a compound to make its way through R&D, or discovery and development in the case of pharmaceuticals, into commercialization. Only one in approximately 10,000 compounds screened is commercialized. According to EFPIA (2007) many thousands or even hundreds of thousands of samples must be screened to identify potential leads for investigation. Identified leads rarely generate compounds that merit serious research. Even fewer generate compounds that possess properties that merit the filing of a patent application; from these, only some are commercialized.

Figure 4: value chain in the pharmaceutical sector



Source: IMAP, 2011

Relevance of bioprospecting

Many of the large pharmaceutical companies that had active natural products programs in the 1990s, with associated bioprospecting activities, have closed their programs (Petersen, 2007; sCBD, 2008). However, many small companies increasingly carry out (specific aspects of) research on natural products such as biosynthetic engineering and other genomic research. These smaller companies develop hits and leads and form alliances with big pharmaceutical companies for the development of pharmaceuticals. This implies smaller companies are more likely than the largest companies to seek access to genetic resources (sCBD, 2008).

Most natural products research is done in academic and government research institutes or smaller discovery companies, especially that involving bioprospecting (sCBD, 2008). Most pharmaceutical companies get genetic resources from those organisations and do not collect genetic resources *in situ* themselves. Biotechnology companies often act as intermediaries between these bioprospecting actors and the pharmaceutical firms (see figure above). Even big pharmaceutical companies that do engage in natural products research, such as Novartis, do not bioprospect themselves but have agreements with research institutes instead (pers. comm., 6 February 2012).

Biotechnology companies are active across the user chain in the pharmaceutical industry, but their primary area of expertise is in the gene identification and target identification and validation stages upstream of product development and commercialisation. Most companies rely on existing (in-house) collections of genetic materials or outsource collection of materials to third parties (intermediaries). Most of this collecting activity is undertaken by non-profit organisations including botanic gardens and universities (including those based in

the EU, but collecting in provider countries and with partners based in provider countries) as well as commercial brokers and importers based outside of but collecting in provider countries (ten Kate & Laird, 1999). Over time, many companies develop their own collections of materials to use in their screening programmes. Companies also license access to their libraries to customers or make their collections available to commercial partners through material sharing and exchange (ten Kate & Laird, 1999).

Relevance of collections, gene banks, seed banks, databases

In addition to their own libraries, pharmaceutical companies may source external libraries of compounds (EFPIA, 2007). They purchase thousands of chemical or biochemical products from private supplier companies each year such as Sigma-Aldrich.[169] Some of these products may be natural products or may have been derived from them. A list of suppliers can be found on websites of commercial compound aggregators such as eMolecules (www.emolecules.com) and ChemNavigator (www.chemnavigator.com). eMolecules is currently the leading supplier for all chemical and biochemical products. ChemNavigator is the first portal of its kind in the life sciences. It provides access to more than 90 million compounds from approximately 300 suppliers. The iResearch Library is ChemNavigator's up-to-date compilation of commercially accessible screening compounds from international chemistry suppliers. Suppliers are from both within the EU and outside the EU.

5. Existing approaches as regards ABS in the sector

General approach towards ABS (voluntary initiatives and best practices)

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has developed "Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization". The IFPMA is a non-profit, non-governmental organization representing national industry associations and research-based pharmaceutical, biotechnology and vaccine companies from both developed and developing countries. Its Guidelines list certain "best practices" to be followed by companies engaging in the acquisition and use of genetic resources. These "best practices", however, are rather succinct and general. For instance, one practice would be to obtain PIC for the acquisition and use of genetic resources controlled by a country or indigenous people. Another would be to disclose the intended nature and field of use of the genetic resources when obtaining PIC (www.ifpma.org).

The IFPMA guidelines are voluntary and are probably not common practice in the pharmaceutical sector. They have been developed mostly in response to political pressures. In addition, the guidelines only apply to direct *in situ* bioprospecting and do not take into consideration sourcing from intermediaries. The pharmaceutical industry considers having

[169] Sigma-Aldrich is a life science and high technology company which supplies chemical and biochemical products and kits to among other pharmaceutical companies, biotech companies, hospitals, commercial laboratories and universities. These products are *inter alia* used in scientific research, biotechnology and pharmaceutical development (Sigma-Aldrich, 2011).

guidelines on sourcing from intermediaries as too complicated. For instance pharmaceutical companies purchase thousands of chemical or biochemical products each year from suppliers such as Sigma-Aldrich whereby these compounds may or may not have been derived from genetic resources. The industry does not consider it feasible to exert due diligence on thousands of transactions every year to ensure whether any of these compounds may have originated from a supplier that has once done a bioprospecting activity with respect to the compound concerned. Therefore the pharmaceutical industry is of the opinion that controlling the whole supply chain through some control or compliance mechanism is infeasible and impractical (pers. comm., 6 February 2012).

Another relevant code of conduct for the pharmaceutical sector is the "Guidelines for Bioprospecting for BIO members", issued by BIO, the world's largest biotechnology association, in June 2005. The guidelines were meant to educate BIO members about the relevant issues that could arise in the conduct of bioprospecting activities and to provide assistance to those members seeking guidance. These Guidelines envisioned that BIO members would enter into a "Bioprospecting Agreement" before collecting physical samples of genetic resources *in situ* or accessing such resources maintained *ex situ*. That agreement would include the grant of PIC as well as list the terms and conditions governing the collection and use of the genetic resources. In the area of compliance, the guidelines stipulate among others that records should be maintained on the handling, storage and physical movement of the collected material and companies should be prepared to share such records with the Providing Party upon its request. They also stipulate that companies should not accept samples of collected genetic resources from a third party that is not able to provide evidence of compliance with PIC and conditions governing use that are applicable to the sample.[170]

Documentation of genetic resources by companies
Many pharmaceutical companies have big chemical libraries amounting to perhaps millions of compounds which they use for high throughput screening. A certain percentage might represent compounds isolated from nature (pers. comm., 6 February 2012). No data could be found on the number of such compounds in chemical libraries of pharmaceutical companies.

For many of these compounds it is often quite difficult to trace back the country of origin. This type of information is not necessarily information that accompanies those compounds/molecules. It is more likely that the previous source (for instance the *ex situ* collection from which the pharmaceutical company got the compound) is being documented. For companies that engage in natural products research it is often easier to trace back the molecule to the country of origin, as they usually source their material from research institutes in the country of origin with whom they collaborate (pers. comm., 6 February 2012).

Forerunners implementing ABS best practices
Forerunners may be found among the large pharmaceutical companies that still engage in

[170] http://www.bio.org/articles/bio-bioprospecting-guidelines

natural products research such as Novartis and Merck & Co (see below) and among biopharmaceutical/biotechnology companies that fully engage in natural products and bioprospecting such as the Spanish company Pharmamar.

Existing access and/or benefit sharing agreements: case examples

Merck & Company and INBio (*Institucio Nacional de Biodiversidad*, Costa Rica) concluded a research collaboration agreement in October 1991 on the basis of which INBio was to collect and process plant, insect and soil samples in Costa Rica and transfer those samples to Merck & Company for further study and evaluation as to whether these genetic resources could be used for drug development. The agreement was renewed several times and came to an end in 1999. These agreements included benefit-sharing with INBio such as access to technology, teams and training. Merck & Co got 27 patents out of this collaboration project (Medaglia, 2004; EC's public consultation, 2011).

INBio was established in 1989 as a non-governmental, non-profit organisation which actively develops bioprospecting in protected wild areas of Costa Rica in collaboration with national and international research institutes, universities and private companies. The research collaboration agreement with Merck & Co was the first of many, followed by agreements with Bristol-Myers Squibb (1994-1998), Indena SPA, Eli Lilly (1999-2000) and Phythera Inc (1998-2000). Agreements have also been set up in the field of animal health, crop protection, agriculture and ornamental horticulture (Medaglia, 2004).

An interesting long-term partnership aimed at natural product discovery is the one between AstraZeneca, one of the largest pharmaceutical companies in the world, Griffith University in Brisbane and the Queensland State Government. They entered into an agreement in 1993 which lead to the establishment of a natural product discovery laboratory in Brisbane. Under the agreement, Griffith University retains intellectual property rights with AstraZeneca having the first right to develop a product arising from the collaboration. Royalties are due to Griffith University for the sale of any resulting product. The laboratory collects specimens from the Queensland rainforest and from the Great Barrier Reef via contracts with among others the Queensland Herbarium and the Queensland Museum. The collaboration has resulted in monetary and non-monetary benefits. Non-monetary benefits include: strengthening of Australia's scientific base through the collections and compound libraries, the advanced natural product discovery laboratory and the enormous gains in taxonomic and ecological understanding, including the discovery of many new marine species (EFPIA, 2007; sCBD, 2008). The partnership has, however, ended as it was considered too expensive and did not identify (sufficient) leads (pers. comm., 6 February 2012).

In April 2011 the World Health Organisation (WHO) reached agreement on a Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits (WHO, 2011). The framework addresses a troubling controversy: should low and middle income countries share influenza virus specimens with the WHO without assurances that benefits derived from sharing will be equitably distributed? The framework ensures that, in case a pandemic occurs, influenza virus samples will be shared with partners who need the information to take steps to protect public health. It helps to respond effectively to future influenza pandemics by making sure

that the roles and obligations among key players are better established and by helping increase and expedite access to essential vaccines, antivirals and diagnostic kits, especially for outbreak areas. In addition, the framework put the world in a better position for seasonal influenza and potential pandemic threats such as the H5N1 virus, because some key activities have to begin before the next pandemic, such as greater support for strengthening laboratories and surveillance, and partnership contributions from the industry. It helped ensure more equitable access to affordable vaccines and at the same time, also guarantee the flow of virus samples into the WHO system so that the critical information and analyses needed to assess public health risks and develop vaccines are available (WHO, 2011).

6. Current problems/issues as regards ABS

Users of genetic resources within the pharmaceutical industry are concerned about (i) the lack of clarity and transparency with respect to national ABS rules and procedures for PIC (if they exist), (ii) the lack of efficiency (bureaucracy) and diversity of these national regimes (EC public consultation, 2011).

Moreover, if ABS rules are in place, these rules often do not work in practice. Companies have for instance been confronted with officials hesitating to establish MAT. Since the CBD was created, the pharmaceutical industry (like other sectors) has experienced increasing difficulties in obtaining access to genetic resources. In many countries, attempts to access genetic resources through PIC and MAT have failed despite good faith efforts to comply with ABS rules (EC public consultation, 2011).

During the avian influenza A (H5N1) outbreaks in late 2006, Indonesia refused to share virus specimens with the WHO, claiming it was unfair to give pharmaceutical companies access. Industry would use viruses to patent vaccines and antiviral medications that Indonesia could not afford. Indonesia asserted sovereignty over viruses isolated within its territory, grounded on the Convention on Biological Diversity. Indonesia also argued that the 2005 International Health Regulations did not require states to share H5N1 viruses (WHO, 2005). The Pandemic Influenza Preparedness Framework, mentioned above, was established against this background.

7. What are key needs and preferred implementation options for the sector as regards ABS rules development and implementation?

Key needs and preferred implementation measures

The pharmaceutical sector is of the opinion that competent national authorities or national focal points should play a central role in any checkpoint system as they have the most expertise and the best connections to CBD institutions in other countries (EC's public consultation, 2011).

The sector opposes checkpoints that may create trade barriers or interfere with existing regulatory procedures such as patent applications, marketing authorisations or customs clearance. In their view, checkpoints should focus on information collection rather than on sanctioning violations.

One pharmaceutical company indicated that there should be also an obligation on importers of genetic resources to disclose specific information on the nature of the genetic resource and evidence of PIC and MAT when genetic resources are imported into the EU (EC's public consultation, 2011).

The pharmaceutical industry insists that the lengthiness of user chains ("supply and development chains") should be recognized and therefore the burden of compliance should be placed on the original party accessing the genetic resources and/or associated traditional knowledge. The sector expects the manufacturers of the final products to demand compliance from their suppliers when the burden of compliance is placed on finished products. The representatives of the sector, however, believe that many, if not most suppliers will not be able to verify whether PIC had been given and MAT had been established at the original point of access despite their best efforts. Such a measure therefore might have significant negative economic consequences on innovation and product development and might also put suppliers which are not able to verify PIC and MAT out of business (EC's public consultation, 2011).

Capacity building needed for the sector?

Compared to others economic sectors the need for capacity building or at least the need for public support for capacity building is limited. Capacity building is primarily needed for research institutes, universities and perhaps for small biodiscovery companies in developing countries from which pharmaceutical companies source their genetic resources/natural products.

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Smits, E, FWO Postdoctoral Researcher, Laboratory of Experimental Hematology (LEH) Vaccine and Infectious Disease Institute (Vaxinfectio), University of Antwerp, e-mail correspondence in April 2012

PUBLIC CONSULTATION MATERIAL

European Commission (EC) Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, October-December 2011.

Replies from:

- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Novartis International AG

CULTURE COLLECTIONS – SECTORAL SHEET

1. The Sector and ABS

Culture collections are collections of living microbial genetic resources. Having at the same time the role of *in situ* bioprospecting, storing and providing MGR, they function as key intermediary in the value chain of MGR, operating across the rights and interests of providers of living microbial genetic resources (countries of origin), collectors, depositors and the recipients/users of microbial genetic resources (commercial and non-commercial entities) to which they provide quality material and scientific services (FAO, 2009). While generally 'utilising' genetic resources merely in terms of basic research (identification/profiling of strains), culture collections are often integrated or closely collected with research institutes engaging in further basic and applied research on MGR of scientific/public/commercial interest.

2. Size and characteristics of the sector

Definition/ description of the sector

The World Federation of Culture Collections (WFCC) defines "culture collection" as an "organization established to acquire, conserve and distribute microorganisms and information about them to foster research and education". The WFCC identified some common features to all culture collections, *inter alia* (WFCC, 1999 in FAO, 2009):

- special preservation methods in order to ensure optimal viability, storage, purity and stability for individual strains;
- authentication and quality control of the strains upon deposit in the collection;
- record keeping for each strain held including information on geographic location, substrate or host, date of isolation, name of person isolating the strain, depositor (or other source of the strain, such as another collection), name of the person identifying the strain, preservation procedures used, optimal growth media and temperatures, any data on biochemical or other characteristics, and any regulatory conditions applying;
- the capability of collections to meet all relevant national and international regulations concerning the control, transportation and health and safety aspects of resource handling and distribution.

While according to the above definition the main role of culture collections is the conservation of microbial genetic resources (MGR), most collections are integrated or connected to research teams or institutions. Collections, moreover, have mostly a strong internal taxonomic branch, as identification of microbial genetic resources is one of the most important services collections perform for researchers (Desmeth, pers. comm., 2012).

Table 2: WFCC statistics on the different services offered by culture collections worldwide.

Service Type	No. of collections
Patent deposits	87
Storage services	259
Distribution	278
Identification	298
Training	253
Consultation	264

***Source*:** WFCC website (http://wdcm.nig.ac.jp/statistics.html#1)

As to the general source of funding (Table 2), more than 75% of the 593 WFCC-registered culture collections belong to public sector entities (universities or governments). The rest are semi-governmental, and in some rare cases within the domain of private non-profit or industry collections (FAO, 2009). While being publicly funded, however, many collections also generate income from the provision of services and the sale of MGR samples.

Table 3: WFCC statistics on ownership of culture collections worldwide.

Supported by	No. of colections
Governmental	235
University	218
Semi-governmental	56
Private	28
Industry	17

***Source*:** WFCC website (http://wdcm.nig.ac.jp/statistics.html#1)

Global market/size and development prospects

There are 593 culture collections in 68 countries registered to the WFCC at present, employing 3058 people worldwide. In 1999 Ten Kate and Laird estimated the downstream annual global market for products based MGR to fluctuate between US$ 500 and 800 Billion (Fritze, 2010). It must be noted however that this figure does not represent in any way the turnover of the sector of culture collections, whose role is mostly the identification, provision of services and MGR samples to downstream users. Being mostly composed of publicly funded and/or non-profit entities, no data is available as to the direct economic turnover of this sector.

As to development prospects of the sector, the utilisation of MGR held in culture collections has increased in the last years (Desmeth, pers. comm., 2012). While plants, insects, marine and other organisms are still of interest to natural products researchers, the trend over the last 5-10 years is towards microorganisms (SCBD, 2008). Metagenomic technology allows

researchers to extract DNA directly from microorganisms found in environmental samples, making available the 99% of microbial diversity previously inaccessible through traditional cultures, while at the same time discovering a far greater number of secondary metabolities in a given organism by 'genome mining' (sCBD, 2008). The genomes of microorganisms can be more easily sequenced than those of plants or insects, and can be grown in culture, rather than collected, making it easier for companies to deal with supply issues as research progresses (sCBD, 2008). Rapid advances in genomic science make it possible to study what is in existing collections, and large numbers of microbial genomes are being published and placed in the public domain (sCBD, 2008).

EU Market (size of market/sector and importance for EU economy)

The majority of the world's collections (WFCC-registered) are based in Europe (203), holding overall 663,725 strains; 158 collections are located in the EU, holding a total amount of around 580,000 strains (33% of the global number of strains collected). The top strain holders within the EU are Denmark, the Netherlands, France, Belgium, Sweden and the UK. The top strain holders outside the EU are Japan and the US, holding respectively 227,880 (13% of global share) and 210,276 strains (12% of global share). Yet, a significant amount of materials is also collected and held in culture collections based in developing countries. For example, among the ten countries with the largest number of strains are China and Brazil, holding a total number of 87,973 and 144,597 strains respectively.[171] A substantial imbalance in terms of funding and capacities is however present between collections from the North and collections from developing countries (Desmeth, pers. comm., 2012).

Being mostly a not for profit/public sector, there is no indicative quantitative data available as to the size of the market of this sector.

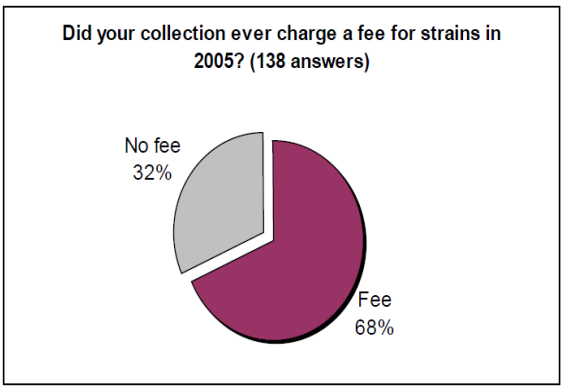
Economic relevance of 'utilisation' of genetic resources for the sector in Europe

It is estimated that more than 500.000 strains are distributed by culture collections annually, out of which 77% are transferred to public sector recipients and 23% to the private sector (Stromberg *et al*, 2006).[172] The increasing commercial value of microbial material for biotechnology and for screening of new compounds is resulting in increasing demands for these materials by the industry as well as by public science. In particular, the income stream generated by the selling of microbial strains is estimated as becoming twice as important as other nongovernmental sources of income, including contract research, identification services, and the income from patent and safety deposits (Stromberg *et al.*, 2012).

[171] WFCC website (http://wdcm.nig.ac.jp/statistics.html#1)

[172] *See figure 2 below* for details on the study conducted by Stromberg *et al.* 2006.

Figure 5: Survey on proportion of collections charging a fee for access to strains



***Source*:** Stromberg et al. (2006), survey of 138 WFCC culture collections worldwide

"Utilisation" of GR is central to the activities of culture collections as their services entail some basic research on the MGR when engaging in the process of isolation and profiling of strains which involve the study of the biochemical and genetic properties of the strain (*see below*, relevance of basic research).

Any EU companies that are market leaders? / Any EU organisations that are leaders in the sector?

As culture collections are often public and/or not for profit entities, the expression "market leaders" is not entirely appropriate in this context. Notably, because collections are often specialised (i.e. there is little overlap in terms of same strains being held in the catalogues of different collections), also very small collections may be "leaders" in their specific sector. For example the "Institut Pasteur", while not being the biggest collection in France, is the leader with regard health-related MGR (Desmeth, pers. comm., 2012).[173] In terms of services, facilities and numbers of MGR available in the collection catalogue, the global leader is the US based ATCC collection (Desmeth, pers. comm., 2012).[174] Among the leaders in the EU is the DSMZ (German Collection of Microorganisms and Cell Cultures), a public service collection. Its collections currently comprise almost 40,000 items, including about 20,000 different bacterial and 5,000 fungal strains, 700 human and animal cell lines, 800 plant cell lines, 1,000 plant viruses and antisera, and 4,800 different types of bacterial genomic DNA. All biological materials accepted in the DSMZ collection are subject to physiological and molecular characterization. Further trans-sectoral research of the DSMZ includes the study of microbial diversity and their underlying evolutionary mechanisms (genome evolution, population genetics) and molecular mechanisms of biological interactions (symbioses, mechanisms of disease, cancer).[175]

Relevance of SMEs

N/A

[173] http://www.pasteur.fr/ip/easysite/pasteur/fr/recherche/les-collections/crbip/informations-generales-sur-les-collections

[174] See further: http://www.lgcstandards.com/epages/LGC.sf/en_GB/?ObjectPath=/shops/LGC/Categories

[175] See further: http://www.dsmz.de/about-us.html

3. Types and role of genetic resources use in the sector/ characteristics of the user chain

The types of genetic resources relevant to culture collections are microbial genetic resources. Microorganisms are commonly understood for this purposes as comprising all prokaryotes (archaea and bacteria), some eukaryotic organisms fungi, including yeasts, algae, protozoan-cellular entities (e.g. viruses), their replicable parts and other derived materials e.g. genomes, plasmids, cDNA (Smith et al., 2009). Some MGR, such as "type strains" are the basic reference materials for identifying microbial taxa, thus serving applied and basic research. Other resources called "model organisms" are used as authenticated reference material which can be reliably cloned for use in cumulative research in microbiology, given the rapid mutation rates of microbial organisms which make cumulative research not possible otherwise. Other MGR have a direct role in commercial applications. The *Bacillus thuringiensis*, for example, is used as a vector for genetic engineering in agricultural biotechnology (Stromberg *et al.,* 2012).

Sector-specific collections or databases of genetic resources

By definition, the main function of culture collections is the collection, storing and distribution of microorganisms. To date, less than 1% of the estimated number of species is described and available to be harnessed by man.[176] Microorganisms of interest to research that are isolated from the environment are often conserved in culture collections, which represent living archives of authenticated and certified microbial material for future studies. Culture collections are fundamental in the study of microbial genetic resources as, in contrast to plants and animals, microbial genetic resources replicate frequently. This property may lead to changing populations in the environment and also in *ex-situ* collections, if not expertly preserved by specialised collections (Fritze, 2010).

Role of the collection in the user chain

The use of MGR that are stored in culture collections include the biological control of pests and diseases in agriculture and horticulture, production of natural products (e.g. valuable drugs, enzymes, and metabolites) for pharmaceutical, food and other applications, agricultural biotechnology, composting, detoxification of wastes (WFCC, 2008) as well as in the production of biofuels and bioplastics (Desmeth, pers. comm., 2012). They also play a major role in soil fertility and plant and animal health and are employed in diagnostics, efficacy testing of drugs, biocides, vaccine production and disinfectants (WFCC, 2008).

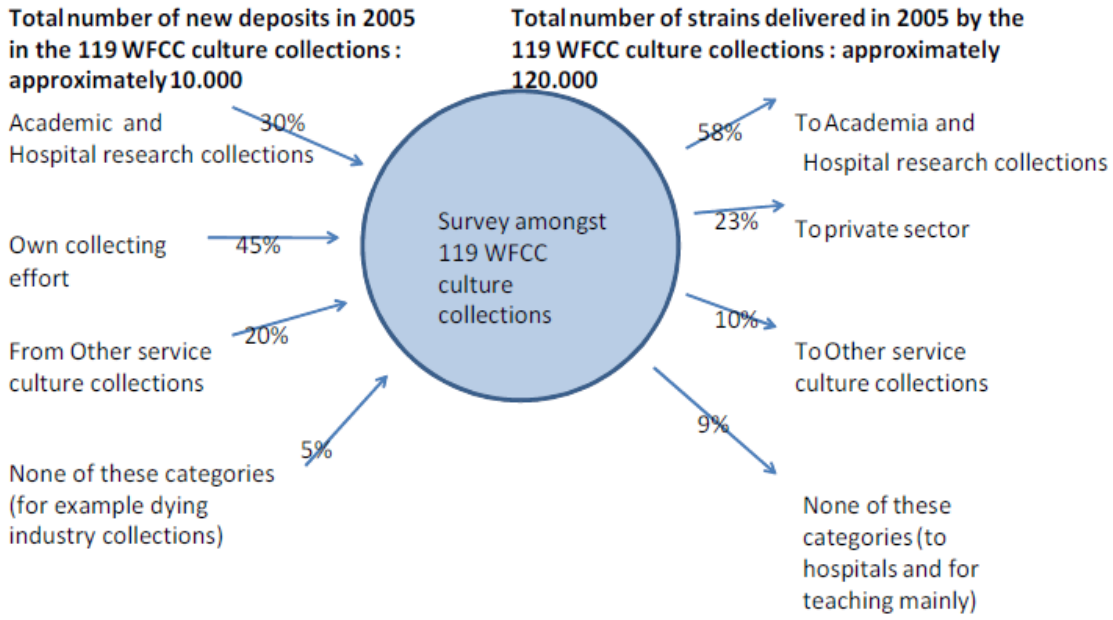
Importantly, downstream microbial research does not only rely on the physical access to microbial genetic resources but also on access to digital resources such as genomic databases (often integral parts of culture collections) and scientific publications. Increasingly, access to results of genetic sequencing, strain information databases and bioinformatics is becoming a key component of microbial research (Dawyndt *et al*, 2006 in Dedeurwaerdere, 2010). Essential information on microbial genetic resources is moreover increasingly available in the public domain through collections' public databases and the use of public genomic data is free of charge as a general rule (Dedeurwaerdere, 2010).

[176] http://www.mirri.org/background.html

Some culture collections serve additionally as depositaries for patent cultures, which represent however a fairly small proportion of the overall transactions. The number of patent deposits involving microorganisms in fact amounts to an average of 3,000 patent deposits worldwide a year, and a total of about 1,250 strains deposited worldwide a year in the International Deposit Authority (IDA).[177]

The survey presented below (Figure 2) conducted on 119 WFCC culture collections gives a clear picture of the location of culture collections in the user chain from acquisition to provision of microbial genetic resources and the proportion of those transactions.

Figure 6: Survey on strain deposits and distribution patterns in culture collections worldwide



Source: Dedeurwaerdere (2010), adapted from Stromberg, *et al*. (2006)

Figure 2 clearly shows that the largest part of transactions in which culture collections are involved relate to their "provider" function. In that regard, notably, the direct addressees of 77% of the material provided by culture collections are public sector institutions, including particularly research institutes, universities and other culture collections (Stromberg *et al*., 2006).

From the statistical assessment on nine representative culture collections (FAO, 2009), it was found that OECD collections had the tendency to provide nearly all the strains (90 to 100%) to users in other OECD countries (FAO, 2009).

Importantly, a large number of exchanges are also carried out informally between scientists and collections in the context of collaborative projects or between researchers that know each other. Those exchanges occur without any written agreement on the presumption that the recipients will only use the strains for purely non-commercial research (FAO, 2009).

[177] http://www.wipo.int/ipstats/en/statistics/micros/deposits_ida.html

While some small collections only distribute the material on an informal basis, the general trend is towards formalisation of transactions in standard or personalised material transfer agreements (Dedeurwaerdere, 2010).

Relevance of basic research 'utilising genetic resources' (for innovation) in the sector
Culture collections conduct basic research when engaging in the processes of isolation and profiling of strains which involve some basic study of biochemical and genetic properties of the strain. The added value of basic research consists not only in identifying the taxonomic nature of microbes, but also in characterising their biological function and sequencing them to identify the genetic code. Such information is organised in databases with molecular and physiological information diffused on collections' electronic databases (Stromberg *et al*., 2012). Thus, exchanges of microbial genetic resources and related information between culture collections also serve the purpose of enhancing individual collection's biochemical profiling software, so that the MGR provided by customers for identification can be more easily identified by being compared to a higher number of profiles (Desmeth, pers. comm., 2012).

Relevance of applied research 'utilising genetic resources' (for innovation) in the sector
N/A

Relevance of genetic resources for product development and for products placed in the market
N/A

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
N/A: Collections do not patent strains as do not engage directly in the development of products or processes. However as established by the EU Biopatent Directive, MGR have to be deposited in service collections when patent protection is sought for a related product or process. In those cases recognised collections function as depositaries of MGR that are part of a patented invention.

Relevance of traditional knowledge associated with genetic resources
The role of TKaGR is very limited in the sector of culture collections. No indicative qualitative and/or quantitative information is available on this subject, particularly with regard knowledge held by indigenous or local communities. Of course the traditional use of yeasts for the sour fermentation of bread and techniques of alcohol fermentation involve MGR, but those have been carried out for millenniums and are generally become part of public/scientific knowledge (Desmeth, pers. comm., 2012).

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting

Due to the fact that most microbial genetic resources are still unknown, bioprospecting remains an essential activity for culture collections and microbiologists.

As microorganisms easily develop novel and valuable properties in response to different environmental stresses, collection from industrial regions may often be as important as collection from 'gene-rich' countries (Fritze, 2010). While general figures related to geographical sourcing locations and procedures (formal/informal) may be extremely different from one collection to the other given the highly specialised nature of every collection (Desmeth, pers. comm., 2012), a statistical assessment conducted in 2005, 2006 and 2007 on nine representative collections (totalling more than 15,000 single accessions), has shown that between 45% and 100% of the new deposits from *in situ* resources in the culture collections were mostly from national depositors, whose 40% of deposits nevertheless originated from strains collected in foreign countries. This suggests that national depositors often collect in other countries and deposit the resulting material in their national collections (FAO, 2009). The geographic origin of those deposits will mostly depend on the specialisation of the particular collection but also depends on the legislation in place in the relevant country of origin. For example after the introduction of burdensome ABS procedures in the Philippines, local collections and researchers have started complaining for the drastic decrease in collaborations projects with foreign collections (pers. comm., 2012). An interesting finding was also that a substantial number of depositors from India, the Philippines, China, Brazil, Columbia and Uruguay, directly deposit strains from their countries in OECD collections (FAO, 2009).

Relevance of EU and non-EU collections, gene banks, seed banks, databases

About 20% of MGR deposited every year in culture collections originate from other culture collections (Figure 2).

The highest proportion *ex situ* accessions are deposited by research collections and individual scientist (30% of annual deposits, *see* Figure 2). Most of those come from researchers who deposit a subset of their microbial strains when publishing their research results, or who deposit strains to keep a safe backup copy of important reference material (see section above).

Relevance of acquisition of genetic resources directly in countries providing such material

As shown by Figure 2, about 45% of microbial genetic resources being deposited every year into culture collections come from direct bioprospecting efforts of the collection itself.

5. Existing approaches as regards ABS in the sector

General Approach to ABS

a) In situ collection

In relation to the acquisition of new strains, it is important to note that generally when microbial genetic resources are collected *in situ* by the culture collection itself they are usually characterised, and – in case the relevant isolated strain is of interest to the collection – deposited in the collection without any intermediaries (FAO, 2009), apart from the local counterparts in the country of origin with which they cooperate for finding and identifying relevant microbial genetic resources (Desmeth, pers. comm., 2012). As Desmeth maintains, most bioprospecting efforts in third countries are carried out through collaborations with local counterparts when the infrastructures exist. Generally the bioprospecting activity starts with the collection or their local counterpart asking for a permit to the CNA to collect ecological samples from certain geographical locations and with a certain local institution. The request for the bioprospecting permit often includes information of a very general nature as it is often impossible to exactly describe the exact strain the collection will be looking for as often the collector will not know what he will collect until the strain is identified. After the ecological samples are collected, in case the local laboratories are of a good standard, the microbial genetic resources will be usually isolated and identified locally. When isolated and identified, the collection will then be able to discern the microbial genetic resources that are of interest to them and the ones that are not and engage directly or through the local partners in ABS agreements with the relevant party (pers. comm., 2012).

An alternative "bioprospecting" practice falling outside the above description is when collections from the North engage in joint research projects with local collections in the South by providing expert taxonomists for the identification and collection of new strains in exchange to free access to the material for research purposes. In that case the relevant sample will either remain in the local collection or may be brought to the external collection for research or identification purposes only (it will not be entered into the official catalogue or distributed to third parties) (Desmeth, pers. comm., 2012).

After having complied with the local export permits and procedures the strain is sent to the main collection through specific parcels which will go through custom authorities. Custom authorities often require, among others, a declaration that the strains imported do not contain dangerous pathogens as part of biosafety and other legal requirements (Desmeth, pers. comm., 2012).

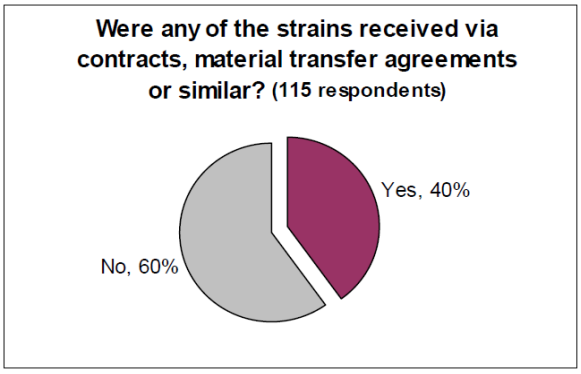
When the microbial genetic resource enters the collection it will receive an internal collection number before being published in the collection catalogue. Before entering in the catalogue, moreover, the strain often goes through a research collection for further identification. Not all the strains that are stored in the collection will necessarily be published in the catalogue. In order to conduct a study on a certain pathogen, in fact, a collection may gather hundreds of pathogens from around the world in order to compare their characteristics. Most of those will remain in the research stock but those entering the collection catalogue will often be those that have been mentioned in scientific publications

and in that way have become visible and interesting for potential customers or future research (Desmeth, pers. comm., 2012).

b) Ex situ collection

When deposits come from research collections or from individual scientists, often the strains are handled by several collaborating scientists before being officially deposited in culture collections (FAO, 2009). Research collections play an important role in the chain as they engage in the first selection and screening of reference materials. It is difficult to estimate the size of the research collections, but as they constantly process vast amounts of raw and still unspecified materials, they probably have much bigger holdings than the culture collections (FAO, 2009). Notably, many strains used by researchers or held in research collections are never officially deposited in service collections: some of them are kept for future research (FAO, 2009), while others are just thrown away after the publication of a research paper (Desmeth, pers. comm., 2012). A study conducted within the EU EMbaRC project, in fact, established that 99% of strains used in published research are not from service collections, concluding that millions of strains are sourced for research often without proper authentication and provenance.[178]

Figure 7: Survey analysing the proportion of formal and informal transactions



***Source*:** Stromberg et al. (2006)

Apart from specific national, EU and international patent law procedures relating to deposits of patent strains , for most other accessions the standard practice for collections is to require to fill an "accession form" to facilitate the management of the deposited strain throughout its *ex situ* lifespan (FAO, 2009). In the survey conducted for FAO (2009), 8 out of the 9 collections studied used formal deposit forms for all new deposits in 2005, 2006 and 2007. Remarkably between 98% and 100% of those deposits were received without any restrictions on the further use (e.g. research purposes only) (FAO, 2009). When microbial genetic resources are deposited the general understanding is that responsibility for PIC lies on the depositor. While in most deposit forms information on PIC is also required, in the majority of the collections surveyed the requirement was considered to be optional, resulting in very few depositors actually disclosing the information. In the survey in only two occasions since 1993 had collections received information on PIC and in only one case the collection rejected a strain because of the lack of PIC/MAT. On the other hand request on the country of origin was a mandatory field in most cases (FAO, 2009).

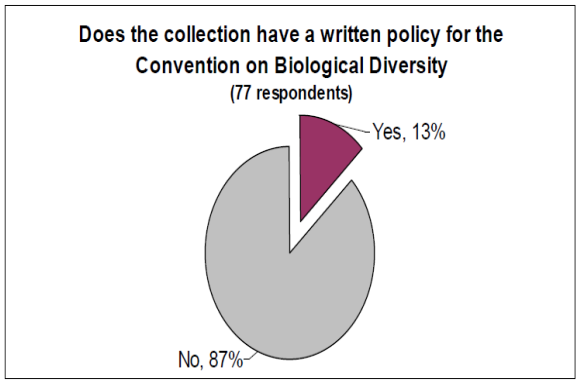
[178] http://www.mirri.org/background.html

While MTAs used in the transfer of strains between collections or from collections to third parties (for non-commercial purposes) often contain limitations on the further distribution, the main purpose of the limitations is to facilitate the tracking of the strain to ensure that the relevant microbial genetic resources keep their original quality and characteristics (FAO, 2009). As to commercial use of strains distributed by collections, most MTAs require a separate authorization by the culture collection and/or the depositor. Most of them contain clauses requiring recipients to go back and negotiate new terms in case of change of use. Benefit sharing is generally agreed *ex post* through bilateral negotiations, as the original reason for *in situ* collection of biological samples will virtually always be for non-commercial scientific research (FAO, 2009; Desmeth, pers. comm., 2012). Some collections also offer to play the role of intermediary in those further ABS negotiations for commercial purposes between the country of origin or depositor and the customer (FAO, 2009). Lastly, except for situation of commercial use or patenting of strains, MTAs do not generally impose any reporting obligation on the users (FAO, 2009).

Voluntary initiatives and best practices

As mentioned above, microbial genetic resources have been traditionally exchanged informally between culture collections and researchers. The recent trend nevertheless has been towards formalisation of transactions. This was partly brought about by the CBD and partly by the recent increase of commercial uses of microbial science and resources (Desmeth, pers. comm., 2012). In order to facilitate transactions while respecting the core requirements of the CBD, several networks of culture collections have developed standardised MTA forms so that the collections adopting the model transfer agreement will work on a level playing field. A number of ABS-related guidelines and voluntary measures have also been developed (see Figure 4); some of them (OECD guidelines on the operation of BRCs, WFCC guidelines) covering a broad range of issues, other focusing specifically on facilitating compliance with obligations from the CBD and the Nagoya Protocol (MOSAICC).

Figure 8: proportion of collections having a written policy for the CBD



***Source*:** Stromberg et al. (2006)

Lastly, considerable developments are taking place in the context of electronic documentation of collection databases and transactions of strains and in the harmonisation and standardisation of strain numbers and documentation practices.

OECD Guidelines for the operation of Biological Resource Centres[179]
The guidelines provide for a code of conduct that must be followed by Biological Resource Centres (the definition of which includes culture collections) if they want to be part of the Global Biological Resource Centre Network (GBRCN). In other words the guidelines are at the basis of a system of accreditation of BRCs as failure or inability to comply with the guidelines may result in an institution being excluded from the network. While those guidelines cover a wide range of internal governance processes, ABS-relevant sections cover four key aspects:

1) *External acquisition of biological material:* BRCs are obliged to disclose the source of the Biological Material (BM). All BM acquired must be accompanied with information on the country of origin, strain and collection number.
2) *Documentation of BM in collection catalogues*: The BRC must store data and produce electronic catalogues based on authenticated and validated information. Data should also be retained for traceability in compliance with relevant national laws. Depositors are however responsible for assuring the quality of data associated with the BM.
3) *Supply of BM:* BRCs have an obligation to supply only GM to which they have been given the rights of distribution. Materials should be distributed according to the policy of the depository which must take account of all national and international legislation. An order can be processed only when all accompanying documents are completed. BRC is moreover obliged to give information to users on any condition attached to the relevant BM. Moreover the BRC must keep record of all requests for BM including requests that have been refused for any reason.
4) *Auditing:* One audit procedure per year must be undertaken internally by the staff of each BRC. In addition an external independent audit procedure/year by a qualified person is also provided for. The external audit will look at whether the correct procedures have been put in place and properly implemented. It will also look at a random BM deposit trail through to storage and a supply trail from the receipt of order to supply.

MOSAICC (Micro-Organisms Sustainable use and Access regulation International Code of Conduct)[180]
The aim of "MOSAICC", a voluntary code of conduct promoted by the BCCM (Belgian Coordinated Collections of Microorganisms) and funded by the European Commission (DG Research), was to translate the CBD and Nagoya Protocol principles into practical procedures designed to facilitate access to and transfer of microbial genetic resources. Contrarily to the OECD guidelines, MOSAICC is merely considered as an educational tool for culture collections around the world, therefore it is not used as a condition for access to any particular network. The reason for this was the risk of only well-established collections being able to comply and the resulting marginalisation of smaller collections (Desmeth, pers. comm., 2012).

[179] http://www.oecd.org/dataoecd/60/44/23547773.pdf
[180] http://bccm.belspo.be/projects/mosaicc/docs/code2011.pdf

The first part of the code of conduct deals with the minimum steps collections must take in order to comply with local PIC and MAT legislation when bioprospecting themselves. Notably, the code of conduct promotes the systematic use of a Global Unique Identifier (GUID) to be attached to any item accessed *in situ* either at the point of isolation of the MGR or at the point of deposit in the culture collection. MOSAICC promotes the use of the WFCC World Data Centre for Microorganisms' strain tagging system to be used as GUID. Secondly, MOSAICC deals with the transparency of all transactions in microbial genetic resources collections engage in, ranging from the request of specific ABS-related information to every depositors to the use of certain model MTAs (*see* ECCO MTA below) and procedures for the transfers of microbial genetic resources to users and intermediaries. Under MOSAICC culture collections are not expected to control GR transferred to police the user chain but to become a transparent depositor of information on the origin and conditions related to any microbial genetic resources they hold, receive or transfer. The idea is that this would facilitate authorised stakeholders, countries of origin or national competent authorities to track the use of any strain (Desmeth, pers. comm, 2012).

ECCO (European Culture Collections Organisation) core MTA

The ECCO core MTA for the supply of samples of microbial genetic resources was adopted in February 2009. Its main purpose is to make microbial genetic resources available from ECCO collections under the same core conditions. The MTA contains specific clauses dealing with the purpose of the use (mainly focusing on research activities), intellectual property rights, liability, safety and security. The ECCO core MTA applies to the distribution of the material to end-users, intermediaries or those involved in the so called legitimate exchange (FAO, 2009). Recipients must not sell, distribute or propagate for distribution, lend, or otherwise transfer the material to any others, except those acting as intermediaries and those involved in legitimate exchanges (i.e. transfer of the material between scientists working in the same laboratory, or between partners in different institutions collaborating on a defined joint project, for non-commercial purposes). This also includes the transfer of genetic material between public service culture collections/BRCs for accession purposes, provided the further distribution by the receiving collection/BRC is under compatible MTA conditions (FAO, 2009). In case the recipient intends to use the genetic material for commercial purposes, it is the responsibility of the recipient, in advance of such use, to negotiate any benefit sharing with the appropriate authority in the country of origin of the material. In any case, recipients of the material should acknowledge the collection as the source of the material in any scientific publication where the relevant genetic material is mentioned (FAO, 2009). As opposed to the US, where collections and universities have well established legal departments, a problem identified in Europe is that often scientists and collections have been more accustomed to relationships and exchanges build upon mutual trust and are therefore less familiar with the technicalities of formal contractual procedures (Desmeth, pers. comm., 2012).

Other efforts in the microbiological community include:

- *The European Consortium of Microbial Resources Centres (EMbaRC)*: The aim of EMbaRC is to improve coordination and validate microbial resource centre delivery to European and International researchers by standardising practical approaches in compliance with international standards, national policies and regulations.
- *The Microbial Resource Research Infrastructure (MIRRI)*: The aim of MIRRI is to build a

pan-European research infrastructure to provide microorganisms and services facilitating access to high quality microorganisms (and their derivatives and associated data) for research development and application.

- *Global Biological Resource Centre Network (GBRCN)*: The aim of the GBRCN is to coordinate and aid the development of common approaches to enhance the availability of microorganisms between organisations, and encourage the provision of standardised information to meet user requirements.

Documentation of genetic resources

Each microbial genetic resource held in a culture collection is usually allocated a unique strain label as locally unique identifier which remains constant even in case of taxonomic changes (Fritze, 2010). Records of depositors, date of access to the collection, taxonomic information and other properties have usually always been kept for scientific reasons and records of recipients of microbial genetic resources for legal reasons (Fritze, 2010). Importantly, culture collections have started using electronic documentation databases much earlier than other *ex situ* collections (Desmeth, pers. comm., 2012). Therefore, while probably **more than 50% of the strains held world-wide were acquired before the CBD** came into force (FAO, 2009), it is not problematic for collections to distinguish pre-CBD and post-CBD material (Desmeth, pers. comm., 2012). However, information related to persons involved in the isolation and identification, PIC and MAT and country of origin of the microbial genetic resources have only been kept by some collections since the coming into force of the CBD (Fritze, 2010), as previously only the immediate source of the material was recorded (Desmeth, pers. comm., 2012).

Microbial genetic resources have to be deposited in service collections when patent protection is sought for a related product or process. While patent law normally does not ask for taxonomic identification, often basic information is provided for safety and conservation reasons. Other pieces of information, such as country of origin, source of isolation, date of isolation, isolator, etc. are usually not indicated as they are not legally required by the EU Biopatent Directive. All information provided to the collection on the patented strain is kept confidential unless release of information is explicitly allowed by the applicable patent regulations (Fritze, 2010). When non-patented material enters the collection, information on the strain may be public or kept confidential depending on the agreement between the depositor and the collection.

World Data Centre for Microorganisms

The WDCM is coordinated by the WFCC and has records of approximately 476 culture collections from 62 countries. While at the moment there is no universal practice to refer to all resources stored in different collections (Desmeth, 2006), the WDCM is working towards the creation of an international system of globally recognised strain numbers. By registering its members through a unique acronym and numerical identifier in its official list and urging them to catalogue their microbiological resources, WFCC has developed a database system allowing the tracking of microbial genetic resources. Its relevance to ABS is that it allows the tracking of all kinds of information about microbial genetic resources, including information related to the location and movements of the resource (Smith *et al*., 2009). The strain number assigned by the WDCM may serve in the future as a global unique identifier of all strains in culture collections' catalogues (Desmeth, pers. comm., 2012). The system has,

however, several gaps. Firstly, as mentioned above, not all strains are deposited in collections or published in catalogues. Secondly, the tracking system only works for exchanges between collections as after the strain is transferred to a user the track is lost, which is one of the reasons why in several MTAs further distribution is not allowed (Desmeth, pers. comm., 2012).

Other electronic documentation projects (e.g. Histri project within Straininfo) are currently being undertaken internationally to complement the above framework. Straininfo, for example, integrates all known equivalent strain numbers and corresponding information into a single strain passport page (Veslyppe *et al*, 2011). Although their purpose is currently mostly scientific, the results may have likely positive effects on the tracking of microbial genetic resources.[181]

Forerunners implementing ABS best practices
ECCO: developed the ECCO core MTA for ensuring that transfers of MGR are CBD-compliant.
BCCM: led the development of the MOSAICC code of conduct.

Existing access and/or benefit sharing agreements: case examples
BCCM in Morocco: BCCM launched a project with a network of Moroccan laboratories and the Moroccan Centre of Coordination and Planning of Scientific and Technical Research with the support of the Belgian Directorate-General for International Cooperation. This project aimed to establish, *inter alia*, a national Moroccan culture collections network.[182] Within this project, valuable strains from the laboratories in Morocco were sent to Belgium for cross-identification and then sent back to local collections well identified and catalogued. While BCCM members retained samples of those Microbial genetic resources in their catalogues, the agreement was that in case customers intended to access one of those samples, the Belgian collections would refer them to the collection in Morocco. While this exchange on paper provides a good example of benefit sharing and capacity building, in practice, because of the lack of clear administrative procedures in Morocco, most of the exchanges took place before the official authorisation was granted (retrospectively) by local authorities (Desmeth, pers. comm., 2012).

[181] For further information see:
http://www.straininfo.net/projects/;jsessionid=7E06F2E04983301965C5DF49378EE74E
[182] BCCM Newsletter, edition 13-03, May 2003; http://bccm.belspo.be/newsletter/13-03/index.htm

6. Current problems/issues as regards ABS (with possible definition/information to be added for specific issues if some issues (very) important for the sector's operations)

Lack of clarity in existing access procedures
So far, ABS relevant legislation seems to be unclear in most countries or not existing. Where it exists, competences and procedures are often unclear. It seems to be difficult to find out which authority to address for which question and for which permit, which permit is needed for which action and in which sequence. The procedures are often unclear to the same local authorities (DSMZ, European Commission consultation, 2011).

Restrictive access legislation
Increasingly restrictive access procedures in third countries may hamper the work of culture collections. For example, if an agreement is required for every microbial genetic resource isolated and for each end use, the number of transactions could become huge (CABI, EC Consultation, 2011). According to CABI, to counter this trend the EU should demonstrate to have an effective ABS system in place (European Commission Consultation, 2011). Restrictive access policies in third countries have also already resulted in serious problems for culture collections based in those countries. Culture collections based in the Philippines, for example, following the implementation of strict national access regimes, have witnessed a serious decrease in collaboration projects with foreign collections (Desmeth, pers. comm., 2012).

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

Key needs and preferred implementation measures

"Checkpoints" relevant to the sector
The following stages and processes where compliance with ABS rules could be checked were mentioned by stakeholders (European Commission Consultation, 2011 and Desmeth, pers. comm., 2012):

- Deposit in a WDCM collection (i.e. accession documents);
- Public catalogues listing collection holdings with all relevant information, making tracing back of MGR possible (DSMZ, Commission Consultation, 2011);
- the collections' individual delivery data bases which might be opened for inspection by authorities (DSMZ, Commission Consultation, 2011);
- Publications including the WDCM strain number (requirement by journal or universities);
- Research funds and project results (requirement by funders to see sharing mechanism);
- Disclosure requirements for genetic material deposited as part of the patent process (WFCC, 2008).

Reporting and disclosure requirements throughout the valorisation chain and the creation of a mandatory international certificate to be distributed by the ABS clearing house were

also considered as relevant procedural and institutional solutions (CABI, EC Consultation, 2011).

Enhancing and formalising existing practices

- From a survey of 16 culture collections, most collections expressed that it would be a good step forward to facilitate the exchange of microbial genetic resources by reaching agreement on a global common policy for the distribution/deposit of the material, so that material is deposited/distributed under the same conditions/restrictions all around the world (FAO, 2009). Support was also given to further standardization of the license conditions used in the various MTAs both for commercial and non-commercial research purposes (FAO, 2009).
- Desmeth maintained that the MOSAICC model may become more mandatory at EU level as the majority of the collections are capable to follow its requirements. Attention should be given, however, to assisting smaller collections that do not have the same capacities to adapt their practices to the MOSAICC procedures (pers. comm., 2012).

Risks of future ABS legislation for culture collections

- A requirement for collections to contact the country of origin for every transaction related to the relevant strain would have the potential to block the existing exchange system (Desmeth, pers. comm., 2012).
- The lower the EU and international harmonisation of rules, the higher is the administrative burden expected on collections and research. Of highest priority, therefore, would be the harmonisation of national legislation; providing an EU wide framework helping to develop harmonised forms and structures for implementing ABS legislation nationally. Additionally, EU could offer cooperation with other non-EU regions / countries with respect to standardisation and harmonisation of regulations (DSMZ, European Commission consultation, 2011).

Will capacity building be needed for the sector or some parts of it (SMEs for instance?)

Capacity building may be needed for small collections based in the EU which still tend to rely more heavily on informal transactions as do not have the financial and human resources, nor the legal expertise to comply with additional bureaucratic and regulatory burdens (Desmeth, pers. comm., 2012).

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INTERVIEWS

Philippe Desmeth, President of WFCC and International Coordination Officer of BCCM, Brussels, 8 February 2012.

PUBLIC CONSULTATION MATERIAL

European Commission (EC), Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity, October-December 2011.

Replies from:

- CABI, Centre for Agricultural Bioscience International
- DSMZ, Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DE)
- NBIMCC, National Bank for Industrial Microorganisms and Cell Cultures (BL)

BOTANIC GARDENS – SECTORAL SHEET

1. The Sector and ABS

The collection and exchange of plant genetic resources (PGR) is an integral part of scientific research programmes, conservation, education and other activities carried out by botanic gardens. This sector primarily engages in upstream activities in the ABS user chain. Botanic gardens, in fact, still substantially engage in bioprospecting activities, identification and documentation of new plant varieties, storage and, in particular, exchanges of PGR (mostly in the form of seeds) with other *ex situ* collections. Botanic gardens further play a key role in the non-commercial utilisation of PGR, acting as providers of genetic resources to universities and other research institutes (which are often the direct owners of botanic gardens) that engage in basic and/or applied research on plant varieties of scientific interest. Scientific research on PGR is also an important activity of botanic gardens themselves, which is carried out by internal scientific teams or in collaboration with external scientists.

2. Size and characteristics of the sector

Definition/ description of the sector

The International Agenda for Botanic Gardens in Conservation defines Botanic Gardens as "institutions holding documented collections of living plants for the purposes of scientific research, conservation, display and education".[183] Activities of Botanic Gardens, nevertheless, generally extend beyond the mere collection and exchange of living plants material. The maintenance of collections such as herbaria, for example, while falling outside the above definition represents an important activity carried out by Botanic Gardens (van den Wollenberg *et al*, pers. comm., 2012). Similarly, plant collections that have ceased all scientific activities or where substantial documentation has been lost may still be commonly considered as botanic gardens (Wyse Jackson *et al*, 2001).

While endorsing the above definition, the Botanic Garden Conservation International (BGCI) has also drafted a non-comprehensive list of indicative criteria to help defining the sector. Those include, *inter alia*:

- A reasonable degree of permanence
- An underlying scientific basis for the collections
- Proper documentation of the collections, including wild origin
- Monitoring of the plants in the collections
- Adequate labelling of the plants
- Openness to the public
- Communication of information to other gardens, institutions and the public
- Exchange of seed or other materials with other botanic gardens, arboreta or research institutions

[183] http://www.bgci.org/resources/1528/

- Undertaking of scientific or technical research on plants in the collections
- Maintenance of research programs in plant taxonomy in associated herbaria.[184]

Van den Wollenberg *et al* (pers. comm., 2012) added that a Botanic Garden must be a legal entity i.e. the mere private property of a natural person normally would not qualify as a Botanic Garden.

A large variety of institutions may fall under the above criteria, displaying important differences in terms of size, funding, ownership and functions. In terms of size, they range from large gardens with hundreds of employees and a diverse range of activities such as the UK-based Kew Royal Botanic Gardens - which includes, *inter alia*, a legal department, laboratories, conservation activities and a public relations department[185] - to institutions with very limited resources such as the Bonn Botanic Gardens, where only one scientist is employed to manage a collection of 10.200 species (van den Wollenberg *et al*, pers. comm., 2012).

In 2001 it was estimated that 30% of the world's botanic gardens belonged to universities or other higher education research institutes. Many others receive public funding and are managed by state, regional or local authorities. Only a relatively small proportion is privately owned (Wyse Jackson *et al*, 2001). The trend at the time was however towards administrative independence and partial financial independence through own fund-raising efforts (Wyse Jackson *et al*, 2001). The functions of different botanic gardens may also vary significantly ranging from historical gardens, conservation gardens, community gardens and university gardens – driven mostly by scientific, conservation and educational purposes - to a minority of institutions potentially qualifying as botanic gardens more linked to the private sector such as horticultural gardens (existing primarily to foster the development of horticulture through the training of professional gardeners, plant breeding, registration and conservation of garden plant varieties), agro-botanical and germplasm gardens (functioning as an *ex situ* collection of plants of economic value or potential for conservation, research, plant breeding and agriculture) (Wyse Jackson *et al*, 2001). The present sectoral sheet will focus primarily on the practices of the former category.

Global market/size and development prospects

Upon the premise that figures may significantly vary depending on how the definition of "botanic garden" is interpreted, the BGCI estimates the existence of 3021 botanic gardens distributed in 148 countries worldwide[186], maintaining more than 6.13 million accessions in their living collections. Amongst their collections are representatives of more than 80.000 species, almost one third of the known vascular plant species of the world.[187] While the majority of botanic gardens are based in Europe and North America, significant numbers may be found also in East and Southeast Asia (particularly in China) and Southern Asia (mostly in India). On the other hand there are relatively few gardens in Africa, Middle East and Caribbean. The trend in the second half of the 21st century has been a general increase of botanic gardens in most

[184] http://www.bgci.org/resources/1528/

[185] http://www.kew.org/about-kew/who-we-are/organisational-structure/index.htm

[186] http://www.bgci.org/garden_search.php: The figure represents the total number of Botanic Gardens that have been registered so far in the BGCI database so far (this includes both members of BGCI and non-members).

[187] http://www.bgci.org/resources/

regions. However the highest proportional increase in the number of botanic gardens has been observed in tropical regions (Wyse Jackson et al, 2001).

EU market (size of market/sector and importance for the EU economy)

Latest figures show that out of the 3021 botanic gardens worldwide 550 are based in the EU (van den Wollenberg *et al*, pers. comm., 2012).[188] According to the 2001 BGCI report more than 50% of living plant accessions in the world are collected in Europe. This figure shows that collections in tropical countries are generally much smaller. This is due partly to an imbalance of institutional resources and partly to the fact that gardens in the developing world are generally younger institutions without the long history of collection of European gardens (Wyse Jackson *et al.*, 2001). The greatest number of botanic gardens in Europe may be found in the UK (117), Italy (106), France (104) and Germany (103) (BGCI Garden Search Database, 2012). Being a primarily publicly funded and not-for-profit sector with the principal purpose of conservation and non-commercial scientific research, the direct importance of this sector for the EU economy may be expected to be marginal. No indicative quantitative or qualitative information is however available.

Economic relevance of 'utilisation' of genetic resources for the sector in Europe

Being the sector primarily not-for-profit and mostly related to non-commercial/academic research, figures as to the direct economic relevance of utilisation of GR by botanic gardens are not available. As far as utilisation of PGR is concerned, in fact, the main activity of botanic gardens is basic research that is primarily related to the identification of new plant material and the scientific study of their properties for non-commercial/academic purposes, often in collaboration with universities (van den Wollenberg *et al*, pers. comm., 2012). This however does not exclude the possibility that utilisation of PGR by this sector may indirectly or directly have some economic relevance for product development downstream. As to indirect economic relevance, the discovery and identification of new PGR and further basic research on their properties made publicly available through publications may trigger the interest of downstream users to develop a product from the new PGR identified by the garden. As the Wollemi Pine case example shows (*see below*), basic research carried out in well-established botanic gardens may also lead to direct collaborations between a garden and the private sector leading to the commercialisation of a product.

Any EU companies that are the market leaders? / Any EU organisations that are leaders in the sector?

Kew Gardens[189]: the Royal Botanic Gardens Kew (UK), hold the largest collection of living plants in the world, including more than 30.000 species as seed samples from at least one population. Over 1.5 billion seeds are held in the Kew Gardens' seedbank. The herbarium, which is also one of the largest in the world, counts over 7 million specimens, including approximately 350,000 type specimens.[190] The garden carries out bioprospecting, conservation as well as substantial scientific research activities, employing 744 staff members out of which 249 in the botanical science department. The garden in fact publishes in average more than 350 scientific publications every year. Its activities however also extend to partnerships and collaborations

[188] *See:* http://www.bgci.org/garden_search.php

[189] Further information available at: http://www.kew.org/index.htm

[190] http://www.kew.org/collections/index.htm

with universities, botanic gardens, conservation organisations, industry and government. While being a charity under UK law, Kew Gardens have a generated annual revenue of £45.5 million (year 2010/2011), with more than half of it originating from public funding and the rest mostly coming from private grants and fees charged for visiting the gardens (1.6 million visitors in 2010/11).[191]

Relevance of SMEs
N/A

3. Types and role of genetic resources use in the sector/ characteristics of the user chain

Virtually all material held by botanic garden's collections is linked to plant genetic resources. Genetic resources exchanged and maintained by botanic gardens are mostly in the form of living plant materials, the primary purpose being conservation, enhancing public awareness and non-commercial research (Von den Driesch *et al*, 2005). Much of the living plant material is stored and exchanged in the form of seeds. A study from 1994 on the basis of information provided by 388 botanic gardens around the world, in fact, concluded that 30.7% possessed an internal seed bank or other seed storage facility (Laliberté, 1997). Activities of botanic gardens however go beyond the collection and exchange of living plants as they often manage many other types of collections including herbaria. The BGCI's 2001 report estimated a total of 42 million herbarium specimens in botanic gardens' herbaria worldwide (Wyse Jackson, 2001).

Sector specific collections or databases of genetic resources
The collection and documentation of plant material is the core activity of botanic gardens. Traditionally botanic gardens have collected and provided access to their collections mostly for scientific, educational and conservation purposes (van den Wollenberg *et al*, pers. comm., 2012; Wyse Jackson *et al*, 2001). This does not exclude however the fact that well established and organised collections sometimes also engage in commercial transactions through the sale of their plant material to companies engaging in commercial R&D or through collaborations in the commercialisation of a new product based on PGR. The number of those transactions remains however quite small compared to the overall non-commercial transactions in plant materials that botanic gardens engage in every year among themselves (van den Wollenberg *et al*, pers. comm., 2012).

Referring to the International Plant Exchange Network (a network covering only the exchange of living plant material), van den Wollenberg estimated that 99% of the living plant material getting out of the IPEN system was provided to users for strictly non-commercial purposes (pers. comm., 2012). These figures however reflect the relatively strict self-regulatory requirements of IPEN (see below) and may be different in the case of transactions by other botanic gardens operating outside the network or in case of exchange of non-living plant material.

Relevance of basic research 'utilising genetic resources' (for innovation) in the sector
By definition, scientific or technical [basic] research on plants genetic resources in the collections is a core activity of botanic gardens. Basic research on plant genetic resources may

[191] Kew Annual Report and Accounts 2010/11, Available at: http://www.kew.org/ucm/groups/public/documents/document/kppcont_038136.pdf

either be undertaken by the garden on its own e.g. taxonomic research for the purpose of identification of new species or varieties or in collaboration with universities and other research institutes.

Relevance of applied research 'utilising genetic resources' (for innovation) in the sector
N/A

Relevance of genetic resources for product development and for products placed on the market
N/A

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
N/A

Relevance of traditional knowledge associated with genetic resources
In relation to traditional knowledge associated with plant genetic resources Van den Wollenberg e*t al* pointed at the role of herbaria collections, which were described as a potential mine of information not only relating to genetic resources. In herbaria collections, in fact, botanic gardens alongside the relevant plant material often also keep related objects and information of ethno-botanical nature, e.g. information about use by indigenous and local communities of the relevant plant materials (pers. comm. 2012).

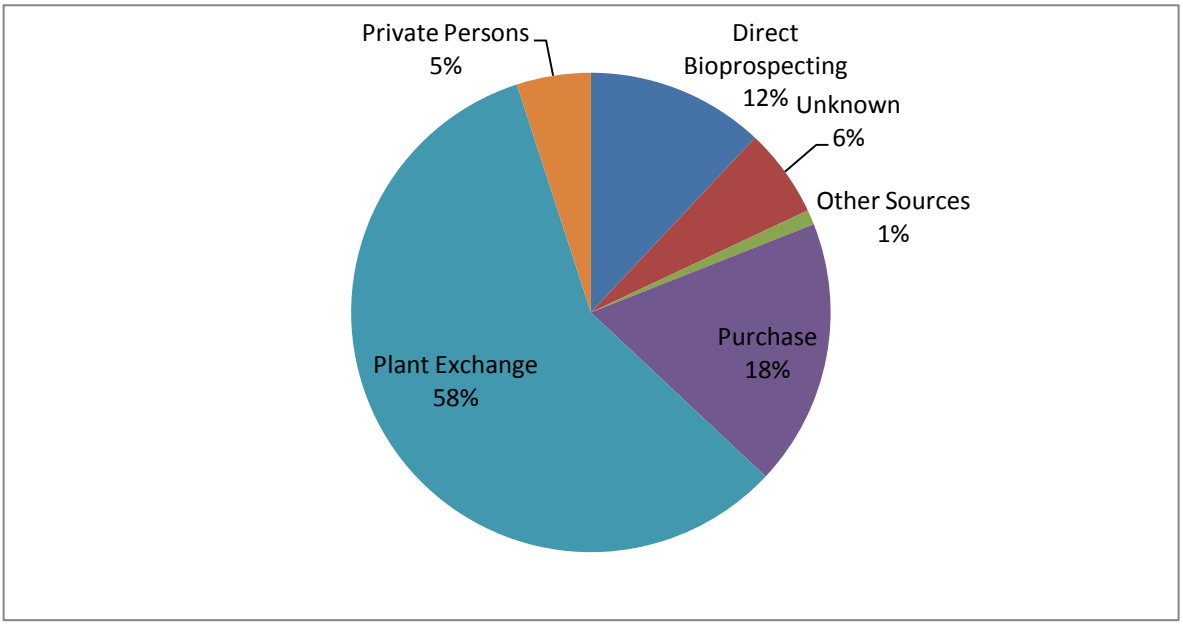
Jan Rammeloo, former director of the National Botanic Garden of Belgium, also provided an example of a benefit sharing agreement between the Belgian National Botanic Garden and some local communities in Africa as a result of an *in situ* research on African edible mushrooms. While no genetic resource was actually taken back to Belgium, the information on traditional knowledge associated with the use of those mushrooms by local communities gathered in the research activity was published in exchange of training programs for local female farmers on how to find, use and differentiate different mushrooms as an alternative economic activity to farming (van den Wollenberg *et al*, pers. comm., 2012).

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting

The collection of plants from the wild is an integral part of scientific research programmes, conservation, educational and other activities carried out by botanic gardens. Many botanic gardens, indeed, still assume special responsibilities for the cultivation and conservation of hundreds of rare and endangered species (Wyse Jackson *et al*, 2001); 42% European threatened taxa, for example, is accessible in *ex situ* collections within their region of origin (Sharrock and Jones, 2009).

Figure 1: Result from a Survey on 84 Botanic Gardens in German-speaking Countries



Source: (Krebs et al., 2003)

Relevance of EU and non-EU collections, gene banks, seed banks, databases

The most important sources of plant genetic resources for botanic gardens are other *ex situ* collections with which they often have established international free exchange networks that provide mutual benefits to all their members. According to the figures of the above study, in fact, 58% of plant material entering botanic gardens – most of which relates to the free exchange of seeds (50% of the overall transactions) - comes from free exchange networks established between botanic gardens around the world (Krebbs *et al*, 2003).

The main movement of plant genetic resources within the EU generally takes place between public botanic gardens. The IPEN network, applying particularly to botanic gardens in the EU, is furthermore facilitating and promoting the exchange of living PGRs between botanic gardens complying with its code of conduct (Van den Wollenberg *et al*, pers. comm., 2012).

The 2003 study conducted by *Krebs et al.* on 95 botanical gardens based in Germany, Austria, Switzerland and Luxemburg also provided good indicative figures on the amount of transactions in PGR botanic gardens engage in every year (Krebs *et al.*). The survey counted the overall non-commercial transactions of seeds between gardens, resulting in some 326.000 transactions

(including both supply and receipt) or an average of around 3430 transactions per year for each botanic garden. Van den Wollenberg *et al* maintain that between 2003 and 2012 there should not have been any significant variation in those figures and guessed that for the whole of EU the overall seed transactions could amount to a number close to 2 million per year (pers. comm., 2012). The huge annual exchange of plant materials - seed exchange in particular (Den Driesch *et al.*, 2005) - between botanic gardens has a strong conservation rationale apart from the object of public information and education about different plant varieties, as it mostly serves the purpose of maintaining alive the *ex situ* collections of living plants around the world (Van den Wollenberg *et al*, pers. comm., 2012).

With regard to sourcing from third countries, there is an increasing trend in acquiring material from *ex situ* collections based in the developing world, although many European botanic gardens sourcing from those collections are still experiencing difficulties in terms of scientific standards and legal certainty (Van den Wollenberg *et al*, pers. comm., 2012).

According to the above study, moreover, a relatively high proportion of plant material (18%) was being purchased by botanic gardens (Krebs et al, 2003) from plant breeders and other unspecified sources, this being the practice of several private and municipal gardens as opposed to gardens managed by universities (Lobin, pers. comm., 2012). Finally, 5% of plant material received by botanic gardens originated from donations by private persons (Krebs *et al*, 2003).

Relevance of acquisition of genetic resources directly in countries providing such material
In situ collection of plant genetic resources through bioprospecting is still an important activity carried out by botanic gardens. Yet, from a study carried out on data provided from 84 botanical gardens in Germany, Austria, Switzerland and Luxemburg it was found that only 12% of the plant material acquired by the botanic gardens every year was directly collected from the wild (Krebs *et al*, 2003).

5. Existing approaches as regards ABS in the sector

General approach to ABS
The IPEN system described below represents to a large extent the practice of the most established botanic gardens in the EU. The same standards are not however necessarily being applied across the board. The proper implementation of those standards by members and non-members is often undermined by the lack of funding and capacity to address the paperwork and develop efficient documentation systems (van den Wollenberg *et al*, pers. comm., 2012). While in fact the trend is towards formalisation of transactions and contractual partnerships with local counterparts in third countries, often gardens lacking the capacity and resources still engage in informal exchanges and transactions of PGR.

Voluntary initiatives and best practices

International Plant Exchange Network (IPEN)
IPEN is certainly the most significant ABS-related self-regulatory mechanism relevant to this sector, consisting in a registration system open for botanic gardens that adopt and abide by a common Code of Conduct. Initially developed by the Verband Botanischer Gärten (an association of gardens in German speaking countries), the network management was taken over

in 2002 by the European Consortium of Botanic Gardens and a "task force" for its implementation was constituted.[192] At present, 150 botanic gardens worldwide are actively taking part in the network. Significantly 130 members are gardens based in EU member states (i.e. around one-fourth of the botanic gardens established in the EU).[193]

The network facilitates the exchange of living plant material between the members while respecting the ABS requirements of the CBD, aiming to create a climate of confidence between the countries owning the genetic resources and the botanic gardens.[194] The Code of Conduct mostly regulates the following four processes:

A) Ensuring the legality of living plant material entering IPEN

In relation to all living plant material received, botanic gardens are required to exercise due diligence to ensure that to the best of their knowledge the material has been originally acquired in compliance with international ABS legislation. When sourcing from *in situ* collections in particular members are required to look for PIC and any other relevant permits required under the provider country legislation.

B) Terms and conditions for material freely circulating within IPEN

Only material obtained without particular restrictions with regard its non-commercial use or supply to third parties may be introduced within IPEN. Moreover, the first garden introducing a plant sample has to provide the accession with an IPEN number (*see below*), which will follow the accession and all its descendants through the exchanges within the network, and must keep appropriate documentation on the source, permits and conditions attached to the original sample. When the material is introduced in the IPEN the supply of plant material becomes easy, as all member gardens share the same policy on access and benefit-sharing and through the IPEN-number one can always easily trace back the origin of the material.[195]

Clearly, while the above procedures ensure that most of the material entering the network has been properly sourced, they cannot ensure the same for all living plant material entering garden's collections which are not entered in the network (van den Wollenberg *et al*, pers. comm., 2012). While happening in a proportionally small number of transactions,[196] it is not uncommon for many botanic gardens to accept donations of plant material without appropriate documentation in case the plants have a particular scientific interest or important conservation function. The sources of this undocumented material are generally scientists or individuals unaware of ABS legislation, including universities in developing countries unaware of their local ABS legislation. This material is not introduced in the IPEN network but enters nevertheless the collection of the garden (van den Wollenberg *et al*, pers. comm., 2012).

[192] http://www.bgci.org/resources/ipen/: The 'IPEN National Nodes' panel ensures that applicants meet the IPEN criteria. This panel consists of representatives of national networks of botanic gardens. The 'IPEN Task Force' is a small group of representatives, appointed by the IPEN National Node Network whose main task is to develop and to update the IPEN instruments.

[193] *Ibid.*

[194] *Ibid*.

[195] *Ibid.*

[196] The 2003 study conducted by *Krebs et al.* indicated that the source of 6% of plant material received by the botanic gardens surveyed was unknown.

C) The sharing of benefits arising from non-commercial use

IPEN members are required to do their best to share benefits resulting from the use of plant material with the country of origin. Since the garden's use of the material covered by this exchange network is non-commercial, the benefit sharing envisaged is primarily non-monetary.

D) The supply of plant material outside IPEN

If the recipient is not an IPEN member that wishes to access the plant material for non-commercial purposes, he will have to sign the IPEN Material Transfer Agreement, which will bind him to the same terms and conditions in relation to further transfers and use. No monitoring or reporting requirement is however put in place except from the obligation to mention and notify the country of origin or the supplying garden in any publication mentioning the relevant plant material. In fact through this agreement the responsibility for legally handling the material is contractually passed upon the recipient. If at one point an IPEN garden wants to start a commercial use with a given plant material, this material will leave IPEN. Therefore the garden will first have to establish PIC and MAT with the country of origin before going forward with the change of use. Only then the commercial use may be started. Similarly, material can only be provided to a company for commercial R&D if the company has negotiated a new PIC and MAT with the country of origin. After the new PIC and MAT has been established, botanic gardens will generally provide the plant sample for free (van den Wollenberg *et al*, pers. comm., 2012). With regard IPEN material, van den Wollenberg *et al* estimated that 99% of material leaving the network is provided to users for strictly non-commercial purposes (pers. comm., 2012).

In terms of enforcement of this Code of Conduct, van den Wollenberg *et al* noted that while it is technically possible to exclude a member for non-compliance with the terms, this has never happened and it is unlikely it will happen (pers. comm., 2012). The main control in the IPEN system is peer pressure and mutual control (van den Wollenberg *et al*, pers. comm., 2012).

Principles on Access to Genetic Resources and Benefit Sharing

Since the entry into force of the CBD several botanic gardens have taken significant steps to ensure their compliance with the new access and benefit sharing obligations resulting in the creation of several codes of conduct. Already in 1997 a Pilot Project coordinated by the Royal Botanic Gardens, Kew, resulted in the development of the "Principles on Access to Genetic Resources and Benefit Sharing for Participating Institutions", a voluntary code of conduct that was endorsed by 28 botanic gardens around the world. The Principles required participating institutions to set up an internal ABS policy in relation to all their collections taking into account broad guidelines setting out obligations with regard to access, use and supply with genetic resources as well as minimum steps to be taken in setting up appropriate MTAs when accessing and supplying genetic resources and in documenting the terms and conditions under which genetic resources were accessed in the first place. To implement those guidelines, for example, Kew Gardens implemented an internal certification system requiring all fieldworkers to receive a registration number from their Overseas Fieldwork Committee for each trip before they could receive funds or insurance (Kew, 2004). For that purpose fieldworkers are to provide information on whether they (a) are working with partners; (b) can identify relevant stakeholders; (c) have obtained or are in the process of obtaining appropriate permits (d) understand the terms of use; and (e) are planning benefit-sharing. Permits are collected and filed with OFC records after each trip. Certain standard acquisition agreements for non-

commercial purpose were also set up to deal with the size and high volume of exchanges in the herbarium. In case the terms requested by the source country or institutions are stricter, the collection manager needs to decide whether Kew is able to curate the material (Davis, 2005).

Documentation of genetic resources

A) *General Practice of Documentation of Collections*

By definition, record keeping is one of the defining features of a botanic garden. In fact, plants in cultivation need to be correctly identified and documented if they are to be useful for conservation or scientific research.[197] Labelling and documentation systems may range from manual index cards and forms to more structured barcoding systems and electronic databases. While the trend is towards computerisation of collections, this often depends on the resources available to individual gardens (van den Wollenberg *et al*, pers. comm., 2012). National databases of plants in cultivation have also been developed as part of national conservation strategies.[198]

Of high relevance to the implementation of the Nagoya Protocol, a thorough survey of hundreds of botanic gardens in 2001 estimated that **around 90% of all living plant collections that could be found in botanic gardens around the world pre-dated the entry into force of the CBD** (Wyse Jackson, 2001). In relation to those resources, it has always been a fairly generalised practice for botanic gardens to introduce information on the year of access or country of origin of plants in the relevant labelling or database system of the collection (van den Wollenberg *et al*, pers. comm., 2012). It is however hard to find a consistent practice. The fact that each garden has a different purpose and related data management system, in fact, makes it hard to have a standardised plant record database for the botanic garden community (Wyse Jackson, 2003). Moreover in many cases source data on the country of origin or on the original *ex situ* source of the material has been lost as collections have passed from garden to garden around the world without restrictions or written contracts (Wyse Jackson *et al.*, 2001).

The practice of keeping record of permits, conditions, benefit sharing obligations and transfers of plant material has been greatly promoted by the IPEN system. Nevertheless the administrative burden of its documentation requirements is an important factor keeping away from the network many small or underfunded botanic gardens (van den Wollenberg *et al*, pers. comm., 2012).

B) *IPEN number*

When a botanic garden enters the IPEN system, it is generally required to establish an electronic documentation system. The system must allow the introduction of IPEN numbers for all plants that shall be distributed within the system. The IPEN number remains connected with that material and its derivatives through all generations to come. With the aid of this number it is possible to trace back where and under which conditions the plant material entered IPEN and indicates the garden possessing the original PIC and MAT documents. The first garden that supplies a specific plant sample within IPEN has to provide this material with an IPEN-number (Von den Driesch *et al.*, 2005).

The IPEN number consists of four elements:

[197] http://www.bgci.org/resources/Info_man_systems_living_c/

[198] http://www.bgci.org/resources/ipen/

- Country of origin (a standardised abbreviation, "XX" for unknown origin).
- Restrictions of transfer (one position, "1" if there is a restriction, "0" if none).
- Garden Code (provided by BGCI to each new registered IPEN member)
- Identification number (accession number of the garden).

Example: LU 0 Lux – 2004-149[199]

C) *Indices Seminum*

An *Index Seminum* is a list of the seeds available in a certain botanic garden that is then freely circulated to other botanic gardens. They have been developed in the last two centuries with the purpose of enabling easy exchange of seeds between botanic gardens around the world for scientific and conservation purposes (van den Wollenberg *et al*, pers. comm., 2012). Since the entry into force of the CBD an increasing number of gardens now exchange the seeds subject to MTAs restricting the use to non-commercial purposes. The terms of the MTAs are often included with the regular seed exchange catalogues sent between institutions (Wyse Jackson *et al*. 2001).

Forerunners implementing ABS best practices

European Botanic Gardens Consortium: the EBGC is a forum comprising the representatives of national botanic gardens networks of the EU MS, established with the primary aim of coordinating the implementation of the CBD and other European biodiversity policies. The consortium has taken responsibility in leading and promoting the IPEN code of conduct in the EU and around the world.

Royal Botanic Gardens, Kew: see "*Principles on Access to Genetic Resources and Benefit Sharing*" above.

Existing access and/or benefit sharing agreements: case examples

There is an increasing trend for botanic gardens to work in close partnership with each other or with local communities and other stakeholders to develop CBD-compatible projects.[200] The trend is also towards longer partnerships with local institutions in fewer countries in order to adapt better to national legislative frameworks and having more effective benefit sharing projects (Davis, 2005). Sometimes those projects are carried out with the help of EU funds or EU member states' foreign cooperation funds (van den Wollenberg *et al*, pers. comm. 2012). Botanic gardens are generally able to generate many different kinds of benefits from their work; these benefits are usually non-monetary and can take many different forms, depending on a garden's activities and resources. These include, *inter alia*, twinning projects with botanic gardens in developing countries, the sharing of research results, training, staff exchanges, donation of equipment and educational material, the funding of joint excursions, community development activities and monetary benefits from commercialisation projects (van den Wollenberg *et al*, pers. comm., 2012).

A) Partnership between the National Botanic Garden of Belgium and Kisantu Botanic Garden

In this "twinning" partnership established between the National Botanic Garden of Belgium and the Kisantu Botanic Garden in the Democratic Republic of Congo (DRC), in exchange for the

[199] http://www.bgci.org/resources/Description_of_IPEN/

[200] http://www.bgci.org/ourwork/case_studies_benefitshari/

supply of local plant material by the Congolese garden, the national Botanic Garden of Belgium restored their herbaria, helped them digitizing the material of their collection and provided training courses on taxonomy. The main problem identified was one of legal certainty as DRC has not yet implemented any clear ABS legislation. As a result the ABS agreement with Kisantu Garden was not the result of any formal contractual agreement with the government, nor did the garden have any formal authority to provide those plant genetic resources to the Belgian National Botanic Garden. As a result of the partnership research outcomes were published but the plant material collected could not be introduced into the IPEN network (van den Wollenberg *et al,* pers. comm., 2012).

B) EDEN Project

Using the endangered Seychelles endemic *Impatiens gordonii* as a parent, a new ornamental hybrid called Impatiens 'Ray of Hope' has been bred by the Eden Project. This plant was sold in the UK in order to raise funds and awareness for conservation of rare and endangered Seychelles plants. Prior informed consent to develop and sell the 'Ray of Hope' was sought and obtained in less than six months through the botanical garden in Mahé from the Ministry of Environment, Seychelles Government. It was felt that the Seychelles Government's decision to give consent was made easier because of the well-established relationship of Eden Project with the botanical garden on Mahé and their involvement in two major collaborative projects in the Seychelles: a Darwin Initiative project looking at the propagation and establishment of 90% of the endemic plants, and a research project in conjunction with the University of Reading investigating the species recovery of *Impatiens gordonii.* Fifty percent of the profits from Eden Project plant retail sales go directly back to the Seychelles to assist in the conservation of their rare and endangered plants.[201]

C) Wollemi Pine Project

Several botanic gardens, including the Royal Botanic Gardens, Kew, have partnered with the Australian government and Wollemi Pine International Pty Ltd to commercialise the Wollemi Pine. The Pine was discovered in 1994 near Sydney, Australia and is one of the world's oldest and rarest plants.[202] There are currently thought to be fewer than 100 adult trees existing in the wild; research is now focused on ensuring the conservation of the Wollemi Pine. The Pine is being grown and sold to the public as a way to generate funds for conservation of wild plants in Australia.

[201] http://www.bgci.org/resources/case_studies/

[202] http://www.bgci.org/resources/ipen/

6. Current problems/issues as regards ABS (with possible definition/information to be added for specific issues if some issues (very) important for the sector's operations)

Lack of clarity existing access procedures
Current PIC procedures in third countries are overly complicated and require the involvement of specialised staff and financial resources to deal with the complex procedures. The issues highlighted included the difficulty in finding the right competent authority, the duration of the procedure, the complexity of the legal framework and language barriers. The complexity of such procedures results in legal uncertainties as to which taxa may be collected, the specific regulations related to protected areas, export requirements, etc (ABGWG, EC Consultation, 2011).

A specific problem with local PIC and MAT requirements is the obligation in certain countries to present a list of taxa intended to be collected before being granted the permit to engage in bioprospecting as their existence cannot be foreseen prior to their discovery, nor can they be named, since naming only happens years after they have been collected. This makes the collection of new species unknown to science virtually impossible, thus hindering the progress of scientific knowledge (IPEN Task Force, EC Consultation, 2011)

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

Key needs and preferred implementation measures

Risks of future ABS legislation for botanic gardens
Most botanic gardens are in favour of the implementation of the Nagoya Protocol and keen to co-operate and be bound by external rules to ensure their sector is compliant. They are however worried by their lack of resources to comply with complex paperwork or contractual requirements. The general fear is that if future access to plants of importance in research and conservation is connected with too much bureaucracy, these facilities would face a significant reduction in competitiveness (e.g., in attracting researchers and seeking funds) and effectiveness (reallocation of staff from research and work in the field to administration). Strict legislation and burdensome bureaucratic requirements could particularly threaten the work of small botanic gardens that do not have the resources and capacity to comply with heavy bureaucratic provisions or complex contractual requirements, and thus would likely incur in the risk of being found non-compliant with future legislation (Van den Wollenberg *et al*, pers. comm., 2012; EBGC and ABGWG, EC consultation, 2011).

A proper implementation of the IPEN Code of Conduct has been similarly undermined by limited staff capacity and limited availability of training of staff. Some gardens have also too much work to do in order to collect the required data in their plant collections and creating a new documentation system (Van den Wollenberg *et al*, pers. comm., 2012).

Harmonisation
A harmonised approach at EU-level is welcomed and expected to also likely reduce the administrative burden on public authorities, especially if elements of best practise and simplified models for material exchange between scientific institutions for scientific purposes are included

(ABGWG, EC Consultation, 2011). Different ABS rules in different EU MS would on the other hand increase confusion and complexity (EBGC, EC Consultation, 2011).

Implementation preferences
A new institution at EU level with the task of developing simplified procedures of exchange for non-commercial purposes between scientific institutions such as Botanic Gardens and standardised tools (e.g. standard MTAs) for encouraging compliance with legal regulations is likely to be highly beneficial especially for smaller institutions with limited capacity to address legal compliance issues on their own (ABGWG, EC Consultation, 2011). On this point, stakeholders also highlighted the need to receive clear guidelines from the EU or Member State authorities in order to know exactly what they have to do in any given situation (Van den Wollenberg *et al*, pers. comm., 2012).

The preferred implementation option for Botanic Gardens would be the recognition of the IPEN code of conduct as a best practice example for fulfilling ABS regulations, which could form part of a legal base for simplified procedures for access to genetic resources by botanic gardens (ABGWG and EBGC, EC Consultation, 2011).

With regard to potential inspections to ensure compliance with future ABS legislation, stakeholders maintained that at EU level the only entities that currently would have the necessary capacity (i.e. knowledge of practices with regard transactions and documentation of PGR) to carry out inspections on compliance with future legal obligations would be the national botanic gardens' networks (Van den Wollenberg *et al*, pers. comm., 2012; EBGC, EC consultation, 2011).

Need to facilitate access in provider countries
Finally, the stakeholders highlighted the need for reforms in provider countries. These should be aimed both at facilitating access and creating legal certainty. The EU should play its part by clarifying what kind of documents and permits from third countries will be accepted as PIC/MAT within the EU (Van den Wollenberg *et al*, pers. comm., 2012).

Will capacity building be needed for the sector or some parts of it (SMEs for instance?)
According to stakeholders many botanic gardens do not have the capacity to comply with future ABS legislation as they have very limited staff with the necessary legal skills to implement ABS measures, to obtain PIC, to discuss agreements, to link genetic resources and their progeny to eventual certificates of compliance (ABGWG, EC Consultation, 2011; Van den Wollenberg *et al*, pers. comm., 2012). EU-wide programs (including financial and technical support) for the training of staff in ABS issues, the development of databases modules for the long term storage of data, the availability of model documents related to ABS-contracts, and an improvement of labelling systems in Botanic Gardens for the whole EU would likely to minimise the overall burden on individual institutions (ABGWG, EC Consultation, 2011).

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Dr. Bert Van den Wollenberg, IPEN Task Force representative, Dr. Steven Dessein, Director of National Botanic Garden of Belgium and Dr. Jan Rammeloo, Former Director of the National Botanic Garden of Belgium, Meise, 2 February 2012.

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PUBLIC CONSULTATION MATERIAL

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Replies from:

- EBGC, European Botanic Gardens Consortium
- ABGWG, Austrian Botanic Gardens Working Group
- IPEN Task Force

PLANT BREEDING OR SEED SECTOR – SECTORAL SHEET

1. The sector and ABS

The plant breeding or seed sector is important for ABS because it relies fully on plant genetic resources. The main source for genetic material for conventional breeders is in modern varieties, though old varieties, landraces[203] and crop wild relatives may be used to introduce specific features into breeding populations (Schloen *et al*, 2011). Moreover, the breeding sector is doing research and development with regard to the use in crossing and breeding of genetic resources (including crop wild relatives), activities which fall under the definition of utilization of genetic resources.

2. Size and characteristics of the sector

Definition/description of the sector

The plant breeding or seed sector engages in developing seeds which are an essential input in crop production. By 'seed' we refer to all planting material used in crop production, including seed grains, cuttings, seedlings, and other plant propagation materials. Farmers either use farmer-saved seed, commercial seed from the public sector or commercial seed from the private sector. Proprietary seed from the private sector dominates markets globally these days. Private companies have been able to capture more value from the new seeds they develop, thanks to technological innovation (genetic engineering) and changes in intellectual property rules. The seed sector is a research-intensive sector: R&D spending (as a percentage of total sales) has increased considerably in the late 1990s (Heisey and Fuglie, 2011).

[203] A landrace is a local variety of a domesticated plant species which has developed largely by natural processes, through adaptation to the natural and cultural environment in which it lives.

Table 1: Companies with over $100 million in crop seed and biotechnology sales in 2009, plus BASF

Company	Country of incorporation	Crop seed and biotech sales	Agricultural chemical sales	Nonagricultural chemical sales and R&D	Pharmaceutical sales and R&D	Agricultural biotechnology research
		Million U.S. dollars				
Monsanto	U.S.	7,297	3,527	Divested 1997	Divested 2000	>80% of crop R&D
DuPont/Pioneer	U.S.	4,806	2,320	Primary product	Divested 2001	>50% of crop R&D
Syngenta	Switzerland	2,564	8,491	Divested 1996	Divested 2000	>15% of crop R&D
Limagrain	France	1,370	0	--	--	>25% of crop R&D
KWS AG	Germany	996	0	--	--	Yes
Bayer	Germany	699	7,535	No	Human and animal health	>85% of crop R&D
Dow	U.S.	633	3,708	Primary product	Divested 1996	>85% of crop R&D
Sakata	Japan	485	0	--	--	Yes
Forage Genetics Int'l (Land O'Lakes)	U.S.	*412*	0	--	--	No
DLF-Trifolium	Denmark	*391*	0	--	--	Yes
Takii	Japan	*347*	0	--	--	Yes
Rijk Zwaan	Netherlands	265	0	--	--	Yes
In Vivo	France	217	0	--	--	Yes
BarenBrug Holland BV	Netherlands	208	0	--	--	Yes
Saaten-Union	Germany	*187*	0	--	--	Yes
RAGT Semences SA	France	*181*	0	--	--	Yes
Florimond Desprez	France	*162*	0	--	--	Yes
Euralis Group	France	154	0	--	--	Yes
Maisadour Semences	France	119	0	--	--	Yes
Stine Seeds	U.S.	*unknown*	0	--	--	Yes
BASF	Germany	*small*	5,065	Primary product	Divested 2000	100% of crop R&D

* Seed sales figures for Land O'Lakes refer to alfalfa/forage seed developed by Forage Genetics International. Land O'Lakes also distributes seed for other companies, such as Monsanto and Syngenta, but these sales are not included in the Land O'Lakes estimate.

Seed sales figures in italics are ERS estimates not derived directly from company data.

Sources: USDA, Economic Research Service using compiled company reports and press releases, Le Buanec (2007), Allison (2007), and PhillipsMcDougall.

***Source*:** Heisey and Fuglie, 2011

Global market/size and development prospects

In 2009-2010 the value of the global commercial seed market was estimated at US $42 billion (ISF, 2011). The seed and green biotech industry has been characterised by an increasing convergence and consolidation of its companies over the past 10-15 years (sCBD, 2008). In 2006 only ten companies accounted for 55% of the seed market. As table 1 below shows, in 2009 there were 20 global companies that exceeded $100 million in total seed sales (conventional and biotech) and were investing resources in breeding and biotech R&D activities (Heisey and Fuglie, 2011). From these companies, 13 were European based, 5 were US based and 2 were Japanese based in 2009.

The first substantial commercial sales of proprietary genetically modified (GM) seed occurred in 1995. Since then the commercial sales of GM seed have increased rapidly. The market sales have exceeded 40% of the total value of proprietary seed since 2006 (Heisey and Fuglie, 2011). Outside the EU, the cultivation of genetically modified (GM) crops is expanding rapidly. In 1996 biotech crops were grown on 1.7 million ha, whereas in 2010 148 million ha were covered. The number of countries growing GM crops has increased consistently from 6 in 1996 to 29 in 2010, mainly USA (66.8 million ha), Brazil (25.4), Argentina (22.9), India (9.4), Canada (8.8), China (3.5), Paraguay (2.6), Pakistan (2.4), South Africa (2.2) and Uruguay (1.1) (Clive, 2011). Developing countries grew 48% of global biotech crops in 2010.

Table 2: Size of the global seed market in 1995 and 2001-2006

Year	Proprietary conventional seed	Proprietary genetically modified seed	Total proprietary seed	Public commercial seed	Farmer-saved seed	Total value of all seed	ISF value of total seed
			Million constant 2006 U.S. dollars				
1995	13,447	95	13,542	5,550	6,333	25,425	
2001	11,847	3,645	15,492	3,539	5,923	24,954	34,173
2002	11,210	4,148	15,358	3,483	6,390	25,231	33,631
2003	11,084	4,938	16,022	3,409	6,694	26,125	32,922
2004	11,525	5,869	17,394	3,315	6,616	27,325	32,013
2005	12,082	6,815	18,897	3,408	6,402	28,707	30,979
2006	11,800	7,800	19,600	3,300	6,100	29,000	34,000

Sources: USDA, Economic Research Service using Context Network (2007) for all columns except ISF value of total seed, which is from International Seed Federation (ISF). Values adjusted for inflation by the U.S. Gross Domestic Product implicit price deflator *(Economic Report of the President,* 2009).

Source: Heisey and Fuglie (2011)

Future market expansion will be determined *inter alia* by the potential for greater use of improved seed in general and GM crops in particular in developing countries; by changes in consumer attitudes towards genetic engineering, especially in developed countries; by the potential for expansion of biotechnology applications to additional crops; and by the development of newer biotechnology applications, for instance, tolerance to drought stress (Heisey and Fuglie, 2011).

EU market (size of the market and importance for the EU economy)

The European Seed Association (ESA) estimates that in 2009-2010 the EU commercial seed market has reached a value of **€6.8 billion** and that it represents **more than 20% of the total worldwide market for commercial seed**. The EU seed markets for cereals and pulses are estimated at €2.5 billion, maize at €1.6 billion, potatoes at €900 million, vegetables at about €1 billion, while oil and fibre plants, sugar beet and grasses are estimated at €200 to 300 million each. The EU counts about 7,200 seed companies with about 52,000 people employed within the sector.

The annual R&D spending of seed companies ranges between 10% and 14% of their turnover. There are about 700 R&D stations with about 12,000 R&D employees. The farm gate value of agricultural products in the EU amounts to more than €70 billion and the value of processed agricultural products in the EU amounts to more than €700 billion.[204] Potato seed occupies around 90,000 ha in Europe; four main countries are the largest producers: The Netherlands (34,000ha), Germany and the United Kingdom (around 16,000 ha each) and France (14,000ha).

Economic relevance of utilization of genetic resources and naturally occurring biochemicals in the sector in Europe

The seed or plant breeding industry is characterised by important investments for R&D. It is estimated that 10-14% of turnover is spent on R&D (ESA, 2012). Given that the size of the EU market was $6.8 billion in 2009, R&D spending in the European seed industry was probably between $680 million and $950 million. The figures in Table 1 show that R&D

[204] ESA: European seed association - www.euroseeds.org

investments in the European seed and biotechnology sector are not only focusing on biotech but also on conventional breeding. EU regulation on GMOs (release of GMO to the environment especially) has an impact on R&D resulting in companies preferring to invest biotech in GMO friendly countries (pers. comm., 2012). In January 2012 for instance BASF announced that it would suspend the development of GM crops in Europe and move its plant science department to the USA (EurActiv, 2012). There is a lot of conventional R&D activity in Europe, both in the private and public sector (universities and research institutes) (pers. comm., 2012): from the 20 global companies, 13 are based in Europe and invest mainly in conventional breeding.

Any EU companies that are market leaders?

From the 20 global companies that exceeded $100 million in total seed sales in 2009, 13 were based in Europe. Limagrain, KWS AG and Bayer ranked respectively fourth, fifth and sixth in 2009 (see table 1).

SMEs

The seed industry includes a significant number of SMEs, although the general trend is towards convergence and consolidation. There are many breeding companies in Europe with five or fewer employees (Plantum, pers. comm., 2012). The green biotech sector, however, mainly comprises big multinational companies (Croplife, pers. comm., 2012). There is however a small number of small and medium-sized green biotechnology companies, that generally do not sell seed but rather seek to commercialise a new genetic trait or biotechnology service or tool to other companies (Heisey and Fuglie, 2011).

According to Tait and Barker (2011), the regulatory requirements in Europe for GMO release in the environment are so high (in addition to safeguard clauses in Member States) that mainly large multinational companies afford it to apply for approval of GM crops. In the EU only eight countries grew GM crops, covering an overall comparatively small surface of 114,507 hectares in 2011 (EuropaBio, pers. comm., 2012).

3. Types and role of genetic resources use in the sector/characteristics of the user chain

Conventional and biotech seed companies rely on different types of plant genetic resources for use in breeding and variety development. The development of new varieties is usually based on the use of advanced genetic material, as it takes time and effort to bring less-advanced genetic material to the same performance levels (Schloen *et al*, 2011). The main source for genetic material for conventional breeders is modern varieties, though old varieties, landraces and crop wild relatives may be used to introduce specific features into breeding populations which allow for the development of varieties adapted to less favourable environmental conditions and low-input production systems (Schloen *et al*, 2011).

Sector-specific collections or databases of genetic resources

Many plant genetic resources are maintained in *ex situ* facilities. In fact, much of the diversity originally found *in situ* has been collected and maintained *ex situ*. These collections are primarily held by public genebanks at national level and by international research

centres. Plant genetic resources are also held in private collections, i.e. in breeding collections of private companies. For more details see paragraph below on *ex situ* collections and the paragraph below on the relevance of basic and applied research for the sector.

Relevance of basic and applied research 'utilizing GR' for innovation in the sector
The relevance of public R&D on unimproved material (landraces, crop wild relatives, etc) is rather high. Characterization, evaluation and pre-breeding largely take place in the public sector, with the product freely available to all breeders on a non-exclusive basis. The private sector is rather reluctant to work with unimproved material (Smolders, 2005).

Based on the interdependence of countries with regard to the major agricultural cops and their genetic resources, International Agricultural Research Centres (IARCs) were established in the 1940-70s in order to provide improved plant material adapted to agricultural conditions in developing countries and conserve plant genetic resources. The Consultative Group on International Agricultural Research (CGIAR) was created in 1970 in order to extend the work (started on wheat) to other species and to create international genebanks for the conservation of agricultural genetic diversity as part of public goods.

Today, the exchange of genetic resources is done within the context of the IT-PGRFA with the standard Material Transfer Agreement (sMTA) for national plant genetic resources or genetic resources which are included in the collection of the 15 IARCs and several other centres acting at global level; the CGIAR is financed by the EU (€5 billion/year), some EU Member States, Canada, USA, Japan, Australia but also Kenya, Nigeria, China, India, Iran, Brazil, international organisations such as the World Bank, IFAD and FAO and private foundations.

Table 2: Top seed companies and their business areas (2006)

Company	**Nature of business**
Monsanto (US)	Maize, soybean, cotton. Traits, Vegetables through acquisition of Seminis
Dupont/Pioneer (US)	Maize, soybean, traits
Syngenta (Switzerland)	Maize, soybean, sugarbeet, vegetables, flowers, traits
Groupe Limagrain	Maize, cereal, forage, vegetables
KWS AG (Germany)	Corn, sugarbeet, cereals, oilseeds
Bayer Crop Science	Vegetables, traits
Sakata (Japan)	Vegetables, flowers
Land O'Lakes (US)	Alfalfa, maize, soybean, forage and turf grasses
DLF-Trifolium (Denmark)	Forage (clover) and grass; grains and flax

Source: Smolders (2005); ETC Group (2007); sCBD (2008)

The work on genetic diversity is commonly done by the public research community (basic or applied research) in association with the private breeding industries.

The ***European Cooperative Programme for Plant Genetic Resources*** **(ECPGR)** (formerly "European Cooperative Programme for Crop Genetic Resources Networks - ECP/GR) was founded in 1980 on the basis of the recommendations of the UNDP, the FAO and the Genebank Committee of the European Association for Research on Plant Breeding. It is a

collaborative project among European countries, aimed at contributing to national, sub-regional and regional programmes in Europe to rationally and effectively conserve *ex situ* and *in situ* PGRFA and increase their utilization. The Programme is financed by the member countries and coordinated by a secretariat hosted by Biodiversity International. It operates through focused networks dealing with groups of crops or general themes related to plant genetic resources.

At global level, they are public-private initiatives which coordinate the international efforts to sequence the genomes of the major agricultural crops such as the wheat (IWGSC, www.wheatgenome.org), rice (IRGSP, http://rgp.dna.affrc.go.jp/IRGSP), barley (IBSC, http://barleygenome.org), or maize genomes, committed to provide researchers, breeders and industries state-of-the-art tools and technologies for crop improvement and understanding of agricultural traits.

As recognised by the IT-PGRFA, plant genetic resources for food and agriculture are a common concern of all countries, in that all countries depend largely on PGRFA that originated elsewhere.

Relevance of utilising GR for product development and for products placed on the market
Plant genetic resources are the raw material indispensable for crop genetic improvement, whether by means of farmers' selection, classical plant breeding or modern biotechnologies, and are essential in adapting to unpredictable environmental changes and future human needs.

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
The innovations in the plant breeding sector can be protected by different means:

- **Plant variety rights**: European legislation authorises only the protection of a new plant variety by means of the community plant variety right system (CPVR – Regulation (EC) No 2100/94) or national systems, in accordance with UPOV (*Union pour la Protection des Obtentions Végétales*); the CPVR system protects mainly ornamental species (60%), agricultural crops (25%), vegetable crops (12%) and fruit species. Currently, less than 14% of registered varieties on the EU Common Catalogues (agricultural and vegetable crops) are protected within the CPVR. More than 18,000 protection titles are in force at EU level. The CPVR and UPOV systems are open systems because the variety, even protected for the commercial use, remains free for research and breeding (compulsory breeder exemption) and for private use; the CPVR includes the farmer's privilege.

- **Patent:** in the EU plant varieties cannot be protected by patents. Patents, however, can be used in order to protect biotechnological inventions (Directive 98/44/EC on the legal protection of biotechnological inventions) if the invention is not limited to a single plant variety. The European Patent Office (EPO) has developed a centralised procedure for the examination procedure, but the protection remains at national level. The biotech protection represents 5% of the work of EPO. The number of plant patent applications represents 600-700 applications per year (S. Yeats EPO, 2011) for a total of 12,000 applications per year. The patent applications are from EPC states:

42% (DE 29%, UK 17%, BE 12%, FR 11%), US 39%, Japan 9%. 1400 protection titles are granted for plant related patents, with 83 on non-GM plants. Biological material (plant gene sequence) which is isolated from its natural environment or technically produced, even if it previously occurred in nature is patentable; conventional breeding processes are not patentable. The patent system does not include a wide EU breeders' exemption (except DE, FR and CH), but does include a farmer's privilege.

- **Trade secret**: some crop varieties can also be protected by keeping their genetic information secret. A classic example of a plant-based trade secret is the genetic information contained in the seeds of the parental inbred lines that are used to produce proprietary hybrid varieties (Kratiger, 2007).

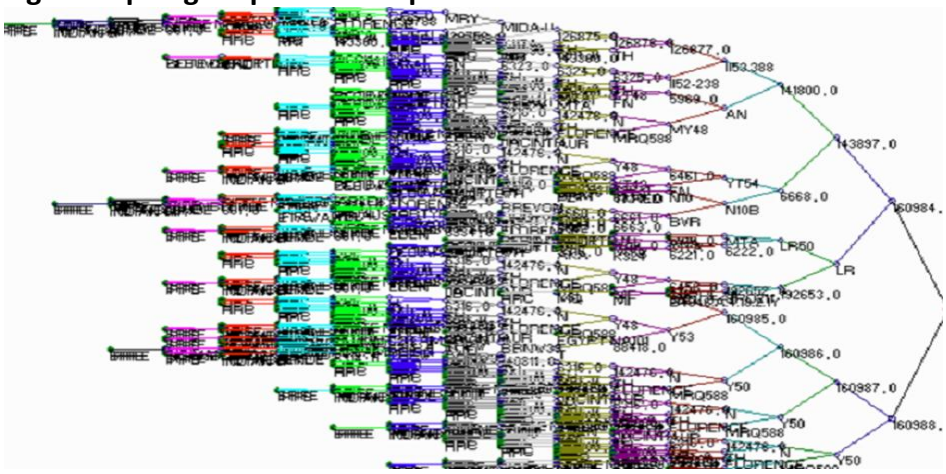
Relevance of traditional knowledge associated with genetic resources

In the seed and plant biotechnology sector, companies prefer to avoid collecting traditional/farmers' knowledge as far as possible because of legal and ethical implications involved. Most prefer to pass the responsibility of resolving these difficult benefit-sharing issues onto the gene banks, governments or intermediary institutions with whom they work (sCBD, 2008; Laird and Wynberg, 2012). The IT-PGRFA recognises the contributions of farmers in all regions of the world, particularly those in centres of origin and diversity, in conserving, improving and making available the PGRFA.

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

Plant genetic resources are maintained *in situ* and *ex situ*. The source of breeding material is usually known. Genetic material is often acquired from *ex situ* collections within or outside Europe. However, after millennia of seed exchange for breeding purposes, it is largely impossible to determine a "country of origin" that could claim sovereign rights. Often multiple plant genetic resources are used in species improvement (Schloen *et al*, 2011): the development of one wheat variety may involve "thousands of plant breeding crosses and dozens of different individual lines, including wild ones, from many countries and over many centuries" (Beattie *et al*, 2005). In other words, plant breeding is a global activity in which many breeders from many different countries are involved (see also Figure 1 below).

Figure 1: pedigree picture of a particular wheat line



Source: CIMMYT

Relevance of bioprospecting

In the plant breeding or seed sector bioprospecting is very limited. The relevance of (new) bioprospecting is limited to some species where the plant genetic diversity conserved *ex situ* is not sufficiently representative. Though a small demand continues to exist for old varieties, landraces and crop wild relatives to introduce specific features such as insect and disease resistance into breeding populations (Schloen *et al*, 2011), the demand for wild genetic resources has been replaced in recent years by *ex situ* and private collections (Laird and Wynberg, 2012). In the plant biotechnology sector, direct *in situ* bioprospecting activities are virtually non-existent (Europabio, pers. comm., 2012).

Relevance of EU and non-EU ex situ collections, gene banks, databases

Many plant genetic resources are maintained in *ex situ* facilities. In fact, much of the diversity originally found *in situ* has been collected and maintained *ex situ* since the 18th century. These collections are primarily held by public genebanks at national level – such as the Centre for Genetic Resources in the Netherlands (CGN) or the Leibniz Institute of Plant Genetics and Crop Plant Research in Germany (IPK) – and by international research centres – such as the centres of the Consultative Group on International Agricultural Research (CGIAR). These *ex situ* collections play a major role in the pre-breeding activities. About 7 million accessions of plant genetic resources are stored in *ex situ* facilities (Schloen *et al*, 2011).

Plant genetic resources are also held in private collections, i.e. in breeding collections of private companies. This stored genetic material, however, is not publicly available and few information is available on the size of these collections (Schloen *et al*, 2011). Conventional breeders usually source their material, i.e. modern varieties, from private collections and from other breeding companies (i.e. from their varieties available on the market: breeder's exemption). Genebanks are also sources, but these are mainly used by universities, small companies and national agricultural research systems in developing countries (Fowler *et al*, 2001; sCBD, 2008). Modern varieties are far more important for breeders as they contain more relevant genetic material than landraces, wild relatives or material from genebanks (sCBD, 2008). Nevertheless, companies allocate budgets to the *in situ* collection of wild genetic resources, though these budgets vary considerably depending on the crop.

Most green biotech companies source their material from their own collections, followed by national genebanks, 'in trust' collections maintained by CGIAR centres, and university collections (ten Kate & Laird, 1999). They only rarely source from botanic gardens. The majority of those materials, in fact, are only sourced after additional evaluation or improvement is done by the centre holding the *ex situ* collection (e.g. CIMMYT, ICRISTAT and IRRI). Green biotech companies also access material from the Multilateral System of the IT-PGRFA through its sMTA. However, very low percentages of material are accessed under the sMTA: ranging from less than 5% to less than 1% for wheat and maize and 1% for rice for certain companies. Some green biotech companies also hold private collections of genetic resources (germplasm), representing a substantial part of these companies' net worth. Many green biotech companies leverage investment in smaller companies and track exploratory work done in universities and small companies. Green biotech companies might enter into an in-licensing agreement with universities or small companies, for instance when the latter have developed interesting germplasm from wild relatives or other unimproved material (Europabio, pers. comm., 2012).

Relevance of acquisition of GR directly in countries providing such material

The acquisition of genetic resources directly in provider countries is limited and occurs mainly in cases where there are no international or national research centres dealing with the crop concerned. Genetic resources are mainly collected directly in provider countries in relation to non-food crops, such as ornamental species (see sectoral sheet on the horticulture sector).

5. Existing approaches as regards ABS in the sector

General approach to ABS (voluntary initiatives and best practices)

The breeders' exemption under the CPVR and UPOV plant variety protection systems means that varieties protected by plant breeders' rights may be used by anyone for the breeding of new varieties. Therefore no agreement, PIC or MAT are required. This implies that many exchanges of plant genetic resources between (conventional) breeders traditionally take place informally, i.e. without any formal agreements or documents.

However, the trend in the seeds industry is towards more formalized exchange practices, primarily through material transfer agreements (MTAs). E.g. transfers of germplasm samples from genebanks are increasingly regulated by MTAs (Schloen *et al*, 2011).

IT-PGRFA: Contracting Parties to the IT-PGRFA (www.planttreaty.org) have agreed to use the standard Material Transfer Agreement (sMTA), a standard contract which has been agreed multilaterally and is non-negotiable, for each transfer of material belonging to the Multilateral System of Access and Benefit Sharing under the IT-PGRFA. This system includes all plant genetic resources for food and agriculture (PGRFA) listed in Annex I of the International Treaty, i.e. 64 crops and forages (Schloen *et al*, 2011). The multilateral system aims among others to facilitate rapid, regular and low-cost exchanges of plant genetic resources for use in training, research and breeding for food and agriculture (Halewood, 2010). The underlying rationale is that all countries are interdependent with regard to PGRFA and that the contracting parties will all gain more by having access to all of the

resources in the multilateral system than they would have by restricting access to their own.

The sMTA is a private contract between the providers and the recipients. In principle the sMTA does not leave room for any additional negotiations, except for 'PGRFA under Development', i.e. materials derived from materials accessed from the multilateral system that are still under development. Recipients must pay 1.1% of gross sales to the multilateral system, if they prohibit others from using the product for research or breeding. This implies the threshold for mandatory benefit sharing is high. Monetary benefits do not go back to individual suppliers or countries of origin of the material, but to the multilateral system to be spent on helping farmers, especially in developing countries, who conserve and sustainably use PGRFA (Halewood, 2010). When the product developed from the genetic resource is freely accessible for further research and breeding, the recipient, on a voluntary basis, could also share some benefits. With the sMTA, 1.5 million samples are included in the Multilateral System (trend: growing), with ~440,000 transfers of genetic material per year, 600-800 documented transfers every day (IT-PGRFA, 2012).

In addition, the sMTA is also used by some national and international genebanks for the transfer of plant genetic resources not listed in Annex I (Schloen *et al*, 2011). The CGN and IPK, for example, which maintain collections of crops in EU, use the SMTA for both annex 1 and non-annex 1 crops.

The IT-PGRFA clearly indicates that access shall be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses. In the case of multiple-use crops (food and non-food), their importance for food security should be the determinant for their inclusion in the Multilateral System and availability for facilitated access.

The biotech industry: Due diligence is key for the green biotechnology companies as they want to be sure that the material they use has been sourced legally. In general companies will not work with material they have doubts about and will therefore only source material through MTAs or sMTAs. According to Europabio, because of remaining legal uncertainties in the use of IT-PGRFA sMTAs, only between 1 and 5% of the PGRFA are accessed through a sMTA. Most commonly bilateral agreements in the form of MTAs are used to source genetic material (pers. comm., 2012). As a result most companies know where the material comes from; at least they know the direct source. Usually they ask for contractual guarantees that the material has been sourced legally. Examples exist where activities were completely stopped because no warranties could be given (pers. comm., 2012).

In this respect, the "Guidelines for Bioprospecting for BIO members", issued by BIO, the world's largest biotechnology association, in June 2005, clearly stipulate that companies should not accept samples of collected genetic resources from a third party that is not able to provide evidence of compliance with PIC and conditions governing use that are applicable to the sample. The guidelines were meant to educate BIO members about the relevant issues that could arise in the conduct of bioprospecting activities and to provide assistance to those members seeking guidance. These Guidelines envisioned that BIO members would enter into a "Bioprospecting Agreement" before collecting physical samples of genetic

resources *in situ* or accessing such resources maintained *ex situ*. That agreement would include the grant of PIC as well as list the terms and conditions governing the collection and use of the genetic resources.[205]

Forerunners implementing ABS best practices
No forerunners have been identified.

Existing access and/or benefit sharing agreements: case examples
As far as genetic resources are sourced from the Multilateral System of the IT-PGRFA, sMTAs are being concluded whereby monetary benefits do not go back to individual suppliers or countries of origin of the material, but to the Multilateral System and more in particular to the Benefit-sharing Fund of the IT-PGRFA. The Fund invests directly in projects supporting farmers in developing countries to conserve crop diversity in their fields and assisting farmers and breeders globally to adapt crops to our changing needs and demands. For the period 2009-2011 eleven projects have been approved under the Benefit-sharing Fund. One project in Costa Rica aims to characterize wild species of potato resistant and tolerant to different biotic and abiotic stresses and obtain new potato varieties adapted to climate change for sustainable agriculture (www.planttreaty.org).

6. Current problems/issues as regards ABS (with possible definition/information to be added for specific issues if some issues (very) important for the sector's operations)

The seed industry and the green biotechnology industry, which access its material from all over the world, is concerned about (i) the lack of clarity and transparency with respect to national ABS rules and procedures for PIC, (ii) the lack of efficiency (bureaucracy) and diversity of these national regimes. The sector is also concerned about the fact that many countries introduce retroactive measures and linking the ABS with intellectual property protection procedures thereby significantly increasing legal uncertainty for companies. In other words the seed industry has experienced increasing difficulties in access to genetic resources. According to representatives of the seed industry the demand for landraces is declining because of these difficulties (EC's public consultation).

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

The seed sector is of the opinion that the implementation of the Protocol should be undertaken on the basis of the principle that plant genetic resources are global public goods and utilization of plant genetic resources by plant breeders are generally of benefit to society-at-large. For the plant breeding sector the Multilateral System approach of the IT-PGRFA (sMTAs) would be the best manner to organize ABS.

Some representatives indicate that an EU checkpoint could be established to work parallel to the Multilateral System of the IT-PGRFA for the report of every product they intend to

[205] http://www.bio.org/articles/bio-bioprospecting-guidelines

market that does not fall under the IT-PGRFA (or other variations on this model). Checkpoints in other words should not function as barriers to trade or interfere with IPRs but mostly as places where all reported information is collected (EC's public consultation, 2011).

The green biotechnology sector states that some elements of the IT-PGRFA can be useful, including the use of sMTAs, although the sMTA itself should be amended and/or clarified before using it as a template for all transfer of GR. The biotechnology sector favours the establishment of a checkpoint either within the national focal point or competent national authorities. This checkpoint should only verify the existence of PIC and MAT and should not evaluate MAT (EC's public consultation, 2011).

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INTERVIEWS

Garlich Von Essen, Secretary General, European Seeds Association (ESA) and Anke van den Hurk, Plantum NL, the Dutch Seed Association, 7 February 2012, Brussels

Valentina Siddi, Europabio and Dominic Muyldermans, Croplife International, 13 February 2012, Brussels

PUBLIC CONSULTATION MATERIAL

EC Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, October-December 2011.

Replies from:

- BDP, German Plant Breeders Association (DE)
- Europabio
- ESA, European Seed Association
- GNIS, Groupement national interprofessionel des semences et plants (FR)
- Limagrain (FR)
- Plantum (NL)
- RAGT Semences (FR)
- Rijk Zwaan (NL)

THE BIOCONTROL SECTOR – SECTORAL SHEET

1. The sector and ABS

The biocontrol sector is distinct from the other economic sectors as it does not engage only in commercial activities and is more generally aimed at protecting common goods like food safety and security, biodiversity conservation or farmer's health (FAO, 2009). The sector's ethos thus meets that of the Nagoya Protocol. Therefore the biocontrol sector, despite being a small sector, should be duly taken into consideration when implementing the Protocol.

The Protocol might be critical for the sector as it relies entirely on the utilization of genetic resources. As such, its future rests on the characteristics of the forthcoming access and user compliance measures. Furthermore, biocontrol companies do not make substantial financial profit and consequently monetary benefit sharing makes little sense to them. However, the way the sector operates resembles a benefit sharing process as information about the innovative products (the effective and safe biocontrol agents) is made publicly available and thus can be copied freely (FAO, 2009). Benefits arising out of biocontrol are thus shared, though not in a monetary form and not on a bilateral and exclusive basis with the source country.

The biocontrol sector represents a marginal economic activity. Nevertheless, when dealt within the context of the Nagoya Protocol, it becomes a highly valuable sector given its general objective and its (partly) non-commercial nature.

2. Size and characteristics of the sector

Definition/description of the sector

The biological pest control sector mainly develops techniques for crop protection (Beattie *et al*, 2005) whereby predatory or parasitic living organisms (bio-control agents) are being used to control pests instead of chemicals (OECD, glossary terms). One must distinguish between classical biological control and augmentative biological control.

Classical biocontrol refers to the introduction of a bio-control agent, usually coming from the pest's area of origin, to control the pest in the new area which it has invaded. Once introduced, the bio-control agent will become established, will reproduce and spread, and have a self-sustaining effect on the target pest. The implementation is normally carried out by national agencies. In developing countries the activity is often carried out with the financial support of international development agencies and the technical support of implementation agencies. They do not generate any monetary profit and tend to put their knowledge into the public domain. The activity is dedicated to the public good and benefits are foreseen for farmers, food safety, consumer health, etc (FAO, 2009).

Augmentative biocontrol involves the production and the release of biocontrol agents, indigenous or exotic, into specific crop situations, where they cause mortality of the target pest, but are not expected to persist from one cropping cycle to the next (FAO, 2009).Two main groups of producers can be involved: commercial and centralised producers. The

commercial producers are independent companies that produce and sell biocontrol agents. They used to operate in developed countries but now tend to have a global reach. The centralised production units are generally public entities which produce natural enemies for a particular niche (e.g. large-scale agriculture or forestry). They are either provided for free or sold to users (FAO, 2009).

Global market/size and development prospects

The global market for augmentative biocontrol was estimated at about US$100–135 million in 2008. With an average net profit margin of around 3-5%, the total commercial augmentative biocontrol industry profit is under US$15 million per year (FAO, 2009)

The growth of the biocontrol industry is constant and driven by many factors including developments of pest resistance to chemicals, stricter legislation on residue levels, development of organic agriculture and more generally environmental protection laws (IBMA, 2005; Guillon, 2004).

EU market (size of the market/sector and importance for the EU economy)

Europe is the largest market in the world for beneficial insects and the second largest for microbial biopesticides (FAO, 2009). However, the range of product proposed in the EU is narrower than that of the US due to stricter legislation in the EU (Jijakli, 2010).

The biggest markets within the EU are the Netherlands, the UK, France and Spain (FAO, 2009; IBMA, 2005; Guillon, 2004).

Augmentative biocontrol is a small activity undertaken by small and medium-sized enterprises and with modest profits (FAO,2009).

Economic relevance of utilization of genetic resources for the sector in Europe

The biological pest control is a research activity entirely based on the utilization of genetic resources. But the number of accessions per year is not very high. For example, the Dutch company Koppert acquires 10 to 30 genetic resources per year (Klapwijk, pers.comm., 2012).

Any EU companies that are market leaders? / Any EU organisations that are leaders in the sector?

Worldwide, some 30 larger commercial producers of augmentative biocontrol agents are active, of which 20 are located in Europe (FAO, 2009). The Dutch company Koppert is a world market leader in biological crop protection.

Relevance of SMEs

SMEs employing an average of 2-10 people represent the vast majority of the biocontrol companies (FAO, 2009).

3. Types and role of genetic resources use in the sector/ characteristics of the user chain

A very broad range of genetic resources are used by the biological pest control sector. Those may include plants, viruses, bacteria, fungi, insects, nematodes and invertebrates. They are almost always collected directly *in situ* as living organisms (FAO, 2009).

Sector-specific collections or databases of genetic resources

Laboratory bio-agent populations are stored to be re-used if necessary. Indeed, during the research process, population bottlenecks are created – through sampling or by moving environment from wildness to captivity and from captivity to wildness again. The genetic characteristics of the population at these different moments are thus different. For that reason, once a biocontrol agent which has been successfully introduced is about to be used again, the material from the laboratory where the research has been undertaken is to be used preferably rather than the material from the field (FAO, 2009).

Relevance of basic research 'utilizing genetic resources' for (innovation in) the sector

Biocontrol is a research-based activity. At the planning stage, biocontrol activity includes surveys about the pest and its natural enemies which are of primary value from a basic research point of view. The aim is to get information about the area of origin of the pest and about the best place to look for natural enemies for further studies. In doing so, these initial studies help gathering information on local biodiversity (FAO, 2009).

Relevance of applied research 'utilising genetic resources' (for innovation) in the sector

Detailed studies on natural enemies are undertaken to assess their potential use as biocontrol agents. At this stage natural enemies are being identified. The identification stage consists of the development of rearing methods for use in the laboratory, the studies on the range of hosts in the field or in the laboratory, the impact studies in the field or laboratory. This stage establishes which, if any, natural enemies are suitable for use as a biocontrol agent (FAO, 2009).

Relevance of genetic resources for product development and for products placed on the market

The last step consists of an evaluation by the target country authority of the risks and potential benefits of the introduction of the relevant pest. Permission for release may or may not be given. In case permission is granted, release strategies and protocols will be developed together with monitoring and evaluation procedures. This implementing stage can be done by a different agency than the one involved in the research stage (FAO,2009)

In the case of re-utilization of a successful biocontrol agent in a different country, which happens 40% of the time, the bio-agent is re-collected either in the country where the introduction has been a success or in the laboratory where the detailed studies have been undertaken to be established into a new area. This operation does not require the whole research process described above but only the following "product development" one, i.e. the release and implementation stage (FAO, 2009).

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
In the case of classical biocontrol, no protection of the innovation is undertaken as it is a non-profit activity. As regards augmentative biocontrol, companies keep secret the production know-how, i.e. the rearing methods used in the laboratory. However, the bio-agent itself is not protected and anyone can collect it in nature for use.

Relevance of traditional knowledge associated with genetic resources
Traditional knowledge can be relevant for the sector as indigenous and local communities hold a wide knowledge on how to control pests or diseases. However, this knowledge is not easily available to biocontrol scientists (Amiri Ardakani and Husein Emadi, 2008).

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting
Genetic materials used in the biocontrol sector are primarily naturally occurring living organisms. These are very often accessed *in situ*, notably all of the insects and mites which are not available *ex situ*. As regards the biocontrol sector, EU *in situ* collections are as important as non-EU *in situ* collections (FAO,2009).

Relevance of ex situ collections, gene banks, seed banks, databases
Less frequently, *ex situ* collection are used such as microbial collections (FAO, 2009).

Relevance of acquisition of GR directly in countries providing such material
Biocontrol researchers almost always go directly in the country providing the genetic material (FAO, 2009).

5. Existing approaches as regards ABS in the sector

General approach to ABS
There is an informal cooperative network of biocontrol practitioners around the world which operates at a personal level or through organisations such as the International Organisation for Biological Control (IOBC). This is a well-established community of practice based on free multilateral exchange of biocontrol agents (FAO, 2009).

Thus there is no codified ABS standard in the biocontrol sector apart from the microbial sub-sector where MTAs containing ABS-relevant clauses are adopted. However, in practice the sector has engaged in similar approaches (Klapwijk, pers.comm., 2012).

Indeed, partnerships have been developed with research institutes in potential source countries. It should be noted that monetary benefit sharing is not suited for the biocontrol activity as the profit margin is inexistent with regard to classical biocontrol, and very small with respect to augmentative biocontrol. Instead, preliminary surveys offers opportunities for sharing of benefits in terms of training in survey methods, capacity building and information generated to better understand local biodiversity. Moreover, as part of the detailed studies undertaken in the source country, benefits can arise from collaboration, joint research and capacity building. With the growing importance of detailed safety studies, such collaborative research is expected to increase (FAO, 2009).

Forerunners implementing ABS best practices
N/A

Existing access and/or benefit sharing agreements: case examples
There are very few examples where ABS agreements have been established. According to IBMA, the lack of clear rules often discourages providers to engage in access agreements, and collecting material *in situ* has become more difficult (EC public consultation, 2011).

Generally, restrictive national ABS legislations have proved to hinder biological control projects, just as the agromyzid pea leaf miner (*Liriomyzahuidobrensis*) case in Peru and Europe shows. The agromyzid pea leaf miner is a fly that became a major pest since it developed resistance to major insecticides during the 1970s in Latin America. The leaf miner has been accidentally introduced in Europe in 1989-1990 and spread until Israel two years after. In Europe, few parasitoids were able to attack L. Huidobrensis and a wide biocontrol project financed by the United State Agency for International Development was set up. A range of non-financial benefits was foreseen, including increasing the taxonomy and documentation of known and new species of natural enemies in Peru, and improving the use by local farmers and national companies of the parasitoids in augmentative biocontrol. Once 15 parasitoids had been selected to be sent abroad for identification, a new Peruvian legislation was released which forbade international transfer of any biological material. Unfortunately, no expert taxonomist in Peru was able to identify the collected material and specimens have thus been left unidentified. By the end of the project much of the benefit sharing planned under the project could not take place because of the strict national legislation on access to genetic resources (FAO, 2009).

6. Current problems/issues as regards ABS (with possible definition/information to be added for specific issues if some issues (very) important for the sector's operations)

Strict or complex regulation on access to genetic resources by a provider country may undermine viability of the biocontrol sector. The sector is indeed inherently international, but also based on limited profit. It depends on international exchange of genetic resources but cannot afford high transaction costs (FAO, 2009; Klapwijk, pers. comm., 2012).

Moreover, as biocontrol research activities involve transfer of living organisms, the time lag between the transportation of the biological material and the associated procedure can be an issue if it cannot be ensured that organisms are kept alive (EC public consultation, 2011; Klapwijk, pers. comm., 2012).

The biocontrol sector does not modify the biological material. Therefore no intellectual property rights can protect the use of those microorganisms once identified. However, lots of research is needed to prove the safety and the effectiveness of an agent. That is why profit margins are small and the sector has little to share in terms of monetary benefits (Klapwijk, pers. comm., 2012).

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

Key needs and preferred implementation measures

The biocontrol sector representatives base their demand on two concerns:

- The need for transparent and clear legislation;
- The recognition of the positive impact of biocontrol on the conservation of biodiversity.

IBMA, representing the biggest biocontrol companies, is concerned by the transparency and the clarity of the upcoming regulation on ABS. It is afraid that any regulation will increase the cost and time of the process of accessing the potential biocontrol agents. Because the biocontrol sector consists of small companies making limited profit, the implementation of the Nagoya protocol could potentially jeopardise the development of the sector. Its future thus depends on its ability to have affordable access to genetic resources. Likewise, procedures would need to be swift as the sector deals with living organisms that may need to be collected and transported rapidly. Finally, lack of clear rules from a provider country can simply deter the access to genetic resource in this country. In this respect, the IBMA recalls that with regard to the biocontrol sector, European countries are potential providers as well as users (EC public consultation, 2011). Half of the insects/mites currently collected come from EU Member States and the other half from third countries (Klapwijk, pers. comm., 2102).

The sector favours harmonisation of ABS legislation within the EU through the adoption of a Regulation in order to limit individual and thus potentially divergent initiatives from Member States. By the same token, it pleads for the negotiation of bilateral agreements between the EU and third countries/regions to broaden the scope of any harmonised legislation. In this vein, they support the ABS clearing house mechanism (EC public consultation, 2011).

With regard to checkpoints, sector representatives suggest that national authorities should be used for it, but considering the general lack of expertise of Member States on biocontrol agents, the concern is that the procedure should be kept clear, simple, predictable and transparent (EC public consultation, 2011).

Furthermore, the biocontrol sector emphasizes its positive impact on food safety, public health and conservation/sustainable use of biodiversity as it represents an alternative to conventional chemical pesticides. In this respect, as for classical biocontrol which is a research activity without any commercial purpose, the EU should create special conditions to promote it following Art 8(a) of the NP. However, concerning augmentative biocontrol research which is conducted for commercial purposes, the IBMA asks for the same special considerations under Art 8a given its objective of biodiversity conservation (EC public consultation, 2011).

The implementation of Art 8(b) and Art 8(c) should also be of relevance for the biocontrol sector. Indeed, the bio-control sector suggests that the EU should create specific access

procedures to genetic resources in case of public health emergencies, and develop a standard Material Transfer Agreement for the sector of genetic resources for food and agriculture (EC's public consultation, 2011).

Capacity building needed for the sector?

The potential burden entailed by the implementation of the Nagoya Protocol will have significant impacts on the biocontrol sector as it is mainly constituted of very small enterprises. Therefore capacity building for the sector might be needed.

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INTERVIEWS

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PUBLIC CONSULTATION MATERIAL

Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity:

- International Bio-control Manufacturers (IBMA), (2011)

HORTICULTURE INDUSTRY – SECTORAL SHEET

1. The sector and ABS

The horticulture industry is important for ABS because product innovation in the sector largely depends on the utilisation of genetic resources, mainly sourced from *ex situ* collections and sometimes from *in situ* collecting activities. The sector has not undertaken any sector-wide initiatives concerning ABS and awareness of ABS requirements remains low.

2. Size and characteristics of the sector

Definition/description of the sector

The horticulture sector includes a range of activities from amateur plant breeding for ornamental purposes (e.g. hobby gardening) to commercial vegetable production. The distinction between horticultural and agricultural production is difficult to make, but can be judged based on the scale of production. Ten Kate (1999) identifies a horticultural product as that which is concerned with quality at the level of the individual unit (the flower stem or tomato), whereas agricultural production is concerned with quality in bulk quantity (e.g. tomatoes processed industrially as paste or juice). Furthermore, most horticultural produce is hand-picked whereas most agricultural products are mechanically harvested. The level of processing can also be used as an indicator—ten Kate (1999) describes potatoes grown for processing as agricultural produce while those destined for the fresh market are horticultural. Nevertheless, she demonstrates the difficulties in these classifications by noting as an example that potatoes are classified as horticultural crops in Canada, regardless of their use.

Global market/size and development prospects

Market data in the horticulture sector are hard to obtain. In particular, reliable data are largely unavailable as the distinction between horticulture and agriculture can be hard to determine as previously described. Definitions of "horticulture" and the bases for statistical calculation vary by country, making comparisons difficult. Products may be sold between major seed companies and to distributors and retailers before sale to the consumer. Available data typically does not distinguish between final sales and the sale of seed for commercial production into cut flowers or potted plants (ten Kate, 1999). A variety of other issues makes it difficult to capture the size and shape of the horticultural market, either at a global or European level.

Some general comparisons can be made, however. Overall, the market size for vegetable seeds is much bigger than for ornamental products. Flower seeds value totalled $249 million in 2010 amongst the 32 countries worldwide reporting more than $1 million in imports (ISF, 2011a). By comparison, vegetable seeds value totalled more than $2.8 billion in 2010 amongst the 100 countries worldwide reporting more than $1 million in imports (ISF, 2011b).

EU market (size of the market/sector and importance for the EU economy)

The Netherlands was the world leader in vegetable crop seeds imports in 2010 ($298 million) and was second only to the US in flower seeds imports in the same year (US imports

were $55 million and the Netherlands were $44 million) (ISF 2010a and 2010b). The top ten importers of vegetable crop seeds also include Spain, Italy, the United Kingdom, and France. The top ten importers of flower seeds include Germany, as well as the United Kingdom, France and Italy.

These trends are mirrored in the vegetable crop and flower seed exports in the same year. The Netherlands led the world in vegetable crop seed exports in 2010 ($1 billion) and was second to the US in flower seed exports (US exports were $72 million and exports from/to the Netherlands were $57 million) (ISF 2010c and 2010d). The top ten exporters of vegetable crops seeds also include France, Italy, Germany and Denmark; the top ten exporters of flower seeds include Germany, France and the United Kingdom.

Economic relevance of utilization of genetic resources for the sector in Europe

Within the horticulture sector, companies utilizing genetic resources are those involved in seed supplying and breeding activities. They comprise a small number of large companies that represent most of the sales in this industry worldwide, a larger number of national companies and hundreds of SMEs. The first group of large multinationals is dealing the most with genetic resources by investing significant resources into the development of new products (ten Kate, 1999). Some breeding programmes use advanced technological approaches for plant breeding, which can costs several million dollars (e.g. for vegetables), while ornamental plants can be introduced with little selection or breeding in a relatively short period of time (ten Kate, 1999).

Any EU companies that are market leaders? / Any EU organisations that are leaders in the sector?

EU companies that are market leaders in the horticulture industry include, *inter alia*, Ball Holland B.V (flowers), Limagrain (vegetables and garden products), and East Mailing (fruit and ornamental breeding).

Relevance of SMEs

The horticulture sector includes a small number of large multinational companies that represent most of the sales in this industry worldwide and hundreds of SMEs (ten Kate, 1999).

3. Types and role of genetic resources use in the sector/ characteristics of the user chain

There are many companies involved in the horticulture industry growing, distributing and selling ornamental plant varieties; however, utilisation of genetic resources becomes relevant only in cases where companies are engaged in the development of new products (ten Kate, 1999). Usually, the innovation consists in the improvement of modern species even though some companies remain interested in genetic resources sourced *in situ* (Laird and Wynberg, 2008).

Relevance of basic and applied research or development 'utilizing genetic resources' for (innovation in) the sector

Research and development tend to be undertaken on a collaborative basis between the

industry and the public sector[206] (NHF, 2011). This is particularly the case in leading markets such as the Netherlands and the UK.

The production of a new horticultural product is knowledge intensive and requires different types of research involving utilisation of genetic resources. Typical fields of research include bioinformatics, phenotyping, applied genetics or physiology.[207]

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
Innovations in the plant breeding sector are primarily protected by plant variety rights: European legislation provides intellectual property protection for new plant varieties through the Community Plant Variety Rights (CPVR) system (Regulation (EC) No 2100/94). National plant variety rights systems also operate in 23 Member States in accordance with UPOV (*Union pour la Protection des Obtentions Végétales*). The CPVR system mainly protects ornamental species (60%), as well as agricultural crops (25%), vegetable crops (12%) and fruit species. Currently, less than 14% of registered varieties on the EU Common Catalogues (agricultural and vegetable crops) are protected by CPVR. More than 18,000 protection titles are in force at EU level.

Relevance of traditional knowledge associated with genetic resources
The IT-PGRFA recognised the contributions of farmers in all regions of the world, particularly those in centres of origin and diversity, in conserving, improving and making available the PGRFA.

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting
Originally, all of the plants used in the horticulture sector came from the wild, though as in the seed sector, the horticultural industry today relies mostly on improving a fairly small number of species (100-200 species in floriculture and approximately 500 species as house plants) developed over decades (Laird and Wynberg, 2008).

There are also several thousand species of herbs, shrubs and trees traded commercially as ornamentals—many of which were introduced from the wild with little selection or breeding (Heywood, 2003 cited in Laird and Wynberg, 2008).

Relevance of intra-and extra EU collections, gene banks, databases
The genetic resources on which the industry predominantly relies exist in *ex-situ* collections and represent the core of the industry. Most genetic resources, therefore, are currently sourced from in-house collections, commercial collections, national collections and botanic gardens (ten Kate, 1999).

Relevance of acquisition of GR directly in countries providing such material
There are companies that seek out new material from the wild in order to introduce novelty

[206] Plantum association, the Dutch association for the Plant reproduction material sector: http://www.plantum.nl/english/plantum-nl/main-issues/research
[207] *Ibid.*

to the market, such as colour and other variations (Laird and Wynberg, 2012). It is thought that this segment of the industry may collect new genetic resources without obtaining the appropriate approvals; it is relatively easy to disguise this behaviour since new germplasm can be readily incorporated into existing resources, which makes it hard to discover this activity (Laird and Wynberg, 2008).

5. Existing approaches as regards ABS in the sector

General approach to ABS/voluntary initiatives and best practices

The horticulture industry is considered to have low levels of awareness concerning ABS requirements. This may be due in part to low overall reliance on wild genetic resources in the industry (Laird and Wynberg 2012 and 2008).

Forerunners implementing ABS best practices

No forerunners have been identified.

Existing access and/or benefit sharing agreements: case examples

The first bioprospecting agreement in the horticulture and floriculture sector was formed in 1999 between Ball Horticulture (based in the US) and the National Botanical Institute (NBI, now the South African National biodiversity institute) (Laird and Wynberg, 2008). The five-year agreement covered research and licensing arrangements between the two organisations, whereby the NBI used its expertise to select South African plant species of horticultural interest for Ball. Three varieties had been introduced by 2005, though at the time, the royalties had not yet exceeded project costs. The negotiation process, however, helped to shape expectations and encourage discussions about benefit-sharing standards in South Africa (Laird and Wynberg, 2008).

6. Current problems/issues as regards ABS (with possible definition/information to be added for specific issues if some issues (very) important for the sector's operations)

The European Commission public consultation on implementation of the Nagoya Protocol in 2011 raised the following key needs for ABS rule development and implementation for the horticulture sector:

- ABS rules under current national frameworks are still largely absent, and where they do exist, lack transparency and clarity. Where rules do exist, they are often impractical, and public officials are reluctant to establish MAT.
- Rules also differ considerably between countries, so that bilateral negotiations for PIC and MAT are required in each case. The time and resources required to determine and implement the correct rules and procedures takes considerable time and resources, which places SMEs and individual researchers at a disadvantage relative to large companies.
- The industry has experienced difficulties accessing genetic resources since the CBD was implemented. Access has worked well only in those cases where a sMTA can be established through the IT-PGRFA, but the Treaty does not currently cover the ornamental sector.

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

Key needs and preferred implementation measures

The European Commission public consultation on implementation of the Nagoya Protocol in 2011 raised the following key needs for ABS rule development and implementation for the horticulture sector:

- Clear and transparent rules and procedures for implementing the Protocol, particularly regarding the certificate of compliance, checkpoints and other compliance procedures. It is important for the sector to be able to determine whether they have complied with all of the obligations with legal certainty.
- Clarity regarding use of genetic resources without a permit (e.g. where genetic resources have already been obtained and did not require a permit originally) – currently, most genetic resources used in commercial products have been legally obtained but do not have a 'permit' as described under Article 6(3)(e) of the Protocol. The sector considers important the question of how the checkpoint will deal with this issue in particular.
- Use of the sMTA under the ITPGRFA as an internationally recognised certificate of compliance and to provide clarity on the accumulation of obligations for use of genetic resources – the sMTA under the Treaty is a well-established tool that provides a good framework for facilitating access to PGRs under the Treaty and is widely accepted by the international plant breeding community.
- A single EU-wide checkpoint for the plant breeding sector in order to ensure that evidence of PIC and MAT is only required once and acceptable amongst all Member States.
- Harmonised, EU-level implementation of the Protocol is preferred with respect to the compliance elements in order to ensure standardised implementation provisions, which can facilitate the smooth functioning of the internal market.

A regulation is preferred to a directive in order to ensure clarity and legal certainty; a directive could result in a range of divergent interpretations and implementation mechanisms amongst the Member States.

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PUBLIC CONSULTATION MATERIAL

EC Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, October-December 2011.

Replies from:

- ASSOSEMENTI (Assoc. Italiana Sementi)
- Plantum
- Rijk Zwaan Zaadteelt en Zaadhandel B.V.

THE ACADEMIC RESEARCH SECTOR – SECTORAL SHEET

1. The sector and ABS

Academic research constitutes a fundamental input for all types of further utilization of genetic resources, be it commercial or non-commercial. As such, academic research is driving the ABS system. Moreover, the ABS mechanism as designed by the Nagoya Protocol refers to specific conditions for non-commercial research. Actually, academic research enjoys a particular status because of its contribution to the conservation and sustainable use of biodiversity.

2. Size and characteristics of the sector

Definition/description of the sector

The academic research sector encompasses the non-commercial research conducted by academics. Academic research is undertaken in various types of institutions and encompasses different kinds of research activities which may themselves have links with commercial research. Within the larger R&D sector, the boundaries of the academic research field are in fact blurry; academic and commercial research should be rather seen as forming a continuum.

Types of research activities

Three different activities need to be distinguished on the basis of their potential proximity to commercial applications:

- **Basic research** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.
- **Applied research** is original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective (like agriculture or medicine).
- [Experimental] **development** is systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed (Frascati Manual, OECD, 2002).

It is quite difficult to draw a clear line between these different types of research and to fit in academic research within this typology. While development activities are more obviously directed to marketization, applied and basic research can be carried out with a non-commercial goal, although their findings might be used at a later stage in a commercial activity. All types of research have a more or less remote link to commercial activity. In fact, any publicly available data can be used for commercial purposes and, for instance, bio-prospecting industries heavily rely on secondary sources for lead identification (WG-ABS, 2005).

Depending on the field of research, however, one can predict its potential commercial output. For instance, with regard to research involving the use of genetic resources,

taxonomy, ecology or evolutionary biology are generally purely basic research activities, the results of which have only very remote links to any commercial application. On the other hand, results or resources used for basic research undertaken in phytopharmacology or genetic engineering can more easily generate some commercial outputs, even if not carried out with a commercial intent. This fact, nevertheless, does not deny the academic character of some genetic engineering or phytopharmacological studies (Martinez, 2010b).

Types of research institutions

Within the large R&D sector, four types of institutions can be identified: business enterprise (BES), government (GOV), higher education (HES) and private non-profit (PNP). Roughly, the BES sector encompasses all organisations aiming at the production of marketable goods/services. The government sector refers to all the bodies furnishing (without normally selling) common services which cannot otherwise be economically provided. The private non-profit sector refers to non-market institutions serving the general public. Finally, the higher education sector includes universities and other institutions of secondary education, whatever their source of finance or legal status. It also includes research institutes, experimental stations and clinics operating under the direct control of or administered by or associated with higher education institutions (Frascati Manual, OECD, 2002).

Public institutions like the government or higher education are not non-commercial by nature. In fact, depending on the home country, these institutions' funding may originate from various sources: BES, GOV, HES, PNP and abroad (Frascati Manual, OECD, 2002). For example, the business sector's financing of higher education R&D amounts to 6.6% in EU, 4.5% in the US, and 2.6% in Japan (EC, 2005).

Moreover, public-private research networks and partnerships are common (EC, 2005). More rarely research institutes even work as brokers, having contacts with all the members of the innovation chain. Research institutions, moreover, may have both internal research programmes and partnerships with the private sector or other public research organisations (Brahy and Louafi, 2007).

Therefore, the institutional environment is neither unified nor homogenous enough to define academic research in terms of a particular type of institution dedicated to it. That said, universities and public organisations, which depend generally on public funding, are in charge of 75% of the basic research (which is typically academic) of all OECD's countries (OECD, 2011).

Table 1: R&D expenditure by sector and by source of funds (2006)

Source of funds	Sector of performance									
	Millions of euro					Percentage of total R&D expenditure				
	Total	Business enterprise sector	Government sector	Higher education sector	Private non-profit sector	Total	Business enterprise sector	Government sector	Higher education sector	Private non-profit sector
Total	215 553	137 431	28 414	47 478	2 230	100.0	63.8	13.2	22.0	1.0
Business enterprise sector	119 327	113 618	2 478	3 005	225	55.4	52.7	1.1	1.4	0.1
Government sector	72 245	9 765	23 445	38 314	721	33.5	4.5	10.9	17.8	0.3
Higher education sector	1 825	22	83	1 695	25	0.8	0.0	0.0	0.8	0.0
Private non-profit sector	3 524	128	508	1 861	1 027	1.6	0.1	0.2	0.9	0.5
Abroad	18 633	13 898	1 899	2 604	232	8.6	6.4	0.9	1.2	0.1

Note:
EU-27: Eurostat estimation.

Source: Eurostat (rd_e_gerdfund)

Global market/size and development prospects
N/A

EU market (size of the market/sector and importance for the EU economy)
In terms of total number of publications globally, the EU maintained in 2003 a comfortable lead. Its share was 38.3%, whereas the US was responsible for 31.1% of global scientific publication output.

Among individual EU Member States, the UK, Germany, France and Italy were the largest producers of scientific publications, with an aggregated world share amounting to 27.6%. These four countries accounted for more than 70% of the EU's scientific publication output in 2003 (EC, 2005).

In terms of total number of patents within Europe, table 2 shows that the government and the higher education sector are responsible for 3.2% of the patent applications to the EPO, whereas the business enterprise sector accounts for 85.7% of them (Eurostat, 2010). If we focus only on biotechnology and organic chemistry related patents, university patents accounted respectively for around 13% and 8% in 2002 (van Zeebroeck, 2008).

Table 2 : Patent application to the EPO by institutional sector, total number and as a percentage of total, EU27 – 2005

	Total	Business enterprise sector	Government sector	Hospitals	Individual applicants	Private non-profit sector	Higher education sector	Sector unknown
EU-27	55 079	85.7	1.4	0.1	6.3	1.6	1.8	2.9
BE	1 408	79.9	0.5	0.0	6.4	2.0	7.9	3.2
BG	24	46.1	0.0	0.0	51.8	0.0	2.1	0.0

Source: Eurostat, 2007

Economic relevance of utilization of genetic resources for the sector in Europe
N/A

Any EU companies that are market leaders? / Any EU organisations that are leaders in the sector?
N/A

Relevance of SMEs
N/A

3. Types and role of genetic resources use in the sector/ characteristics of the user chain

The academic research sector is not directed to one particular research activity and potentially undertakes all kinds of research. As a result, all types of genetic resources are being used within academic research, coming both from *in situ* and *ex situ* collections. It may use dead genetic resources coming from museums or herbaria or living genetic resources coming from botanical gardens, seed banks or culture collections.

Sector-specific collections or databases of genetic resources
Institutions dedicated to academic research maintain their own research collections. Nevertheless, in order to make genetic resources publicly available to their peers after the publication of results, researchers deposit their data collections on genetic resources in *ex situ* collections (SCNAT, 2010).

Relevance of basic research 'utilizing genetic resources' for (innovation in) the sector
Basic academic research utilizing genetic resources is the first step in the "utilization chain" of genetic resources. It covers the inventory of biodiversity through identification, classification, phenotype and functional characterization, measuring and basic molecular analyses (e.g. DNA sequencing). It has some direct application in the field of systematics, evolutions and ecology and but the publication of results/data/analysis will be an input for further basic, applied or development research, thereby contributing to innovations (SCNAT, 2010).

The specific role of basic research on innovations hard to determine as the distinction between the different types of research (basic/applied) is not always clear. For instance the same staff might undertake all sorts of research or a project dedicated to applied research might include a basic research part (Frascati, 2002).

One should not ignore the role of basic research outside the academic sector. Business enterprises may use academic work results (via publications) without it being obvious as long periods of time may separate the publication of research results from the development of a related good/service. This is partly due to the lack of linkage between fundamental disciplines and applied ones (Brahy, 2007) and partly due to the potential geographical disconnection between the place where the genetic resource has been collected and the place where further research is undertaken (Martinez, 2010b).

Relevance of applied research 'utilising genetic resources' (for innovation) in the sector
The typical fields of applied research utilizing genetic resources are genomics or proteomics where the goal is to identify, isolate and characterize active compounds. It uses biotechnology processes to purify, synthesize, and multiply an organism or parts thereof. It can give rise to publication of new data and chemical formulas, or isolated/identified genes and new methods of technologies which can subsequently be patented (SCNAT, 2010).

Relevance of genetic resources for product development in the sector
The sector of academic research may be engaged in product development based on genetic resources, It may include the improvement of products in agriculture, forestry, and medicine. This involves the isolation and the insertion of target genes, molecular cloning and transformation of genes (structure and characteristics), multiplication of cells and organisms (SCNAT, 2010).

Relevance of genetic resources for products placed on the market in the sector
N/A

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
Innovations of the academic sector are not supposed to be protected because the aim of academic research is to increase knowledge without commercial perspective. Therefore, results/data are made publicly available through publications.

However, patenting has become more common in Europe since the 1990s, notably in the field of biotechnology where the shift from basic research to potential industrial applicability is easier to make (van Zeebroeck *et al*, 2008).

Relevance of traditional knowledge associated with genetic resources
Traditional knowledge plays a relatively important role in the academic research sector. A survey conducted on 87 projects involving international transfers of genetic material, concluded that about 20% of the projects worked with traditional knowledge. 79% of the projects focused on the genetic resources itself only, 17% on the genetic resources and the associated traditional knowledge, and 3% on traditional knowledge only (WG-ABS, 2006).

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting
Bioprospecting is more relevant in the field of basic research where the general aim is to describe biodiversity. In particular, taxonomic studies are associated with bioprospecting activities and cover a significant part of academic research activities. A survey undertaken within the academic sector has shown that a third of the projects utilizing genetic resources were taxonomic studies (SCNAT, 2010).

Relevance of intra-EU collections, gene banks, seed banks, databases
Academic researchers have strong ties with culture collections and/or botanic gardens because these organisations are crucial for academic research activities. Researchers generally need to publish and disclose sufficient information so that their peers can evaluate their work. For this purpose, they often need to record and store collected data in *ex situ*

collections in order to make them available to the scientific community (Martinez, 2010b).

Subsequently, *ex situ* collections are also supplying the academic research sector with genetic resources. For example, a survey has shown that 58% of the transfers of genetic resources from public culture collections to other organizations were addressed at academic research collections (Dedeurwaerdere, 2010).

Relevance of acquisition of GR directly in countries providing such material

Academic scientists are very likely to be part of ABS contracts as they are usually the main actors in bioprospecting activities. This is also the case where the bioprospecting project aims to collect genetic resources for utilization by a company, thus falling outside the scope of academic research. As regards to traditional knowledge, academic researchers are necessary intermediaries which enable traditional knowledge to be further used. As such, they maintain direct ties with holders of traditional knowledge and are likely to participate in ABS contracts (Brahy, 2007).

5. Existing approaches as regards ABS in the sector

General approach to ABS

As opposed to the US, where universities and other academic research institutes have well established legal departments, a problem identified in Europe is that often scientists have been more accustomed to relationships and exchanges build upon mutual trust and are therefore often less familiar with international legal obligations and the technicalities of formal contractual procedures (Desmeth, pers. comm., 2012). On the one hand, academic scientists cooperating with well-established ABS practices (i.e. botanic gardens, culture collections, pharmaceutical firms, etc) may be exposed and/or compelled to endorse and comply with the ABS guidelines and model MTAs that are being used by those entities (e.g. IPEN code of conduct, ECCO model MTAs, MOSAICC and other guidelines).[208] Royal Botanic Gardens, Kew, for example, in line with the "Principles on Access to Genetic Resources and Benefit Sharing for Participating Institutions" which they have been promoting since 1997, implemented an internal certification system requiring all associated fieldworkers (scientists, taxonomists, etc.) to obtain a registration number from their Overseas Fieldwork Committee for each trip before they could receive funds or insurance (Kew, 2004). For that purpose fieldworkers were to provide information on whether they (a) were working with partners; (b) could identify relevant stakeholders; (c) had obtained or are in the process of obtaining appropriate permits; (d) understood the terms of use; and (e) were planning benefit-sharing (Davis, 2005). On the other hand, because of the abovementioned reasons combined with the diversity of research and genetic resources used between one academic research institute and the other, examples of structured sector-wide approaches to ABS are still scarce. Nevertheless, in light of the rise in ABS-related legal requirements in countries of origin of genetic resources, recent years have witnessed a progressive proliferation of voluntary codes of conduct and guidelines aimed at facilitating researchers involved in bioprospecting activities in complying with local and international ABS legislation (SCNAT, 2010).

[208] *See* other sectorial baselines for details on those guidelines.

Voluntary initiatives and best practices

Agreement on ABS for Non-Commercial Research (Swiss Academy of Sciences) (2010)
This agreement, drafted by the Swiss Academy of Sciences, is a model contract designed to assist academic research institutes in establishing MAT with the provider of genetic resources. It is devised to address the specific situation of non-commercial research and assumes that research will be carried out by a scientist under the responsibility of a research institute and that research will be for the primary purpose of providing publicly available results (although, depending on the type of research, the results may later lead to the utilization of the research in a commercial context) (SCNAT, 2010). The agreement is a comprehensive model contract containing core requirements as well as optional requirements or definitions to address different situations (e.g. obligations to conclude ancillary agreements if traditional knowledge is involved). The agreement specifically includes model terms for:

1) Access: the agreement envisages that the user will provide a list of genetic resources to be accessed to the provider, nevertheless in case the species/strains are unknown at the time of collection the user may provide the information at a later stage when the species/strains have been identified.
2) Utilization: Any commercialization of the material is prohibited.
3) Change of Use (including patents on GR): Will require a new PIC/MAT agreement with the original provider.
4) Transfer of GR to third parties: is allowed under an MTA to other non-commercial users and with a contractual guarantee that further transfers will be under the same terms. As to specific terms under the MTA, the agreement proposes, *inter alia*, reporting (or documentation) requirements on further transfers with notification to the transferor or the original provider and different levels of conditions to be requested when depositing the GR into an *ex situ* collection.
5) Benefit-sharing: Core benefits to be shared include scientific cooperation, acknowledgment of the source of GR in publications and the sharing of research results with local communities and other stakeholders. Other non-monetary benefits are listed in Annex I.
6) Reporting Requirements
7) Publications: the origin of GR appearing in the publication must be acknowledged. An option is that if the user finds during prior publication that the results may potentially have some commercial application, it must share this information with the provider, over which the provider may decide to engage in agreements with the user on patents or commercial use.

CIRAD, INRAD and IRND Guidelines on the Access to Genetic Resources and their Transfer (2011)[209]

Those guidelines have been developed by CIRAD, INRAD and IRND, three French public research institutes that engage in different research on living plant, animal and microbial genetic resources. The aim of those guidelines is mostly to instruct the researchers working in those institutes how to comply with the main provisions of the CBD and Nagoya Protocol while performing their bioprospecting and research activities. Relevant aspects treated under the guidelines include, *inter alia*:

1) PIC requirement: In absence of national legislation users must nevertheless inform the provider on the envisaged uses of relevant GR. Users are advised to always receive written consent as what is not written will be assumed not to have been consented.
2) Sourcing from intermediaries: when sourcing from an intermediary it is recommended to include in the acquisition agreement a clause guaranteeing that the partner has respected the national ABS legislation of the provide country.
3) Transfer of GR to third parties: In case the research centre in France has become a provider of post 1993 GR by having acquired it from a foreign country they should either act as an intermediary between the future user and the country of origin in order to acquire a new PIC and MAT with the country of origin, or require the prospective user to do that itself.
4) MTAs: They must contain certain provisions to ensure traceability of genetic resources and their related publications and property rights acquired on them. It should be made clear that subsequent transfers should be done under the terms of the original MTA.

Forerunners implementing ABS best practices

N/A

Existing access and/or benefit sharing agreements: case examples

The case example presented here is about a project undertaken by a Swiss research institute on the ecological impact of repeated wild plant harvesting in a biodiversity hotspot of Asia. The project required access to 1) wild plants, 2) cultivated plants, and 3) the use made of the plant (TKaGR). The parties who granted access and authorised the export of the samples were different depending on the type of plants. As to the wild plants, the contracting party was represented only by the responsible state agencies. As regards to the cultivated plants, individual owners of the plants and sometimes the community also participated to the contract. Finally, when the Swiss research institute had to deal with traditional plant use, different individuals and/or communities participated in accordance with the national and local laws and customs. The research institute also had to obtain PIC from local communities to place traditional knowledge in the public domain. Finally, the sharing of benefits comprised the training of PhD students, the provision of duplicate herbarium samples for

[209] Lignes directrices pour l'accès aux ressources génétiques et leur transfert (September 2011), Availableat : http://www.cirad.fr/actualites/toutes-les-actualites/articles/2011/ca-vient-de-sortir/lignes-directrices-pour-l-acces-aux-ressources-genetiques-et-leur-transfert (Accessed: 7 February 2012).

the national collection, the documentation of results to local communities and feed backs on the sustainability of their harvesting practices (SCNAT, 2010).

6. Current problems/issues as regards ABS

The actual distinction made in the Nagoya Protocol between commercial and non-commercial research in order to decide whether a project can benefit from the simplified access procedure is not of great relevance for the sector (SCNAT, 2010; EC public consultation INRA and CIRAD). Indeed, any non-commercial research result can be used commercially. However, not every result has the same probability to be used commercially. According to INRA, this is especially the case for research on breeding programmes and the development of improved strains or varieties, particularly for species not already covered by a treaty such as the IT-PGRFA (EC Public consultation, INRA, 2012).

Access procedures are generally designed for industrial R&D where benefits are realised after a certain period of time. Instead, the academic sector is able to generate benefits for the provider in parallel to the research on the field like scientific cooperation, technology transfer, training of students etc.

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

Key needs and preferred implementation measures

Given its features, the academic research sector, primarily needs or asks for simple, rapid, harmonized and flexible procedures for the implementation of the Nagoya Protocol.

With regard to the establishment of PIC and MAT, the sector fears the complexity of the administrative processes as academic researchers do not have the financial or organizational means to follow administrative procedures and undertake lengthy negotiations (EC's public consultation, INRA, (2011), SCNAT (2010)). The sector also supports the creation of standardized MTAs inspired by the MTAs of the IT-PGRFA with collective management of ABS. Such a solution is expected to save time and costs (EC's public consultation, INRA, 2011).

More administrative burden can result from the heterogeneous implementation of the Protocol across states. The sector is of the opinion that potential restrictions on access implemented by states as part of their compliance with the Nagoya Protocol is contradictory as academic research has a positive impact on biodiversity conservation and sustainable use of resources (EC's public consultation, CIRAD, 2011). Therefore, for example, exchange of DNA should be simplified when it is aimed at the characterisation of genetic diversity (EC's public consultation, INRA, 2011).

As to the provision of PIC in countries of origin, worries have been expressed as to the possibility to clearly identify the right party having rights over the genetic resources, especially when the GR is available in several countries. Moreover, information on foreign legislation is often insufficient making it difficult to comply with this legislation. This lack of legal certainty might deter the creation of partnerships, as a result of a mutual lack of trust (EC's public consultation, CIRAD & INRA, 2011).

With respect to checkpoints, the various fields of research are subjected to existing procedural requirements which could serve as checkpoints (e.g. sanitary controls for agronomic research). Relevant stakeholders, in fact, expressed a preference for the use of existing procedures instead of creating additional ones (EC's public consultation, CIRAD, 2011).

In terms of EU implementation options, the sector would favour legislation which would limit the differences and inconsistencies between Member State's legislations. Furthermore, they favour the EU taking a role in negotiating bilateral agreements to facilitate access to GR and traditional knowledge for non-commercial purposes. Some within the sector are not convinced by the efficiency of the distinction between commercial and non-commercial use (INRA). This appears for instance to be problematic for research on breeding programmes and the development of improved strains or varieties, particularly for species not already covered by a treaty such as the IT-PGRFA (EC's public consultation, INRA, 2011).

Capacity building needed for the sector?
The academic sector does not possess the necessary organizational and financial resources to cope with the new requirements induced by the implementation of the Nagoya Protocol. Without capacity building academic research involving genetic resources might be discouraged (EC's public consultation, INRA, 2011).

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INTERVIEWS

Philippe Desmeth, President of WFCC and International Coordination Officer of BCCM, Brussels, 8 February 2012.

PUBLIC CONSULTATION MATERIAL

Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity:

- The University of the Azores (2011)
- INRA, Institut National de Recherche Agronomique (2011)
- CIRAD, Centre de Coopération Internationale en Recherche Agronomique pour le Développement (2011)

COSMETICS INDUSTRY – SECTORAL SHEET

1. The sector and ABS

There is a niche market in cosmetics for which wild genetic resources collected through bioprospecting are very important. Overall, however, the demand for wild genetic resources in the cosmetics sector is limited, as most cosmetics are reformulations of existing products. This sector generally has low awareness of ABS requirements, yet a few initiatives have been undertaken to improve compliance with ABS obligations.

2. Size and characteristics of the sector

Definition/description of the sector

Cosmetic products include 'traditional' cosmetic products, such as make-up and perfumes as well as personal hygiene products such as tooth-care products, shampoos and soaps (EC Consumer Affairs, 2012). Within the cosmetics sector, characterising the segment working on 'natural' products is quite difficult (Laird, 1999). Many companies use a small amount of botanical ingredients in their products, often for marketing purposes but with little or no effect on product efficacy. Another set of companies focuses on products that are '100% natural' in order to replace artificial or petrochemical components. A third set of companies works to produce the most efficacious product, whether natural or synthetic, and screens both types of compounds to find new product development leads (similar to the pharmaceutical industry) (Laird, 1999).

Research and development programmes are small and fairly conservative in most cosmetics companies. Although R&D has grown in this sector in recent years, it is much less important than in the pharmaceutical or biotechnology sectors (Laird & Wynberg, 2012; Laird, 1999). Nonetheless, companies must increasingly focus on efficacy and product safety to meet consumer demands and EU regulations. Today, the lifespan of a typical cosmetic product is less than five years. Manufacturers reformulate 25% of their products every year to remain competitive (EC Consumer Affairs, 2012).

Global market/size and development prospects

The global market amounted to about three times the European market in 2006 (Global Insight, 2007). The ten largest cosmetics corporations together control more than half of the global cosmetics market (Beattie, 2005).

EU market (size of the market/sector and importance for the EU economy)

The European market for cosmetics was valued at €63.5 billion in 2006, which is approximately the same size as the US and Japan combined. The market employs over 142,000 people (Global Insight, 2007).

Within the EU-27, Germany has the largest share of the cosmetics market, which was valued at €11.7 billion in 2006. Together with Germany, France (€10.4 billion), the UK (€10 billion), Italy (€8.8 billion), and Spain (€7.4 billion) are the top five markets for cosmetics products in the EU, and represent more than 75% of the total EU cosmetics market (Global Insight, 2007). In 2006, the cosmetics market in the EU-27 was expected to grow at an average rate

of 4.4% per year to 2016, with a higher rate of growth projected for the new Member States (8.8% annually) compared with the EU-15 (3.7% annually) (Global Insight, 2007).

More than 140,000 people were employed in the cosmetics industry in Europe in 2006. Six countries account for nearly 130,000 of these jobs: France, Germany, Italy, the UK, Spain and Poland (Global Insight, 2007). Employment growth has been particularly high in the new EU Member States, particularly Poland (Global Insight, 2007).

Economic relevance of utilization of genetic resources for the sector in Europe

Wild harvested or cultivated products are used in many cosmetics products. Demand for access to the genetic resources used in the cosmetics sector is expected to grow, particularly where these can help to create novelty and therefore differentiation in the market (Laird and Wynberg, 2012).

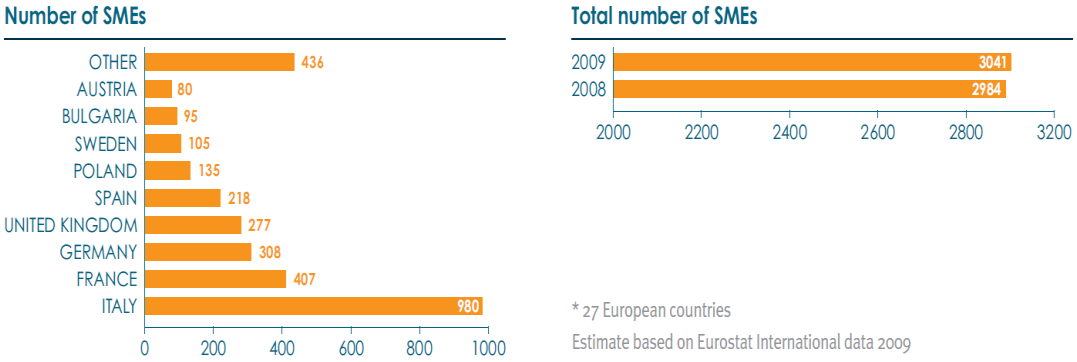
Any EU companies that are market leaders?

The EU is a leading market in the cosmetics industry and as such a number of EU companies are market leaders; for instance, L'oreal Group, LVMH, Chanel and Yves Rocher (France), Uniliver PLC (United Kingdom) and Henket KGAA (Germany) (Global insight, 2007).

Relevance of SMEs

Two thirds of the 4,000 EU cosmetics companies are SMEs (Colipa, 2010). The sector is nevertheless composed of a significant number of major international companies mainly based in France and Germany (Global Insight, 2007).

Figure 1: Number of SME Manufacturing Enterprises in 2010, Europe:



***Source*:** Colipa, 2010

3. Types and role of genetic resources use in the sector/ characteristics of the user chain

The cosmetics industry makes use of different types of genetic resources in different ways. First, raw material, typically bulk sourced, can be sold as such or slightly processed. The raw material in this case consists mainly of dried plant products or oil from a variety of organisms (Laird and Wynberg, 2012; Beattie, 2005). The natural products of most interest are derivatives of genetic resources sourced from the wild such as saponins, flavonoids, amino acids, anti-oxidants, and vitamins (Beattie, 2005). Cosmetics industries also engage in

screenings to identify active compounds following the same R&D process of pharmaceutical companies (Laird and Wynberg, 2012).

Relevance of basic and applied research 'utilising genetic resources' (for innovation) in the sector

The EU cosmetics industry employs around 17,000 scientists to carry out its R&D programmes, from a wide range of disciplines, including microbiology, biology, toxicology, and genetics (Colipa, 2010).

It may take between six and eight years of research and screening involving as many as 100 ingredients before a new cosmetic product goes to market (EC public consultation, 2011).

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)

Trade secrets are traditionally used to protect innovation in the sector. However, ingredient labelling requirements have led to increased patenting activity (O'Lenick, 2011). This industry accounted for 10% of all patents granted in Europe in 2009 (Colipa, 2010).

Relevance of traditional knowledge associated with genetic resources

Traditional knowledge is used for different purposes within the sector. It can be relied on as the starting point for new product development based on novel species. Moreover, new ingredients which are regularly sought in nature are identified through traditional knowledge. Finally, traditional knowledge is also used as a marketing tool to demonstrate product efficacy and safety (Laird and Wynberg, 2012).

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

There are several stages in the value chain for cosmetics products. Materials are often produced through cultivation and the material is then purchased by a series of intermediaries including exporters, importers, wholesalers, brokers or traders (Beattie, 2005). The materials are then developed into a finished product by processors or manufacturers. These products are then sent to distributors and finally retailers (Beattie, 2005).

Relevance of bioprospecting

Materials are often bioprospected and bioprospecting activities are expected to continue to grow in this sector. New ingredients are regularly sought in nature, and identified through traditional knowledge.

Relevance of EU and non-EU ex situ collections, gene banks, databases

No information could be found.

5. Existing approaches as regards ABS in the sector

General approach to ABS

Some companies in the cosmetics industry have already developed procedures internal to the company to verify compliance with ABS requirements in provider countries (EC public consultation, 2011). Despite the increasing trend towards the development of codes of

conduct, this sector is generally considered as lacking awareness of their ABS obligations and remains poorly organised and represented at CBD meetings—a problem which has been noted for some time (see, for example, Laird, 1999; Laird and Wynberg, 2012).

Benefit-sharing practices in this sector are not widespread but where agreements have been made, benefits are linked to the supply of raw materials and have taken the form of technology transfer, training and capacity-building (Laird and Wynberg, 2012). Benefits have also included charitable donations through a percentage of sales (Laird, 1999).

Voluntary initiatives and best practices

Companies are currently engaged in a range of initiatives designed to improve their understanding of, and commitment to the development of ABS agreements; these include the Natural Resources Stewardship Circle (NRSC), the Union for Ethical Biotrade (UEBT) and the BioTrade Initiative (EC public consultation, 2011). For example, the UEBT requires new members to agree to gradually adjust their sourcing practices to meet CBD objectives and principles as a prerequisite for membership in the organisation.

UEBT standard

The UEBT standard was developed in 2007 and is designed to help companies advance the objectives of the CBD. In particular, Principle 3 of the standard focuses on equitable benefit-sharing through guidance on negotiating access and benefit-sharing agreements for the use of genetic resources or the traditional knowledge associated with genetic resources (EC public consultation, 2011). UEBT is also working with its members to develop tools that can facilitate the implementation of such agreements such as agreement templates and model contractual clauses.

The standard covers cases where a UEBT member's activities require ABS measures in a given jurisdiction. Independent verification of compliance can be obtained through the Rainforest Alliance or Ecocert to assess their biodiversity management system and report on their progress towards implementation (EC public consultation, 2011). Public summaries of audits and annual progress reports are also provided for through the standard.

NRSC guidelines

The NRSC presented guidelines at the 2010 CBD Conference of the Parties in Nagoya, Japan, which define the criteria and bases for 'fair and sustainable cooperation between the parties' while also protecting biodiversity (NRSC, 2012). The NRSC is a voluntary initiative amongst 24 companies working with indigenous and local producer communities (NRSC, 2012; EC public consultation, 2011).

BioTrade initiative

The BioTrade initiative was launched by the United Nations Conference on Trade and Development (UNCTAD) in 1996 to support the objectives of the CBD. The BioTrade Initiative now includes a range of regional and country programmes that incorporate, amongst other objectives, policy development, knowledge exchange, capacity building for the introduction of new conservation-friendly and sustainable technologies, and support to the mobilisation of financing to businesses in producer regions (BioTrade, 2012).

Forerunners implementing ABS best practices

Some companies have developed long-term sourcing partnerships with local groups that include fair pricing agreements and assistance in connecting these groups to other buyers. Plant-based hair care products company Aveda and cosmetics company Natura are two examples of companies that have developed these types of agreements (Laird and Wynberg, 2012). Partnerships of this kind require significant resources, however, and are therefore relatively uncommon amongst companies (Laird and Wynberg, 2008). Given the relative importance of traditional knowledge to the cosmetics sector, there has been relatively little benefit-sharing linked to traditional knowledge (Laird, 1999).

Existing access and/or benefit sharing agreements: case examples

PhytoTrade Africa is the trade association for the natural products industry in South Africa. It was established in 2002 and represents private sector businesses, development agencies, individuals and other interested parties in eight countries: Botswana, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia and Zimbabwe (PhytoTrade, 2012). PhytoTrade is a non-profit organisation that seeks to assist African rural producers develop and market natural products for export.

PhytoTrade undertakes research to help producers identify and build the business case for regional or global development of new products, including cosmetic oils and health care products. The organisation focuses on a limited number of products with market potential that are suitable for small-scale rural development (PhytoTrade, 2012).

One example in the cosmetics sector is Kigelia extract (from the African sausage tree), which is being developed for the international market through partnership between Afriplex and UK-based Blue Sky Botanics. Afriplex is a South African company that specialises in African plant extracts international markets, including the beverage, pharmaceutical, cosmetic and nutraceutical industries. Blue Sky Botanics is a UK manufacturer of botanical ingredients for the beauty, food and beverage and herbal medicine industries.

A second example is a PhytoTrade partnership with Alivida, a French natural and organic ingredient cosmetics manufacturer. Through the partnership, Alivida has create a line of lipid oils (Ubuntu™) that have the natural oxidative stability and antioxidant properties of virgin oils, but that also meet international quality requirements amongst skin care companies (PhytoTrade, 2012).

A third example includes a partnership between PhytoTrade and Vital Solutions, an international natural ingredients company headquartered in Germany to develop new cosmetic products.

6. Current problems/issues as regards ABS (with possible definition/information to be added for specific issues if some issues (very) important for the sector's operations)

The Personal Care Products Council (PCPC) represents hundreds of companies in the personal care product industry worldwide, including many in Europe. The PCPC cited reputational and legal risk as significant reasons why the industry may not choose to use

genetic resources and traditional knowledge from countries that do not have a clear legal framework in place (EC Consultation, 2011). Indeed, the PCPC indicate that these risks have been borne out already in several cases. Furthermore, in countries where a legal framework has been established, the laws and regulations may not be available, may lack transparency, or may be impractical, creating difficulties for the industry to establish PIC (EC Consultation, 2011).

The European Commission public consultation on implementation of the Nagoya Protocol in 2011 raised the following current problems and issues as regards ABS for the cosmetics sector:

- Liability – long supply chains for raw materials in this sector create challenges to trace PIC and MAT to the original access point.
- Compliance costs – experience to date has indicated significant compliance costs, mostly in provider countries.
- Absence of ABS legislation – most countries have not developed or operationalized their ABS rules; without a clear legal framework, companies are facing significant uncertainty and difficulty in working with genetic resources. It can be difficult, for example, to identify relevant stakeholders. Companies have also faced challenges in gaining agreement amongst government ministries and/or stakeholder groups.

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

Key needs and preferred implementation measures

The European Commission public consultation on implementation of the Nagoya Protocol in 2011 raised the following key needs for ABS rule development and implementation for the cosmetics sector:

- Companies in this sector are concerned that additional requirements linked to market approvals could increase administrative burdens; however, where flexibility is provided, these costs can be minimised. This may include streamlined procedures for SMEs.
- The cosmetics sector would prefer that the ABS competent national authority serve as a checkpoint for compliance, since they are most likely to be familiar with the original user who obtained PIC and MAT at the point of access. A harmonised EU checkpoint may also be helpful to facilitate user and provider relationships.
- Legal certainty is required to understand what is covered under the Protocol as it relates specifically to the cosmetics industry—particularly for raw material suppliers.
- Clear definitions are required, particularly concerning the terms ‘genetic resources’, ‘derivatives’, and ‘fair’ and ‘equitable’.

A harmonised, EU-wide approach is preferred over national legislation in each EU Member State in order to reduce administrative burdens and costs. A directive is not preferred, as it may create divergent implementation procedures (e.g. certificates, checkpoints, compliance procedures, and access rules) and MS interpretations.

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PUBLIC CONSULTATION MATERIAL

EC Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, October-December 2011.

Replies from:

- European Federation for Cosmetic Ingredients (EFfCI)
- Fédération des Entreprises de la Beauté (FEBEA)
- Personal Care Products Council (PCPC)
- Union for Ethical Biotrade (UEBT)

ANIMAL BREEDING INDUSTRY – SECTORAL SHEET

1. The sector and ABS

The importance of ABS for the animal breeding sector is lower compared to most of the other sectors as the sector's reliance on 'wild' genetic resources and genetic resources from the South is limited. The demand for wild resources might increase somewhat in the future because of climate change. Many of the traits necessary to adapt to climate change may be found in locally adapted breeds.

2. Size and characteristics of the sector

Definition/description of the sector

The farm animal breeding (and reproduction) sector engages in the breeding and reproduction of farmed and companion animals. The sector is a knowledge intensive and highly competitive sector at the beginning of the food chain with many SMEs, as well as several mid-sized and large international players. The five most important species for global agriculture are cattle, sheep, goats, pigs and chickens (see Table 1 below) (FAO, 2009). Pig meat accounts for over 40% of global meat supplies, poultry meat for 26% and meat from cattle and small ruminant accounts for the remaining 30% (Nimbkar and van Arendonk, 2010). Exchange, property issues and the breeding structures involving farm animal genetic resources are substantially different from the ones involving plant genetic resources, but also major differences exist between animal species, the abovementioned five in particular. These differences may have implications for the legal and policy frameworks that may be required to manage them (FAO, 2007; FAO, 2009).

Global market and development prospects

Both national and international market forces influence the breeding of farm animals. The international market for genetic resources, together with the competitive positions of international breeding companies, determines the developments of genetic diversity in farm animals. Globally, the number of breeding organizations is decreasing, whereas the average size of the remaining breeding organizations is on the increase (LNV, 2002). In particular the management of poultry, pig and cattle breeding is increasingly concentrated in a few international breeding corporations (Hiemstra *et al*, 2010). Livestock farmers choose breeding stock from these breeding programs for the superior economic qualities of their products, leaving fewer opportunities for local breeding programs (LNV, 2002).

Livestock contributes significantly to food production and economic output in all regions of the world. Livestock production accounts for 40% of the value of world agricultural output (FAO, 2006). Due to a lack of data on many types of genetic material, the overall value of international trade in AnGR is difficult to estimate. Gollin *et al* (2008) estimate the value of international trade in bovine animals for breeding between US$ 300 million and US$ 500 million per annum in the recent past; the value of trade in bovine semen in 2005 was estimated at US$ 180 million; and the value of trade in breeding pigs in 2005 was about US$ 80 million (FAO, 2009).

Worldwide consumption of animal-derived food has been increasing rapidly since the early 1980s (FAO, 2009). Furthermore, livestock keeping is of major importance for the world's poor, as many hundreds of millions are to a greater or lesser extent dependent on livestock keeping for their livelihood (FAO, 2009; Thornton *et al*, 2002).

Worldwide, an increasing proportion of our food is produced by a declining number of highly productive breeds/lines. Many breeds have been lost, narrowing down the genetic diversity among farm animals. The survival of a large number of breeds is threatened (LNV, 2002). 20% of all recorded breeds are considered be at risk (Ivankovic, 2008).

EU market (size of the market/sector and importance for the EU economy)
According to the FABRE Technology Platform (2008) the economic gain (or added value) of animal breeding in the EU/Europe amounts to €1.89 billion per year. The economic gain[210] of animal breeding in the various segments of the sector is as follows:

- Dairy cattle: €430 million per year;
- Beef cattle: €70 million per year;
- Pigs (Europe): €520 million per year;
- Sheep/goats (Europe): €156 million per year;
- Broilers (Europe): €610 million per year;
- Layers (Europe): €125 million per year;
- Salmon/rainbow trout/seabass/seabream/turbot: 80 million per year.

Major breeding organizations with business globally are based in Europe or European owned, with high global market shares (FARBE-TP, 2008). In the poultry sector, European owned or based breeding organizations had a global market share of 72% for broilers and a share of 95% for layers in 2007. In the pig sector, EU breeders had a global market share of 28.5% and a share of 60% in the market of developed countries. For ducks and turkeys, global market shares were even 90% and 100% respectively (Ibid).

Economic relevance of utilization of genetic resources in the sector in Europe
The animal breeding sector is a knowledge intensive sector. In the global animal breeding industry, R&D investments are however lower than in the crop seed industry. R&D intensity in 2006-2007 for the (global) animal breeding sector was about 7.3% across species, compared to 10-15% for the crop seed industry (15% in 2000 and 10.5% in 2009 to be more precise). Private R&D into animal breeding and genetics experienced growth from $253 million in 1994 to $316 million in 2010, according to the report. In nominal U.S. dollars, private R&D spending in 2010 reached $339 million for animal breeding and genetics, whereas R&D spending in 2010 was $3,726 million for crop seed and biotechnology (Fuglie *et al*, 2011). Genetic diversity is a major asset of the breeding organisations which are differently organised across species. Management of genetic diversity and control of inbreeding are integral part of breeding programmes (EFFAB, pers. comm. 2012).

[210] Economic gain = number of animals * % genetic progress per year * added value of 1 unit genetic progress

Any EU companies that are market leaders?

European animal breeding organizations are world leaders in many segments of the sector. The EU company PIC (= Genus) lead the global pig breeding market with a 10% share (FARBE-TP, 2008). In the poultry breeding sector, in which there are few organizations owning and executing poultry breeding globally, all large layers except Cobb-Vantress (30 % of global broiler breeding) are European owned. As for broilers (poultry) Aviagen (Wesjohann GE Europe) lead with a global market share of 50%. As for layers, Lohmann (Wesjohann GE Europe) and Hendrix (e.g. ISA, Euribrid, HPB NL Europe) had global market shares of 45% and 50% respectively. In the turkey sector, BUT, Nicholas (Wesjohann GE Europe) lead with 65% of the global market share. Hybrid (Hendrix Genetics NL Europe) had a share of 35%. In the duck sector Cherry Valley (UK, Europe) lead with 50%, whereas Grimaud (Grimaud Fr Europe) had a share of 40% (FARBE-TP, 2008).

Relevance of SMEs

The animal breeding sector includes many SMEs, as well as several mid-sized and large international players. Differences however exist among the various animal breeding subsectors. For instance, most European beef cattle breeders are individual farmers who are members of farmer's cooperatives or breed societies, whereas dairy cattle breeders are mostly dairy farmer cooperatives. In the poultry sector, however, just a few large-scale but still relatively small (max €500-700 million annual turnover) private companies supply breeding stocks. European pig breeding organizations (only 14 in 2007) are half organized in cooperatives and half privately owned companies (FARBE-TP, 2008).

R&D

Basic scientific research is mostly conducted in the public domain, whereas companies protect their knowledge generated in more applied research and breeding (Hiemstra *et al*, 2010).

3. Types and role of genetic resources in the sector/ characteristics of the user chain

It is obvious that all products of the animal breeding and reproduction sector are derived from genetic resources. Exchange of genetic material between owners has been and will remain crucial for the development of livestock breeds and the livestock sector in many parts of the world. Genetic variation within lines or breeds is the main source for genetic improvement. Although (new) breeds and lines are being developed continuously in commercial breeding programs, the introduction of 'foreign' genetic material or 'wild relatives' is much less relevant in animal breeding than in plant breeding (Kaal-Lansbergen and Hiemstra, 2003). Few wild relatives exist which are relevant for animal breeding (Hiemstra *et al*, 2010). For many domesticated livestock species no wild relatives exist, as they have become extinct, and for others wild relatives are very rare (Schloen *et al*, 2011). Furthermore, little or no demand exists in the developed countries for breeding animals or specific (adaptive) traits from developing countries. This situation, however, could change as a result of climate change. The breeding industry emphasizes that their breeding programs are not dependent on introduction of new genes from developing countries; their genetic improvement programs are mostly based on selection within breeding populations. The industry claims that existing stocks offer sufficient diversity to achieve changing breeding objectives and to generate breeding stock for different production environments. The few

examples of introduction of breeds from developing countries into breeding programs in developed countries have illustrated the difficulty of (large-scale) commercialization of South-North transferred material (Hiemstra *et al*, 2010).

The animal breeding and production sector is characterized by a diversity of stakeholders or users. There is, however, no universally accepted typology of AnGR users. At one end of the spectrum you have the group of "breeders" or "specialized breeders". These are the ones that specialize in the selective breeding of animals for sale to others, who in turn use them for production (i.e. *inter alia* to provide goods such as milk, meat, eggs) or in some cases for further breeding. This group includes private companies, cooperative breeding enterprises, state-run breeding farms and individual operators (FAO, 2009). Large-scale private breeding firms have become particularly dominant in the poultry and, to a lesser extent, pig sectors (Schloen *et al*, 2011). On the opposite side of the spectrum lie the so-called "end users" of genetic material, i.e. those who specialize in production, without any involvement on selective breeding. These end users are for instance commercial producers in developed countries who source their animals from specialized breeders. In between those two groups lie the "livestock keepers", i.e. those who combine production with breeding (producing breeding animals for sale or for their own future use). Particular attention should be paid to "small-scale" livestock keepers, whose "role as custodians of much of the world's AnGR has received growing attention in recent years" (FAO, 2009).

Sector-specific collections or databases of genetic resources

Only a limited amount of AnGR is stored *ex situ* (in genebanks) for conservation purpose or for breeding activities such as artificial insemination and embryo transfer. The majority of AnGR are kept in the form of live animals *in situ* (in their production environments). Breeding organisations do not source from genebanks. They are however a valuable resource for local breeds.

Relevance of basic/applied research 'utilizing genetic resources' for (innovation in) the sector

The animal breeding sector is a knowledge intensive sector. Research in *inter alia* quantitative genetics and genomics, research in reproduction techniques, highly sophisticated data gathering, data management and breeding value estimation programs are key for developing and implementing technologies for balanced breeding. In many countries, a very close relationship exists between breeding organisations and scientists working at universities and research institutes. In the animal breeding sector basic scientific research is mostly conducted in the public domain, whereas companies protect their knowledge generated in more applied research and breeding (Hiemstra *et al*, 2010). Just like in the crop seed industry the emergence of biotechnology has been very relevant for the animal breeding industry. R&D intensity in 2006-2007 for the (global) animal breeding sector was about 7.3% across species (Fuglie et al, 2011).

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)

Traditionally livestock breeders protect their investment in innovation by staying ahead of the competition and by making use of biological protection tools. Today, legal instruments such as trade secrets and patents to protect intellectual property are being used more and more (Schloen *et al*, 2011).

Relevance of traditional knowledge associated with genetic resources
N/A

4. Sourcing of genetic materials

The majority of AnGR are kept in the form of live animals *in situ* (in their production environments). Only a limited amount of AnGR is stored *ex situ* for conservation purpose or for breeding activities such as artificial insemination and embryo transfer. AnGR are therefore primarily held under private ownership and their exchange takes place mostly on a commercial basis. Generally stakeholders in the breeding sector start from the assumption when selling animal genetic material (breeding animals, semen, embryos, …) that the value of this material as a genetic resource is reflected in its price and that the buyer will be free to use it for further research and breeding (FAO, 2009; Schloen *et al*, 2011). However, in some case parties may agree restrictions on the further use of breeding material and its transfer to third parties, either through contracts or through "gentlemen's agreements". Traditionally livestock breeders protect their investment in innovation by staying ahead of the competition and by making use of biological protection tools. Today legal instruments such as trade secrets and patents to protect intellectual property are being used more and more (Schloen *et al*, 2011).

Relatively few AnGR are held in the public domain. Public *ex situ* collections and genebanks mainly fulfill conservation purposes and are less involved in the exchange of genetic material and its provision for breeding purposes. Public sector breeding programs mostly play a minor role as a source of improved genetic material, as they lack the resources and the size to do so (Schloen *et al*, 2011).

European animal breeders usually source their material from within the company or from connected farmers, from both within and outside Europe. The introduction of "foreign" genetic material or "wild relatives" is much less relevant in animal breeding than in plant breeding (Kaal-Lansbergen and Hiemstra, 2003). Major flows of genetic material in the commercially relevant breeds that are widely exchanged, occur between developed countries or from developed to developing countries. Genetic material of some breeds adapted to (sub)tropical environmental conditions is also exchanged among developing countries. Many breeds, however, are used rather locally and are not heavily exchanged internationally. This may change in the future because of climate change. Many of the traits necessary to adapt to climate change may be found in locally adapted breeds. Climate change is therefore likely to increase the exchange of genetic material across the board, but might also lead to a bigger flow of genetic material from the South to the North (FAO, 2009; Schloen *et al*, 2011).

Relevance of bioprospecting
The introduction of "foreign" genetic material or "wild relatives" is much less relevant in animal breeding than in plant breeding. European animal breeders usually source their material from within the company or from connected farmers, from both within and outside Europe (Kaal-Lansbergen and Hiemstra, 2003).

Relevance of ex situ collections, gene banks, databases

The majority of AnGR are kept in the form of live animals *in situ* (in their production environments). Only a limited amount of AnGR is stored *ex situ* for conservation purpose or for breeding activities such as artificial insemination and embryo transfer breeding (FAO, 2009; Schloen *et al*, 2011).

Relatively few AnGR are held in the public domain. Public *ex situ* collections and genebanks mainly fulfill conservation purposes and are less involved in the exchange of genetic material and its provision for breeding purposes. Public sector breeding programs mostly play a minor role as a source of improved genetic material, as they lack the resources and the size to do so (Schloen *et al*, 2011).

5. Existing approaches as regards ABS in the sector

General approach to ABS (voluntary initiatives and best practices)

Animal breeding is primarily based on the exchange of material within a company and with connected farmers. Exchange is regulated by private law agreements and a common understanding among breeders of the rights on the material. As a result no ABS code of conduct has been developed by this sector. Access to AnGR is agreed between providers/suppliers and users in bilateral transfer agreements. All kinds of flows of AnGR exist: flows among developed countries, flows from developed countries to developing countries and *vice versa* and flows among developing countries. How access and benefit-sharing of these flows are agreed upon, depends of the suppliers and users concerned (Kaal-Lansbergen and Hiemstra, 2003).

In general, AnGR are protected by "physical ownership". The owner of farm animals determines to what extent and under which conditions breeding animals or their germplasm is made available to others. The selling and purchasing of material *de facto* regulates access to genetic resources. The seller of genetic material may retain some rights to the next generation of animals (or germplasm) or rights to dictate how they are used. Pig and poultry breeding companies often use contracts forbidding the buyer from selling breeding material from the purchased animals or requiring the payment of a royalty when breeding stock is sold. In the pig breeding sector "gentleman's agreements" are made that stipulate that genetic material from competitors' pigs will not be used for further breeding (Hiemstra *et al*, 2006; FAO, 2009). Since the owner determines to what extent genetic material is available to third parties and at what prices, the price of animals in fact includes a benefit-sharing agreement: the owner/supplier gets money in exchange for providing access to the genetic material (Kaal-Lansbergen and Hiemstra, 2003). The price consists either of a clear-cut payment per animal or some kind of royalty system based on the generated progeny and its output (EC public consultation, 2011).

There is no multilateral system regulating the international exchange and access and benefit-sharing of AnGR, such as the one that exists for several crops under the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA). No SMTA is being used to regulate and standardize the exchange of AnGR (FAO, 2009). There is however a multilateral system regulating the international trade of AnGR (WTO).

Current practices of exchange and ABS in the research sector
Within the research sector, exchanges of AnGR are usually governed by classical scientific cooperation contracts, whereby each party keeps the property of its inputs in the project and whereby the scientific results, publication and potential IPRs are shared (EC public consultation, 2011).

Forerunners implementing ABS best practices
No forerunners have been identified.

Existing access and/or benefit sharing agreements: case examples
N/A

6. Current problems/issues as regards ABS

Compared to other sectors not many problems have been identified in the animal breeding sector with respect to access to genetic resources. This might reflect the fact that most exchanges in animal genetic material take place between developed countries or from developed countries to developing countries, whereas exchanges from developing countries to developed countries are low. Furthermore, no access legislation exists in provider countries (neither in developed or developing countries) which specifically addresses AnGR (for food and agriculture).

7. What are key needs and preferred implementation options for the sector as regards ABS rules development and implementation?

Key needs and preferred implementation options
International trade of seed stock for animal production is the most important factor that increases the efficiency of animal production. Therefore the European Forum of Farm Animal Breeders (EFFAB) is concerned that any regulation that blocks this trade will substantially limit progress in animal production. It further recommends the EU to adopt measures that encourage voluntary transparency initiatives by the animal breeding industry and link checkpoints to existing regulatory procedures. In this respect EFFAB refers to the EU zootechnical legislation which governs the commercial trade of AnGR and in particular to the existence of harmonised certificates for intra-Community trade of breeding animals, semen, ova and embryos with detailed information on the origin and genetic values. Measures should rely on the existing documentation of health status and pedigree information, and extend it, where needed, by specifying the region of origin of the animals (EC public consultation, 2011).

Hiemstra *et al* (2010) state in their summary report of an international technical expert workshop on AnGR, which was held in Wageningen (NL) in December 2010, that the South-North exchange of AnGR can only generate limited benefits for the purpose of conservation of local genetic diversity and for poor livestock keepers in developing countries. These results from the fact that most exchanges in animal genetic material take place between developed countries, whereas exchanges from developing countries to developed countries are low, especially in comparison to other types of genetic resources for food and

agriculture. Therefore it is doubtful that sufficient revenues can be acquired through "classical benefit-sharing mechanisms". At the workshop several suggestions were made for alternative measures to raise funds to support conservation: public-private partnerships in establishing local breeding programs; a tax on international exchange and foreign introductions; and, the development of regional and global strategies to establish a multilateral pool of AnGR.

The workshop participants were not in favour of a dedicated international legally binding instrument for AnGR, as the costs of developing such an instrument would outweigh the expected benefits. Instead it was recommended to focus on the implementation of the FAO Global Plan of Action for AnGR to get substantial funds for capacity building and to support conservation of AnGR in developing countries and countries with economies in transition (as a non-monetary form of benefit-sharing). In addition, guidelines for international exchange (including genetic impact assessments) and model MTAs and model contract clauses for the exchange of AnGR might be developed. It was also suggested to continue developing and implementing Biocultural Community Protocols, which would also address more adequately "Livestock Keepers' Rights" issues (Hiemstra *et al*, 2010).

The global research community considers the facilitated exchange of research material between countries something of major relevance. Researchers are mostly in favour of the establishment of clear exchange procedures for research materials, including through the use of a model or sMTA (Hiemstra *et al*, 2010). A substantial part of AnGR research is currently initiated in Europe, but involves AnGR from outside Europe (EC public consultation, 2011).

Capacity building needed for the sector?

N/A

Table 1: characteristics of the "big five" livestock species

	Ruminants				Monogastrics	
Species	Cattle		Sheep	Goats	Pigs	Chickens
	Dairy	Beef				
Birth type	Single	Single	Single > twins, triplets	Single > twins, triplets	5 to 15	Many
Age at first delivery	22 months to 4 years	22 months to 4 years	1 to 2 years	1 to 2 years	10 to 18 months	5 to 18 months
Time between two deliveries (calving interval)	350 to 730 days	350 to 730 days	180 to 360 days	180 to 360 days	6 to 12 months	
Offspring per female per year	0.5 – 0.9	0.5 – 0.9	1 to 3	1 to 3	8 – 22	20 – 200
Generation interval for breeding	> 4 years	> 4 years	2 years	2 years	1 year	1 year
Use of artificial insemination and reproductive biotechnology	+++	+	+	+	+	+
Control of genetic progress	+++	++	+	+	+++	+++
Structured breeding programmes	Cooperatives, private companies		Breeders' organizations	Breeders' organizations	Private companies	Private companies
Natural diet	Herbivory		Herbivory	Herbivory	Omnivory	Omnivory
Feed types	Roughage > concentrates		Roughage > concentrates	Roughage > concentrates	Concentrates	Concentrates
Land dependence	++	+++	+++	+++	+	+
Products	Milk > meat	Meat	Meat, milk, wool	Meat, milk, fibre	Meat	Meat, eggs
Products perishable within a few days	Milk	Meat	Milk, meat	Milk, meat	Meat	Meat
Mechanization of slaughter and product processing	+++	++	+	+	++	+++

Source: FAO (2007)

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Replies from:

- European Forum of Farm Animal Breeders (EFFAB)

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(INDUSTRIAL) BIOTECHNOLOGY – SECTORAL SHEET

1. The sector and ABS

The biotechnology sector is important for ABS because the sector relies by definition on genetic resources. The texts of the CBD and the Nagoya Protocol define biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (Art 2 CBD and Art 2 NP).

This sector sheet focuses on the biotechnology sector in general and the industrial biotechnology sector in particular. Though some references are made to the pharmaceutical and agricultural biotechnology sectors, these are analysed in more detail in the respective sector sheets on the pharmaceutical industry and the plant breeding/seed sector. Less information is available on the industrial or white biotechnology sector than on the green and red biotechnology sectors.

2. Size and characteristics of the sector

Definition/description of the sector

The biotechnology industry is part of the user chain in the pharmaceutical, agricultural and industrial sectors:

- **Pharmaceutical (i.e. red biotechnology)**: the techniques of biotechnology are most often applied in the pharmaceutical sector to develop new drugs.
- **Agricultural (i.e. green biotechnology):** agricultural biotechnology is characterised by the development of plant traits to improve farming efficiency for major crops (CBD, 2010).[211]
- **Industrial (i.e. white biotechnology):** industrial uses of biotechnology are an emerging area of activity within the biotechnology sector. The sector includes companies that develop, manufacture and sell product and services that "use or contain biological material as catalysts or feedstock to make industrial products", including companies that develop enzymes, apply enzymes in biotransformation, develop whole cell catalysts and apply these in fermentation systems (HM Government, 2010). Industrial biotechnology uses enzymes and micro-organisms to make bio-based products in sectors such as chemicals, food and feed, detergents, paper and pulp, textiles and bioenergy (such as biofuels or biogas).[212]

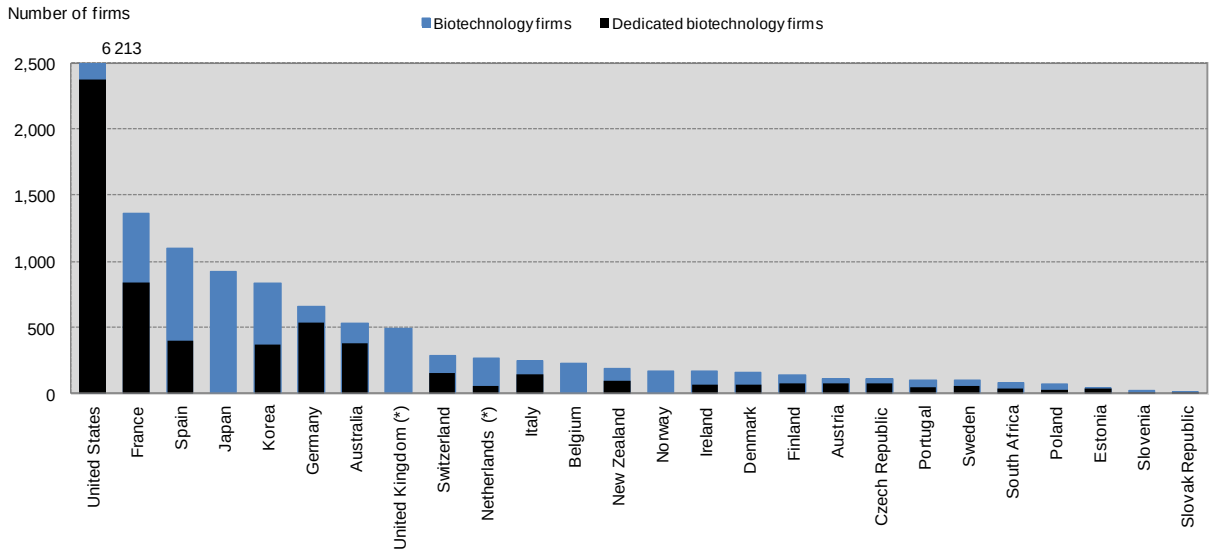
The use of genetic resources in biotechnology across these three sectors varies significantly, including the development of specialty enzymes, enhanced genes or small molecules for crop protection or drug development; enzymes that act as biological catalysts to produce polymers and specialty chemicals, or for use in industrial processing; and gene insertion for trait development in crops (Laird and Wynberg, 2012).

[211] CBD (2010) 'Uses of Genetic Resources', Factsheets in the ABS series, www.cbd.int/abs.
[212] www.europabio.org

Global market/size and development prospects

Global biotechnology industry revenues were valued at $84.6 billion in 2010—12% more than in 2009 (Ernst & Young, 2011).

Figure 9: Number of biotechnology firms in 2010 (or latest available year)



***Source**:* OECD, Biotechnology Statistics Database, December 2011 (StatLink http://www.oecd.org/dataoecd/6/58/47023351.xls)

**For NL, provisional data; firms with >10 employees only; For UK, approximately 66% of the firms undertake R&D.*

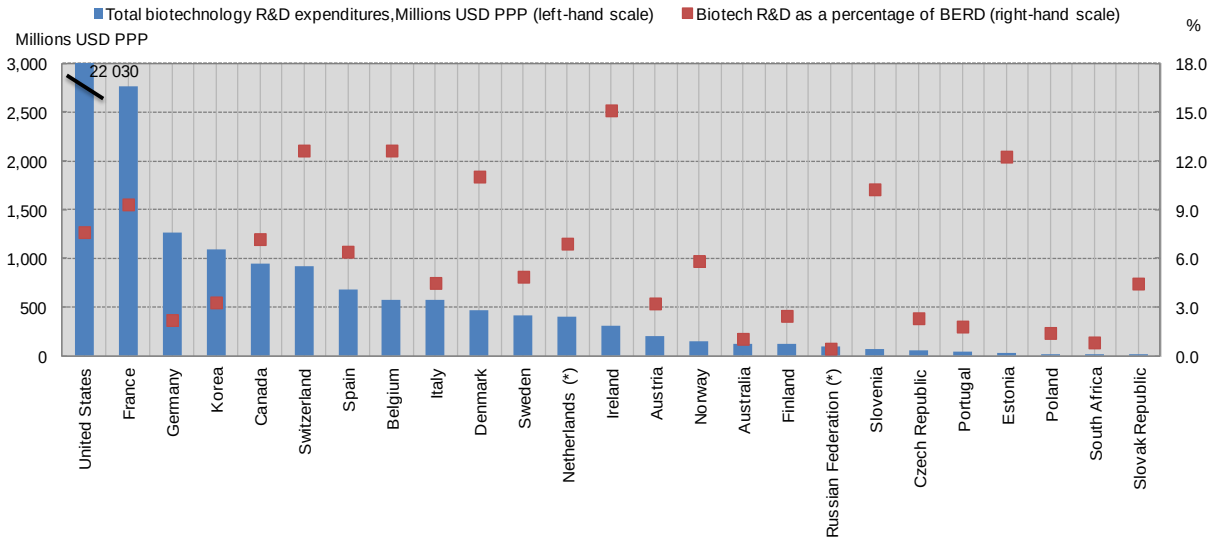
EU market (size of the market/sector and importance for the EU economy)

The EU is one of four established biotechnology centres internationally; the US, Canada and Australia represent the other three. Revenues of the EU biotechnology industry amounted to $13 billion in 2010 with a share in global revenues of 15% (Ernst & Young, 2011) and a share of 34.5% of global biotechnology patent applications at the European Patent Office (EC, 2007). Ernst and Young report that there were 49,060 employees working in publicly traded biotechnology companies in 2010. There were 172 publicly owned companies and 1,662 private companies for a total of 1,834 European biotechnology firms in 2010 (Ernst & Young, 2011).

The OECD collected information on the biotechnology industry from 18 EU Member States; these 18 Member States together reported 5,398 biotechnology firms in total in 2010. Of these, the largest number of firms are located in France (1,359 firms), followed by Spain (1,095). Most biotechnology firms have fewer than 50 employees (OECD, 2011).

Figure 10: Total biotechnology R&D expenditure in the business sector, 2010 or latest available year

Millions of USD PPP and as a percentage of Business Enterprise R&D



***Source**:* OECD, Biotechnology Statistics Database, December 2011 (StatLink http://www.oecd.org/dataoecd/6/43/47025000.xls)

**For AU, CZ, DE, NL, PL, Russian Federation, SK, SL, 2009 BERD was used to calculate the biotechnology R&D intensity; 2010 BERD was not available; For Australia, Korea and the United States, 2008 BERD was used to calculate the biotechnology R&D intensity; 2009 BERD was not available. For NL, provisional data (firms with ≥ employees only). For the Russian Federation, a proxy indicator is used.*

Economic relevance of utilization of genetic resources for the sector in Europe

The biotechnology sector entirely relies on genetic resources. The sector is characterised by important investments for R&D.

Amongst the 25 countries for which data are available, private sector biotechnology expenditure is on average 6% as a share of all business expenditure on R&D (BERD) (OECD, 2011). The US biotechnology BERD represents approximately 7.6% of total BERD (USD 22,030). Ireland spends the most on biotechnology R&D as a function of all private sector biotechnology expenditure (15.1%), followed by Switzerland, Belgium and Estonia.

In the public sector (government and higher education), biotechnology R&D expenditures are highest in Germany, followed by Korea and Spain (OECD 2011). The share of public biotechnology R&D in total public R&D is highest in Korea (20.4%), followed by Germany (18.3%) and Spain (13.3%).

As far as industrial biotechnology is concerned, a JRC study from 2007 (Zika *et al*.) provides data on the economic contribution of modern biotechnology to the EU's gross value added (GVA) in the following subsectors: the manufacture of soap, detergents, cleaning and polishing products; food products manufacturing; textile finishing; pulp manufacturing; refined petroleum products manufacturing; and other chemical products manufacturing. The study concludes that modern biotechnology contributes 33% to the GVA of these

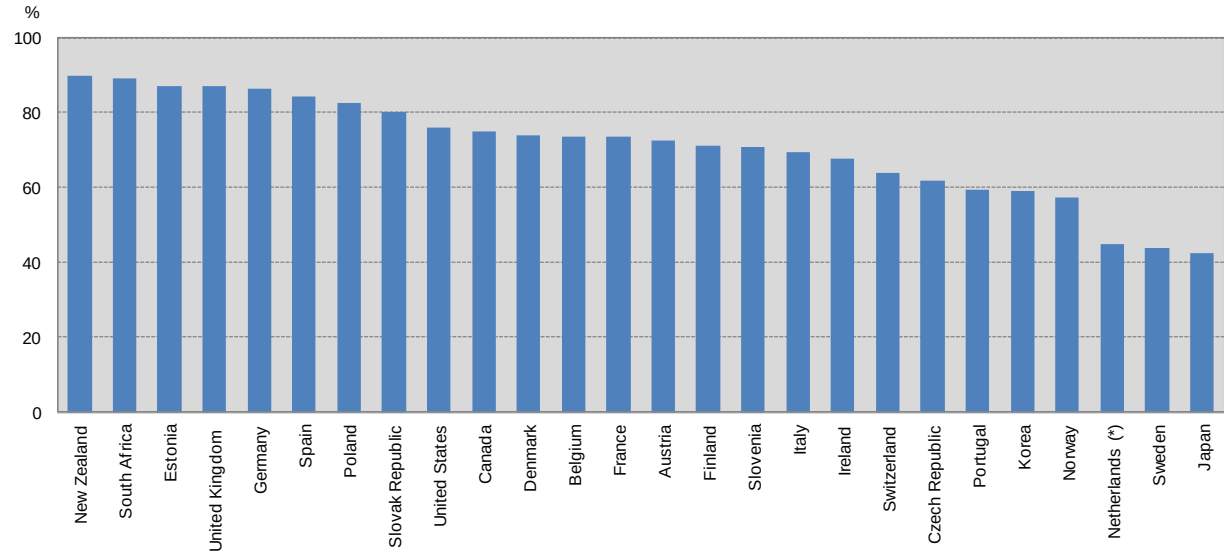
subsectors and about 0.88% to EU GVA.

Uptake of modern biotechnology in these subsectors and their economic contribution vary. Food processing (0.8% of EU GVA), detergents (0.05%) and textile finishing (0.02%) represent the largest economic contribution. In these subsectors, uptake of modern biotechnology is comparatively high (i.e. between 40% and 100%) and occurs early in the value chain. Enzyme production contributes comparatively little to the EU's economic performance (0.008%). Bioethanol contributes even less (0.0002%), as it is still at an early stage of development (Zika *et al.*, 2007).

Any EU companies that are market leaders?

In 2005 the EU companies Novozymes (Denmark) and Danisco/Genencor (Denmark) were the leading detergent enzyme producers with 50% and 20% of the world market, respectively. Despite this, enzyme production contributes comparatively little to the EU's economic performance (0.008%) (Zika et al., 2007).

Figure 11: Percentage of small biotechnology firms (<50 employees) in 2010 (or latest available year)



Source: OECD, Biotechnology Statistics Database, December 2011 (StatLink http://www.oecd.org/dataoecd/6/57/47023510.xls)

*For NL, provisional data; firms with >10 employees only

Relevance of SMEs

Most biotechnology firms in Europe have fewer than 50 employees (OECD, 2011). A large proportion of companies working in healthcare biotechnology are research-intensive SMEs (Degen et al., 2011; Croplife, pers. comm., 2012). The green biotechnology sector is dominated by big multinational companies, however, though a small number of small and medium-sized green biotechnology companies exist that generally do not sell seed but rather seek to commercialize a new genetic trait or biotechnology service or tool to other companies (Croplife, pers. comm., 2012; Heisey and Fuglie, 2011).

3. Types and role of genetic resources in the sector / characteristics of the user chain

The use of genetic resources in biotechnology varies widely across the pharmaceutical, agricultural and industrial sectors and includes animal, plant, fungi, bacteria, prokaryotes, viruses and other microorganisms (CABI, pers. comm., 2012):

- **Industrial biotechnology:** Microorganisms are the primary genetic resource used in industrial biotechnology. Companies are interested in genetic resources found in 'areas with high species diversity, as well as in extreme or unique environments', including salt lakes, deserts, caves and hydrothermal vents (CBD, 2011).
- **Pharmaceutical biotechnology:** Biotechnology applications in the pharmaceutical sector are the most widespread amongst all applications. The main product groups include: biopharmaceuticals (e.g. recombinant insulin or monoclonal antibodies for cancer treatment), recombinant vaccines (e.g. targeting hepatitis B), and biotechnology-based *in vitro* diagnostics (IVD) (e.g. HIV detection through nucleic-acid-based tests) (Zika *et al.*, 2007). In this sector, drug development continues to rely on the use of chemical compounds or 'substances produced by living organisms found in nature' for the discovery of leads (CBD, 2011).
- **Agricultural biotechnology:** The plant biotechnology industry relies entirely on genetic resources, though most companies mainly source their material from their own collections, followed by national genebanks, 'in trust' collections maintained by CGIAR centres, and university collections (Beattie *et al.*, 2005; ten Kate & Laird, 1999). The market value for plant biotechnology-based products has experienced significant growth (CBD, 2011).

Statistics
Amongst resources collected and stored in culture collections, only approximately one in 250,000 organisms collected end up in a use that reaches the market place (CABI, pers. comm., 2012).

Product examples
Industrial biotechnology**:** Heat-tolerant industrial enzymes could enhance industrial processes that destroy most enzymes (Beattie et al.., 2005). For example, *Pyrodictium* inhabits hydrothermal vents and grows at high temperatures ranging between 85 - 121°C (Kashefi and Lovley, 2003).

Relevance of basic and applied research 'utilizing genetic resources' for (innovation in) the sector
Applied research is understood here as research with the objective of adding value to genetic resources to enable the development and commercialization of genetic resource based products. From that perspective applied research plays a major role in the biotechnology sector, in the sense that the sector is to a large extent involved in this stage of the innovation process.

Protection of innovations in the sector (e.g. patents, plant variety rights and trade secrets)
The number of patent protection applications has grown significantly in recent years in the field of biotechnology (Ugalde, 2007), which is now among the 10 most active fields for

applications before the European Patent Office (EPO). In 2011, biotechnology operators based in Europe filed 5,865 applications before the EPO, representing 4.1% of the overall number of European patent applications before the EPO.[213] While a number of innovations in the academic research sector are not protected because the main aim of academic research is to increase scientific knowledge by disseminating research results through publications, patenting has increased in this sector since the 1990s in the field of biotechnology, where basic research is often likely to lead to industrial applications (van Zeebroeck *et al.*, 2008).

Relevance of traditional knowledge associated with genetic resources

The use of traditional knowledge associated with genetic resources is small in the biotechnology sector, especially in the industrial biotechnology sector where micro-organisms are the primary genetic resource used.

4. Sourcing of genetic materials

Relevance of bioprospecting

Industrial biotechnology researchers regularly collect their own samples of materials, contrary to the case in the agricultural and pharmaceutical sectors (ten Kate & Laird, 1999). Ten Kate & Laird (1999) found that of the companies and organisations surveyed for their study, this collecting activity was a relatively unimportant method of acquisition for half of the respondents. For the other half, however, staff collecting activities represented more than 90% of their acquisitions. Many of these collectors come from universities, or from small companies spun off from universities.

Most biotechnology companies in the pharmaceutical sector rely on existing (in-house) collections of genetic materials or outsource collection of materials to third parties (intermediaries) (ten Kate & Laird, 1999). In the plant biotechnology sector, direct *in situ* bioprospecting activities are virtually non-existent (Europabio, pers. comm., 2012).

Relevance of ex situ collections, gene banks, databases

In addition to bioprospecting, the industrial biotechnology sector also relies heavily on culture collections to obtain genetic resources. Most of the cultures held in these collections predate the CBD (CABI, pers. comm., 2011). Samples are also obtained from intermediaries including universities or from external collectors based in the country that provides the resources. Companies also maintain their own collections of genetic resources and their derivatives. For some of these, building and improving their collections is their primary activity, in order to license these to other users for research and product development (i.e. culture collections). For others, their collections form the basis for in-house product development (ten Kate & Laird, 1999).

Over time, many biotechnology companies in the pharmaceutical sector develop their own collections of materials to use in their screening programmes. Companies also license access to their libraries to customers or make their collections available to commercial partners

[213] *Ibid.*

through material sharing and exchange (ten Kate & Laird, 1999).

Most green biotech companies mainly source their material from their own collections, followed by national genebanks, 'in trust' collections maintained by CGIAR centres, university collections (ten Kate & Laird, 1999) and other (smaller) companies. They only rarely source from botanic gardens. The majority of genetic resources obtained by green biotech companies come from outside the EU (Croplife, pers. comm., 2012).

5. Existing approaches as regards ABS in the sector

General approach to ABS

For the biotechnology industry generally, the "Guidelines for Bioprospecting for BIO Members" issued by BIO, the world's largest biotechnology association, is the most important code of conduct for ABS (see below). In addition, it was maintained that for the green biotechnology sector it is a key practice of companies to take steps to ensure that genetic material has been properly sourced, whereby companies generally will only work with material acquired through MTAs (CropLife International, pers. comm., 2012).

Voluntary initiatives and best practices

European Association for Bioindustries (Europabio) – 'Core Ethical Values'.

Europabio, the European Association for Bioindustries, has developed 'Core Ethical Values', by which all members are bound. The Core Values express support for the principles of the CBD, including access and benefit sharing.

The Biotechnology Industry Organisation (BIO) – BIO Bioprospecting Guidelines and Model MTA

BIO created a set of guidelines for bioprospecting, which set out principles and practices for organisations to follow when engaging in bioprospecting activities (BIO, 2005). The Guidelines were developed to assist BIO members understand the relevant issues in this area and identify best practices for companies to follow. These Guidelines also provide for a model material transfer agreement (EC public consultation, 2011).

International Federation of Pharmaceutical Manufacturers and Associations – Guidelines for members on access to genetic resources and benefit sharing

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has established a set of 'Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization' (IFPMA, 2012).

6. Current problems/issues as regards ABS

A significant challenge reported by the European Association for Bioindustries (Europabio) is the lack of clarity in national ABS regimes and rules and procedures for obtaining PIC in provider countries (EC public consultation, 2011). This makes it difficult for users to verify conformity with existing rules. Different and diverse bureaucratic procedures in provider countries increase the inefficiencies and challenges users face in gaining access to genetic resources. Moreover, in some cases, MAT are not recognised.

Plant biotechnology companies are concerned that the Protocol could restrict access to species that are not covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (Andersen, 2008). The biotechnology industry overall is concerned that if implementation results in different regulations across Member States, or particularly restrictive conditions, then negative impacts may include (EC public consultation, 2011):

- Increased investment in time and resources to fulfil administrative requirements, especially where the rules are unclear or lack transparency;
- Decreased product development and commercialisation where genetic resources are used, which could undermine biodiversity conservation and benefit-sharing opportunities; and
- Decreased EU R&D for plant breeding, especially advanced plant breeding, across the user chain.

7. What are key needs for the sector as regards ABS rules development and implementation?

Key needs and preferred implementation measures

The following key needs for the biotechnology sector were registered by Europabio through the European Commissions' public consultation on implementation of the Protocol (EC public consultation, 2011):

- Legal certainty, including: unambiguous definitions; recognition of diversity in genetic resources and clearly defined rules and procedures to regulate their use; harmonised rules and procedures for checkpoints throughout the EU; a clear, simple and transparent process for obtaining PIC; and consistency amongst Member State (national) legislation to implement the Protocol.
- Clarity on the use of genetic resources where a permit does not accompany legally obtained genetic resources (e.g. because the resources were obtained before a permit was required, or from a country that does not issue permits).
- Viable checkpoints for which the authority should have the technical ability to assess compliance and where transparency, efficiency and legal certainty can be provided and maintained. Europabio advocates for a checkpoint established either within the designated national focal point or the competent national authority.

Capacity building needed for the sector?

As many biotechnology companies in Europe have fewer than 50 employees, capacity building might be needed for this segment of the sector.

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Valentina Siddi (Europabio) and Dominic Muyldermans (Croplife International), 13 February 2012, Brussels

PUBLIC CONSULTATION MATERIAL

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Replies from:

- CABI
- Europabio
- EFPIA

FOOD & BEVERAGE– SECTORAL SHEET

1. The sector and ABS

Different activities of the Food and Beverage (F&B) sector may trigger the application of ABS requirements :

- Research leading to an innovation of a food bio-process. For instance, in the cheese production sector, the introduction of genetically modified chymosin from yeast replaced rennet (a complex of enzymes extracted from the stomach of calves). This type of biotechnological innovation relies on the utilisation of genetic resources (particularly microbial genetic material).
- Research leading to innovation of the food product itself, through the introduction of a new nutritive ingredient or a new flavour or colour. This kind of activity may involve the utilisation of genetic resources. As the innovation is based on the novelty of the resource, it will likely involve bioprospecting of new or rare genetic resources as well as traditional knowledge associated to it.
- The commercialisation and marketing of a food product based on the properties associated to its genetic specificities. This applies to food products (raw material) in relation to which the academic research sector has discovered some particular properties. Whether the targeted material is newly marketed or not, the industry can base its marketing on the latest knowledge and claim further properties in relation to the specific food product (e.g. functional food). Bioprospecting of wild genetic resources and the use of traditional knowledge associated with them are relevant for this activity. Yet, in this case, the material acquired through the bioprospecting activity of the F&B industry is not collected with the purpose of utilisation, but for the purpose of direct commercialisation as bulk material.

2. Size and characteristics of the sector

Definition/description of the sector

The Food and Beverage (F&B) industry is a sector which covers a wide range of activities from farming (agriculture, aquaculture etc.), to food processing, distribution, retail and catering (IMAP, 2010). However, for the present analysis, the focus will be on food and beverage manufacturing which covers food production and processing and excludes farming, distribution, retail and catering (Leis, 2010).

Within the F&B industry, multiple subsectors undertake different activities as described in Table 1 below.

Table 1: Food and Beverage Industry branches

Branch	Description
Meat	Production, processing and preserving of meat and meat products. Concerns meat of all species of animals
Fish	Production, processing and preserving of fish and fish products. Includes fish, crustaceans and molluscs. Excludes activities of vessels engaged in fishing, processing and preserving.
Fruit and vegetables	Production, processing and preserving of fruit and vegetables. Includes processing and preserving of potatoes, manufacture of fruit and vegetable juices and processing and preserving of fruit and vegetables not elsewhere classified.
Oils and Fats	Manufacture of vegetable and animal oils and fats. Includes production of crude oils, non-edible animals' fats, refined vegetables oils, manufacture of margarine and similar edible fats.
Dairy	Manufacture of dairy products.
Cereal based	Manufacture of grain mill, starches and starch products. Manufacture of bread, fresh pastry goods and cakes Manufacture of rusks and biscuits, preserved pastry goods and cakes Manufacture of macaroni, noodles, couscous and similar products
Beverages	Manufacture of beverages Excludes fruit and vegetable juice.
Sugar	Manufacture or refining of sugar Excludes sugar confectionery.
Food industry	Manufacture of food products and beverages.

***Source*:** EC, 2006

Within the various activities undertaken by the F&B industry, food processing and manufacture is the process by which bulky, perishable and inedible raw materials are transformed into useful, shelf stable and palatable foods or potable beverages (FAO, 2011).

Innovation in the food processing activity is not equally spread among the various branches of the sector. Fruit and vegetable preservation, dairy production and the processing of grain mill products, starches and starch products tend to be the more innovative fields whereas fish and meat processing are the less innovative (Leis, 2010).

More generally, the F&B sector does not follow the same pattern of other sectors as regards innovation. Continuity and traditional food production are very valuable to the consumer (Leis, 2010). Moreover, for safety reasons, incremental innovations are favoured to radical ones (Senker and Mangematin, 2006). In sum, radical innovations are not the drivers of the whole F&B industry and existing innovation are often not visible in the end product (Leis, 2010). This does not mean that the sector does not innovate. The novel food, ingredients and flavours subsectors rely on innovation and research-intensive activities.

It is possible to classify the different food products upon their innovative characteristics.

- Traditional food: the value of the food product lies in the continuity of the production methods. It covers for instance, wine, cheese and beer. Food technology can nevertheless bring novelty in the process though not in the end product. For instance, bioprocesses like fermentation require enzymes which can be produced through the genetic modification of microbial material.
- Novel food: as opposed to traditional food, the characteristic of such food is

"novelty". According to EU law, novel food is: "food and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 may 1997 (Regulation 258/97)". Those food products are generally highly innovative. They can rely on food chemistry, food biotechnology or the discovery of new natural products (Leis, 2010).

- Functional food: functional food products are characterised by the fact that they are marketed on the basis of their particular effects on health. They include sports and energy drinks or dairy products like margarine (Leis, 2010).
- Nutraceuticals: They refer to dietary supplements which are meant to also have therapeutic effects (Leis, 2010).
- Natural and organic food and ingredients: the innovation of these food products mostly consist in the substitution of artificial additives (like flavour, colour or conservatives) by natural ones. This subsector is thus interested in natural functional ingredients with specific properties (Leis, 2010).

Besides these different classifications of food products, two broader types of companies can be distinguished:

- Agriculture-oriented firms either process raw food materials to be suitable for further manufacture (e.g. sugar refining) or preserve the commodity. Innovation may focus on processing the raw material into its basic component (sugar, fat, proteins) so as to produce standardised intermediate products with well-defined technological and nutritional characteristics (e.g. thickeners, sweeteners, concentrates, flavouring, colouring) (Senker and Mangematin, 2006). Ingredients, flavours & colours companies belong to this category.

- Consumer-oriented firms manufacture more highly processed convenience food (e.g. breakfast cereals) based on inputs of agriculture-oriented firms. Innovation is connected with preservation or packaging techniques that extend shelf life and new process technologies that allow them to introduce new consumer products (Senker and Mangematin, 2006).

Global market/size and development prospects

The global F&B industry was valued $5.7 trillion in 2008 and is expected to grow at a compounded annual growth rate of 3.5% to $7 trillion in 2014, following the global population growth. Those figures include the global food product industry (from agricultural products to packaged food) generating $3.2 trillion revenue and the beverage industry (soft drinks, beers, ciders spirits and wines) valued $1.4 trillion in 2008 (IMAP, 2010).

EU market (size of the market/sector and importance for the EU economy)

The European F&B sector accounts for the largest share in the global F&B industry market, with a turnover of €956.2 billion in 2010 and employing 4.1 million people (FoodDrink Europe, 2011). In the EU, five countries, namely France, Germany, Italy, Spain and the UK, hold around 70% of the overall turnover. However, when looking at the turnover per capita, the leading Member States are Ireland, Denmark and Belgium (EMCC, 2006). The F&B industry is the largest manufacturing sector in the EU, accounting for 16% of the turnover of manufacturing in the EU27 area (FoodDrink Europe, 2011).

While the EU continues to be the world's largest food and drink exporter, the EU market share of global exports of food and beverage products has been slowly declining over the last years (from 20.1% in 2001 to 17.8% in 2010), mostly to the benefit of emerging economies: Brazil, China, Thailand and Argentina (FoodDrink Europe, 2011).

Economic relevance of utilization of genetic resources for the sector in Europe
Food biotechnology and to a lesser extent food chemistry are the main research fields utilising genetic resources in the sector. R&D can focus either on food processing activities (e.g fermentation, disease diagnosis) or food stuff production (e.g additives, flavours, probiotics in dairy products) (FAO, 2011; Senkers and Mangematin, 2006; EFB, 1994).

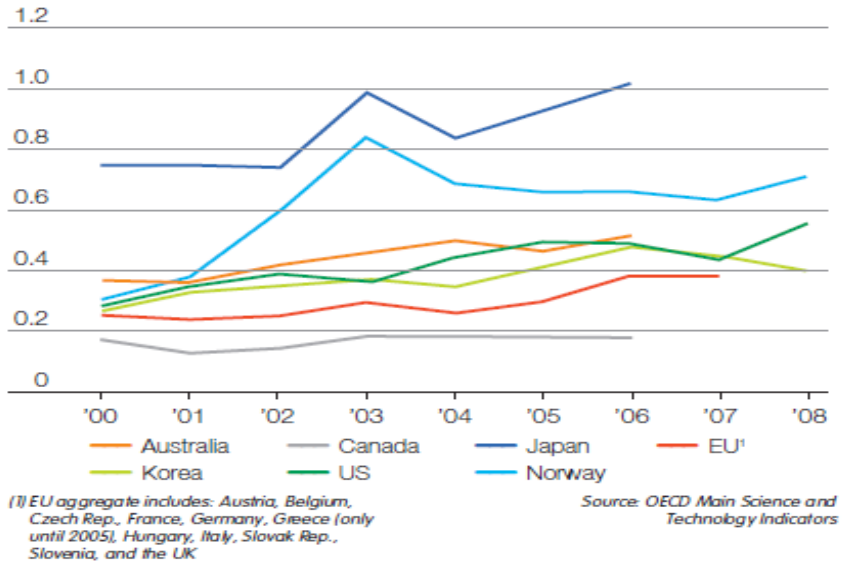
- Fermentation/biocatalysis: this particular process is based on the anaerobic activity of microbial organisms (fermentation) or isolated enzymes (biocatalysis) transforming complex organic substances into simpler ones. Fermentation is a biotechnological process which has the primary aim of extending the product shelf life and/or enhancing the quality and safety of a given product. It is also used to produce a variety of metabolites including vitamins, antimicrobial compounds enzymes, flavour, fragrance and food additives. Innovation of the fermentation process will not necessarily modify the end product (Lidder, 2011). The global economic turnover of the production of enzymes relevant to the food industry is estimated to be around €390-585 million (Zika *et al*, 2007).

- Probiotics: it refers to live microorganisms which are administered in a certain amount in order to confer a health benefit. It is widely used in feed for livestock, fish or dairy products (Lidder, 2011).

- New ingredients / additives: the process consists in adding a new ingredient to a standard food product, whether it is natural or artificial. The end product based on this kind of innovation will have a new composition and properties. "Additive" is defined in EU law (Council Directive 89/107/EEC) as "any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods". In other words, it refers to artificial or natural emulsifiers, stabilisers, thickeners, sweeteners, antioxidants, preservatives, flavour enhancers and colours.[214]

[214] European Food Information Council website, (2006), "Food Additives". Available at http://www.eufic.org/article/en/food-safety-quality/food-additives/expid/basics-food-additives/

Table 2: R&D as a percentage of industry output for food and beverage industries (%)



***Source*:** FoodDrink Europe, 2011; OECD Main Science and Technology Indicators, 2008.

The general R&D expenditure in the food and beverage industry, however, represents only 0.38% of the industry output (FoodDrink Europe, 2011). This R&D figure is particularly low as in this sector innovation primarily comes from know-how and on-going process improvements rather than formal R&D (Senker and Mangematin, 2006). The food ingredients subsector (flavouring and colouring) is an exception, relying on high-tech and more radical innovation, with R&D activities more similar to the pharmaceutical industry (Senker and Mangematin, 2006). Compared to the pharmaceutical industry, however, development cycles in the F&B sector are much shorter. In fact, the development of food products generally does not take more than three years (Laird and Wynberg, 2012).

A major segment of scientific innovation activities relevant to the F&B sector, moreover, appears at earlier stages of the user chain. For instance, to modify food raw materials, the sector mostly relies on the innovation activities of the seeds and green biotechnology industries (Senker and Mangematin, 2006). In sum, as the innovation activity in the F&B sector is not predominantly science based - focusing mostly on incremental change to, *inter alia*, product formulation or design (Senker and Mangematin, 2006) - the overall economic relevance of "utilisation" of genetic resources by the sector itself is be expected to be relatively low.

Any EU companies that are market leaders? / Any EU organisations that are leaders in the sector?

Many EU F&B companies are global market leaders in terms of global sales. Those include, *inter alia*, Anheuser-Busch InBev (Bel), Unilever (UK-Nth), SABMiller Plc (UK), Heineken (Nth), Danone (Fr), Lactalis (FR), Associated British Food (UK) and Diageo Plc (UK).

Table 3: Ranking of World Agri-food companies by Food and Drink sales

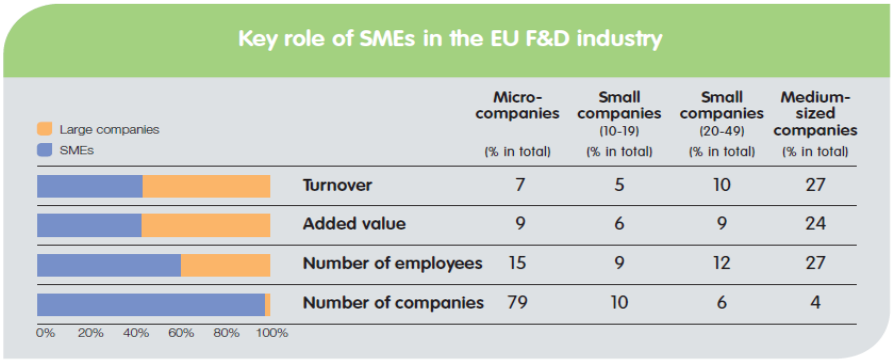
Name	Head-quarter	Fiscal year end	Sales in € billion	Net growth to previous year (%)	Employees (x1000)	Main sectors
Cargill	US	May11	88.8	18.0	130	*multi-product*
Nestlé	CH	Dec11	67.8	7.5	328	*multi-product*
Archer Daniels Midland	US	Jun11	60.2	24.0	31	*cereal processing*
PepsiCo Inc.	US	Dec11	47.8	15.0	285	*beverages, snacks*
Kraft Foods Inc.	US	Dec11	39.1[1]	6.6	127	*dairy, snacks, beverages*
The Coca-Cola Company	US	Dec11	33.4		146	*beverages*
Anheuser-Busch InBev	BE	Dec11	28.6	4.6	114	*beer*
Tyson Foods Inc.	US	Oct11	23.2	13.6	115	*meat*
Unilever Plc/Unilever NV**	NL/UK	Dec11	22.8	6.5	171	*multi-product*
Mars Inc.	US	Dec11	21.6		65	*prepared foods, confectionery*
SABMiller Plc	UK	Mar11	20.3	7.4	70	*beer*
Kirin Brewery Company Ltd	JP	Dec10	18.7	4.9	32	*beer, alcoholic beverages*
Heineken N.V.	NL	Dec11	17.1	6.1	64	*beer*
Groupe Danone	FR	Dec10	17.0	6.9	81	*dairy, waters, baby & med. nutrition*
Suntory Ltd.	JP	Dec10	15.0	12.4	25	*alcoholic beverages*
Lactalis	FR	Dec10	14.7		52	*dairy products*
Asahi Breweries Ltd.	JP	Dec10	13.4	1.2	17	*beer, alcoholic beverages*
Associated British Food	UK	Sep11	12.8	9.0	102	*sugar, starch, prepared foods*
Diageo Plc	UK	Jun11	11.4	3.0	24	*alcoholic beverages*
Fonterra	NZL	Jul11	11.3	19.0	17	*dairy products*
General Mills Inc.	US	May11	10.7	2.0	35	*prepared foods*
Kellogg Company	US	Dec11	9.5	6.5	31	*breakfast cereals, convenience food*
FrieslandCampina NV	NL	Dec10	9.0	10.0	19	*dairy products*
Vion	NL	Dec10	8.9	-2.0	27	*multi-products, ingredients*
ConAgra Foods Inc.	US	May11	8.8	1.8	23	*prepared foods*
Smithfield Foods Inc.	US	Apr11	8.8		46	*meat, processed foods*
Dean Foods Company	US	Dec10	8.7	3.3	26	*dairy products*
HJ Heinz Company	US	Apr11	8.1	2.8	35	*prepared foods*
Ferrero	IT	Aug11	7.2	9.1	22	*confectionery*
Sara Lee Corporation	US	Jun11	6.5	4.1	21	*prepared foods*

Source: FoodDrink Europe, 2011

Relevance of SMEs

A large number of SMEs dominate the food industry in the EU: 99.1% of the enterprises are SMEs, which employ 63% of the workers in the industry and account for 48.7% of the industry's total turnover. More specifically, micro-enterprises (1-9 employees) represent 79% of all companies. Small (10-49 employees) and medium-sized (50-249 employees) companies account for 16% and 4% respectively, while large companies (250+ employees) account for close to 1% percent of all European food industry companies (FoodDrink Europe, 2011).

Table 3: Role of SMEs in the EU F&B industry in 2009



Source: FoodDrink Europe, 2011

As regards innovation, SMEs have a lower impact than large companies (see Table 4).

Table 4: Innovation activities growing with the size of companies

Major innovators[3] in the last 3 years (%)	
Micro companies	30
Small companies	31
Medium-sized companies	42
Large companies	62
No innovation in the last 3 years (%)	
Micro companies	23
Small companies	15
Medium-sized companies	12
Large companies	7

***Source*:** FoodDrink Europe, 2010

3. Types and role of genetic resources use in the sector/ characteristics of the user chain

Food biotechnology is developing food processing techniques based on microbial genetic resources that are used for the manufacturing and the bioprocessing of food and drinks. Genetic resources involved in the processing-technique are not necessarily present in the end product (Zika *et al*, 2007). Moreover, the F&B industry undertakes bioprospecting in relation to genetic resources which are then used as new ingredients, especially in the flavouring industry or other ingredient supply companies (Laird and Wynberg, 2012).

Sector-specific collections or databases of genetic resources
No information available.

Relevance of basic and applied research 'utilizing genetic resources' for (innovation in) the sector
Generally, the F&B industry itself is a low tech industry which generally does not heavily rely on basic sciences (EC, 2006). However, firms maintaining close links with academic research may often take advantage of the general improvement of the knowledge created by academic research for further innovation in their field (Senkers and Mangematin, 2006).

Applied research "utilising genetic resources" for innovation in the F&B sector is particularly carried out in the field of food biotechnology (see section 2 above). Food biotechnology is not so much undertaken by dedicated biotechnology firms. Rather, multinational companies will often collaborate with one or several public research institutes (Senkers and Mangematin, 2006).

Relevance of genetic resources for product development and for products placed on the market
As mentioned above, the food and beverage industry relies significantly on genetic resources for product development and marketing (Laird and Wynberg, 2012).

Protection of innovations in the sector

Innovations in the sector are typically incremental and through on-going improvement rather than formal R&D leading to radical innovations. New products are mainly extensions of older ones (EC, 2006). However, exceptions exist, particularly in the subsector of food ingredients with flavours and colours (Senker and Mangematin, 2006) and more generally where food biotechnology is involved.

- **Trade secret**: Innovations in the F&B sector are mostly protected by trade secrets, either in terms of a particular process or formulation of a product (e.g Coca Cola) (Leis, 2010; Senker and Mangematin, 2006).

- **Patent:** The F&B sector is responsible for a relatively low number of patent applications. This is not surprising given the very low R&D expenditure in the sector and the fact that the sector is dominated by SMEs which have a lower propensity to make patent applications (Senker and Mangematin, 2006). While food/drinks products and processes for food/drinks production are technically patentable, e.g. low-fat products or products that due to shape or composition have visible advantages, most of them do not fulfil the criteria of usefulness, novelty and non-obviousness for getting a patent granted (Leis, 2010). Among subsectors, it can be noted that grain mill and starch product industries record the highest amount of patent, followed by the fruit and vegetable processing and preservation, then drinks and other food product sectors. However, the relevance of utilisation of genetic resources in the patent applications of those subsectors is unknown. Finally, while biotechnological innovations with application to food and drinks production are more likely to be related to the utilisation of genetic resources and to be protected by patents, those are often developed by research institutes or companies which are technically considered to be outside the F&B industry (Leis, 2010).

Relevance of traditional knowledge associated with genetic resources

The food and beverage industry, together with the cosmetics industry, relies significantly on traditional knowledge, which is often the starting point for new product development. Novel species have become increasingly important in this sector, as well as the traditional knowledge associated with these species. Traditional knowledge may also be used as a marketing tool to demonstrate product efficacy and safety (Laird and Wynberg, 2012).

4. Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting

The food and beverage industry relies significantly on genetic material sourced from the wild for their product development and marketing. The interest of the F&B industry in "wild resources" and associated traditional knowledge has also increased in recent years (Laird and Wynberg, 2012). However, generally the F&B industry itself tends to be mostly interested in the sourcing of bulk raw (biological) material for the further production of the final food product (Laird and Wynberg, 2008). In fact, the F&B industry undertakes bioprospecting mostly in relation to resources which are then used directly as new ingredients, especially in the flavouring industry or other ingredient supply companies

(Laird and Wynberg, 2012).

Relevance of EU and non-EU collections, gene banks, databases
Ex situ collections that are most relevant to the F&B sector are culture collections, from which microbial genetic resources are widely sourced for their application in food biotechnology (FAO, 2011).

Relevance of acquisition of GR directly in countries providing such material
As the case study described in the section below demonstrates, F&B industries are sometimes the direct addressees of PIC and MAT. Quantitative information is however not available.

5. Existing approaches as regards ABS in the sector

General approach to ABS
Food & beverage companies have very little awareness of ABS obligations (Laird and Wynberg, 2008). The sector at EU level has also shown little interest in the stakeholders' consultation process relating to the Nagoya Protocol implementation at EU level.

Voluntary initiatives and best practices
Union for Ethical Biotrade (UEBT): The UEBT standard was developed in 2007 and is designed to help companies advance the objectives of the CBD. In particular, Principle 3 of the standard focuses on equitable benefit-sharing through guidance on negotiating access and benefit-sharing agreements for the use of genetic resources or the traditional knowledge associated with genetic resources (EC public consultation, 2011). UEBT is also working with its members to develop tools that can facilitate the implementation of such agreements such as agreement templates and model contractual clauses.

The standard covers cases where a UEBT member's activities require ABS measures in a given jurisdiction. Independent verification of compliance can be obtained through the Rainforest Alliance or Ecocert to assess their biodiversity management system and report on their progress towards implementation (UEBT, EC public consultation, 2011). Public summaries of audits and annual progress reports are also provided for through the standard.

However, only two members of this initiative are EU companies connected to the food and beverage sector (Blue Sky Botanics, UK and Organic Herb Trading Co., UK).

Forerunners implementing ABS best practices
No information available.

Existing access and/or benefit sharing agreements: case examples
The Dutch company Health and Performance Food International concluded an ABS agreement in order to introduce the traditional Ethiopian cereal Teff to the western market. This cereal had the benefit of not containing any gluten which some people cannot digest. In 2004, the company signed an ABS agreement with the Ethiopian government whereby monetary as well as non-monetary benefit sharing were considered. Monetary

benefits included royalties on the net profit of the sale of basic seeds, percentage of the gross income of the company and the contribution to a fund dedicated to local farming communities. Non-monetary benefits included the sharing of results of research related to the resource, the involvement of local scientists in the research, contribution to the local economy by the company establishing profitable joint venture Teff businesses in the country (FAO, 2010; Turkensteen, 2008).

6. Current problems/issues as regards ABS (with possible definition/information to be added for specific issues if some issues (very) important for the sector's operations)

Due to the very low interest and awareness as regards ABS legislation and the lack of internal information on the role of genetic resources in the sector by representatives of the EU food and beverage industry, this sector did not get involved in the stakeholder consultation process. Several representatives of the F&B industry were not able or willing to entertain interviews for the purpose of complementing the information contained in this sectoral sheet. As a result, current problems and issues for this sector with regard ABS could not be identified.

Nevertheless, from the similarities between the supply chain of this sector and the supply chain of the cosmetics industry, potential problems and issues may be inferred by looking at the relevant section in the cosmetics industry sectoral sheet.

7. What are key needs for the sector as regards ABS rules development and implementation and what are preferred implementation options?

Due to the very low interest and awareness as regards ABS legislation and the lack of internal information on the role of genetic resources in the sector by representatives of the EU food and beverage industry, this sector did not get involved in the stakeholder consultation process. Several representatives of the F&B industry were not able or willing to entertain interviews for the purpose of complementing the information contained in this sectoral sheet. As a result, the key needs for this sector with regard ABS rules development and implementation could not be identified.

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Interviews
No interviews have been conducted, as representatives of the food and beverage industry have not been found able or willing to participate in this study.

Public Consultation Material
EC Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, October-December 2011.

Replies from:

- Union for Ethical Biotrade (UEBT)