EU submission in response to Notification 2008-104 to the ABS Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches - Windhuk 2-5 December 2008

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I - GENERAL COMMENTS

Article 2 of the CBD defines "biological resources" as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity". "Genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity", while "genetic resources" are defined as "genetic material of actual or potential value".

Gelöscht:

Following from these definitions genetic resources are a subset of biological resources and genetic material. As such, all biological resources could contain a genetic resource. What distinguishes genetic resources is that they are material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value. In this regard, there seems to be a common understanding of the Parties that they do not wish an international regime to cover biological resources in the sense of bulk commodities, such as timber.

There is a diversity of interpretation of genetic resources. Given the context of Article 15, most of these interpretations focus on utilization, whether that is the "intended utilization" of a genetic resource or typical utilization activities that result in capturing the real or potential value of genetic resources

Genetic resources are used in a variety of different ways in different sectors. However, it is quite difficult to establish strict boundaries among different (economic) sectors using genetic resources as defined by the CDB. Pharmaceutical industries, plant breeding and animal breeding sectors, cosmetics and perfumes companies, food production and processing firms, have been identified as main users groups. The "biotechnological sector" is more difficult to characterize. Some biotechnology companies are involved in bio prospecting activities. Other biotechnology companies are best characterized as providers of genetic resources or genetic material for a diversity of economic activities and may thus resemble more what is commonly referred to as "intermediaries".

Research activities must be considered with particular attention. The research sector, including biodiversity research, and research on genetic resources, plays a key role in developing critical knowledge for the effective implementation of the CBD and the achievement of its three objectives. In that respect the EU wants to underscore the eminent importance of simplified access to genetic resources for non-commercial research while recognizing that steps to clearly identify non-commercial intent is important for generating confidence and trust with providers of genetic resources.

It is critical that the international ABS regime provides the flexibility to accommodate differences in the current or future utilization of genetic resources in and between different user groups. If this is not achieved, the international ABS regime risks preventing potential users from seeking access to genetic resources that fall within the scope of the international ABS regime. This would run counter to the CBD, its objectives and provisions relevant to access and benefit-sharing.

One important option for taking into account different characteristics of groups or sectors utilizing genetic resources while disseminating best practices in ABS across sectors is the development of sectoral model clauses for potential inclusion in Material Transfer Agreements. Such optional model clauses could enhance legal certainty for both providers and users of genetic resources and support the fair and equitable sharing of benefits arising.

II. SPECIFIC COMMENTS ON THE TERMS OF REFERENCE OF THE TECHNICAL EXPERT GROUP

What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

Genetic resource / biological resources

Article 2 of the CBD defines "biological resources" as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity". "Genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity", while "genetic resources" are defined as "genetic material of actual or potential value".

It follows that genetic resources are a subset of biological resources and genetic material. As such, all biological resources could contain a genetic resource. What distinguishes genetic resources is that they are material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value.

In addition, Articles 15(1) and (2) recognise the ability fo Parties to determine access to genetic resources while requiring them to endeavour to facilitate access for environmentally sound uses. In addition, Article 15 (7) requires Parties to take appropriate measures with the "aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting party providing such a resource…". Article 15(6) also refers to scientific research based on genetic resources.

The actual or potential value of genetic resources is therefore determined by the potential for utilisation, i.e. it is their use of the functional units of heredity which will distinguish them from genetic material or biological resources.

Various interpretations of genetic resources have been put forward by commentators[1]. Given the context of Article 15, most of these interpretations focus on utilisation, whether that is the intended utilisation of a genetic resource or typical utilisation activities that result in capturing the real or potential value of genetic resources.

The EU takes note of the ongoing discussion on genetic resources that constitute pathogens in the World Health Organization. It emphasises that the international ABS regime needs to be sufficiently flexible to address, if necessary, such emerging issues.

Derivatives and Products

The CBD does not include a definition of the terms "products" nor of "derivatives" in relation to Article 15. The terms are used in the Bonn Guidelines in the context of Mutually Agreed Terms (MAT)[2]. As such, the EU recognizes that users and providers will determine whether and to what extent "derivatives" or "products" will be covered by benefit-sharing arrangements established on mutually agreed terms. Mindful of Article 19(2), the EU maintains that "derivatives" or "products" should remain outside the scope of any additional and more specified international obligations established by an international ABS regime.

Implications for (a) sectoral approaches and (b) commencial/non-commercial research

As fas as the definition of genetic resources are concerned, it will be necessary to examine how genetic resources are used within different sectors. In focusing on specific uses within different sectors/groups of users, it may be easier to distil which activities would constitute a "utilization of functional units of heredity" of genetic resources, as compared to the use of biological resources as a commodity.

As regards research on genetic resources, distinguishing between research with non-commercial intent and other research activities seems to present similar issues. The difference seems to lie at the purpose of the research activity, rather than in the character of the research activity as such. In view of this, there may be a need to closely examine how access is

[1] Medagilia and Silva, "Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty", IUCN EPLP 67/1 discusses these interpretations in more depth.

[2] Bonn Guidelines, paragraphs 36 and 44(f)(i)

granted for the two activities and the nature of the benefit sharing, rather than the inclusion of the activity within the international regime as such. It is therefore necessary to identify practical and meaningful steps for distinguishing non-commercial research from other, including commercial, uses of genetic resources and for ensuring that simplified access procedures for non-commercial research are established but will not be abused.

As far as derivatives and products are concerned, these should be addressed in the context of mutually agreed terms. Providers and users negotiating mutually agreed terms might benefit from loosely identified "typical" derivatives and products arising from different sectoral activities. It would also raise the level of information available to providers of genetic resources and thereby support levelling the playing field in negotiations on mutually agreed terms.

As regards steps to distinguish between research with non-commercial intent and other research activities, discussions should include the following points : the appropriate classification of research depending on its varying form and objective; steps to ensure that obligations are passed on to subsequent users (see i.a. example of the International Plant Exchange Network IPEN Annex 6 or the Standard Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture); steps that address potential changes in intent by non-commercial users, including through identification of clear reference points for changes in intent, among other.

Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors

This section provides an overview of the main characteristics, different forms of utilization, as well as different ABS arrangements of a selected number of sectors, taking into account the following three questions raised in the terms of references of the technical expert group:

- Identification of stakeholders dealing with genetic resources and their main industrial characteristics;
- Identification of different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;
- Identification and description of sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

1. Pharmaceutical industry

Purpose and main characteristics:

Production and marketing of medicinal products

The pharmaceutical sector is characterised by a great diversity of products/drugs, technologies and markets. A significat part of the pharmaceutical sector's turnover is invested in research and development (R&D). In the interests of reducing research investments and product development time, the pharmaceutical industry relyies heavily on high technologies, such as combinatorial chemistry and computer-based drug design, based on pre-processed electronic data rather than plant material or similar.

Main forms of utilization of genetic resources:

To meet an increasing demand for new products to address a range of illnesses, the pharmaceutical industry is one of the most research intensive industries in the world. Genetic resources have been an important component of that research work. This research work can be characterised in two phases: drug discovery and drug development. Genetic resources contribute in a range of ways to drug discovery.

In the Holm-Muller, Richerzhagen and Tauber study of users of genetic resources in Germany, the pharmaceutical sector responses indicated that the majority of its uses for genetic resources were for development for marketable products, followed by research and development for intermediary purposes and research purposes3.

[3] Holm-Muller, Richerzhagen and Tauber, "Users of Genetic Resources in Germany. Awareness, participation and Positions regarding the Convention on Biological Diversity", BfN-Skripten 126, 2005, p. 96.

Typical acquisitions of genetic resources:

The sector organization is characterised by multiple partnerships with small and medium-sized biotechnology companies. These companies play a leading role in the identification of active ingredients. Pharmaceutical companies get access to genetic material through this type of partnership and certain collaborations with research in provider countries, and more particularly those related to ex-situ collections.

Few pharmaceutical companies engage in bioprospecting activities in provider countries for the acquisition of in-situ genetic resource/material. In those cases where pharmaceutical companies undertake in-situ bioprospecting activities, there seems to be an increasing use of local partner institutions that take on responsibility for obtaining the required approvals and permits. This is one element of an increasing use of partnerships to gain and secure legal access in accordance with national legal requirements. These long term partnerships with bodies in provider countries seem to provide a more stable framework for access and benefit sharing arrangements4.

In terms of benefit sharing, a package of monetary and non-monetary benefits is standard practice5. As many agreements are confidential, it is difficult to provide an accurate guide for monetary benefits. Many will involve royalty payments, combined with certain milestones payments. Non-monetary benefits could include capacity building in the form of information sharing, training as well as establishing and developing scientific and technical facilities in provider countries. These capacity building benefits often form part of partnership arrangements.

In practice it can be noted that there is little standardisation of transactions. The industry is characterised by a web of agreements rather than just one agreement, as well as increasing use of phased agreements. In these cases, there may be an initial research agreement, which is followed by a commercial agreement where the research indicates potential products. In this way, the potential benefits can be more realistically agreed in light of advanced information on potential for development.

There is increasing evidence of pharmaceutical industry interest and engagement in ABS issues. In 2006 the International Federation of Pharmaceutical Manufactures and Associations (IFMPA) agreed "Guidelines for IFPMA members on access to genetic resources and equitable sharing of benefits arising out of their utilisation"6. The Guideline's objective refers to supporting a positive approach to CBD implementation, while providing an outline of industry best practice.

2. Biotechnology

Purpose and main characteristics:

Biotechnology is a cross-sectoral technology providing tools and solutions in various fields of research as well as for the improvement of processes to be used by various industries, e.g. pharmaceutical and seed industries as most common partners, but also used in a wider context such as chemical engineering, information technology or environmental remediation

Gelöscht:

The biotechnology sector is characterized by its variety of activities, thus acting both as a user and provider of genetic resources. Biotechnology industries span a range of sectors but are important features within the pharmaceutical and agricultural sectors.

Main forms of utilization of genetic resources:

The pharmaceutical industry contains the largest segment of biotechnology and its techniques are increasingly used in the research procedures describe above. The second largest segment of biotechnology is found in the agricultural sector. Biotechnology is speeding up the process of both drug development and development of new varieties of crops and breeds. In the seed industry, e.g. biotechnology processes are applied to improve plants, in particular the major crop varieties. In particular, they are used for the accurate selection and delivery of desired characteristics, to transfer genes from one species to another, to remove undesirable characteristics, such as allergenic and toxic compounds, and to produce varieties, e.g. with better performance and enhanced environmental adaptation.

[4] See in particular, Sarah Laird and Rachel Wynberg in "Access and benefit sharing arrangements in existing sectors", UNEP/CBD/WG-ABS/6/INF/4/Rev 1, p. 30, paragraph 16

[5] Sarah Laird and Rachel Wynberg , "Access and benefit sharing arrangements in existing sectors", p. 23.

[6] See http://www.ifpma.org/Issues/CBD

Biotechnology companies are largely involved in the development of products and processes in a variety of sub sectors, including chemicals, pulp and paper, textiles, food, environmental technologies (e.g. disposal of waste and bioremediation) and energy. The industry is heavily reliant of the use of enzymes, many of which are derived from micro-organisms, in order to catalyse and speed up biological processes. For example, in environmental technologies, bioremediation systems are based on the degradation functions of micro-organisms7. In particular, there has been increasing interest within the biotechnology industry in micro-organisms for extreme environments, as they may provide novel and valuable characteristics that can withstand heat or cold or toxic environments, which can be utilised within industrial processes. As such, this sector is likely to continue to rely on genetic resources found in-situ, on farm as well as material in existing collections.8.

Typical acquisition of genetic resources:

Biotechnology industries acquire their genetic resources from ex-situ sources and intermediaries (catalogues, gene banks, certified centres). Some rare exceptions engage in-situ activities. Given the diversity within this sector, there is again little standardisation of transactions and multiple forms of arrangements and contracts.

The establishment of partnerships is one way of arranging transactions within this sector, with both monetary and non-monetary benefit sharing provisions. For example, the Novozymes and Derversa agreement with the Kenyan Wildlife Service and International Centre for Insect Physiology and Ecology includes running royalties on any commercial product developed (the rate of which is confidential), plus an upfront payment, a lump sum for the costs of collection and laboratory work and milestone payments, as well as establishment of a microbial discovery laboratory,and materials for screening and training9. In terms of royalties, Laird and Wynberg indicate the range of royalty payments for the industrial enzyme sector is lower than for the pharmaceutical given its lower profit margin approximately 0.5-2%10.

3. Agricultural sector

a. Plant Genetic Resources for Food and Agriculture (PGRFA, incl. Plant Breeding Sector and Horticulture)

Companies involved in the production of new varieties of plants are directly concerned by the use of genetic resources. An important part of the R&D in this sector is financed jointly by public research and private investments. The seed sector is mainly dependant on *ex-situ* collections. A great part of the genetic material is acquired via intermediaries, through gene banks and botanic gardens or/and using their own collections. Some companies have undertaken certain bio-prospecting activities in developing countries in order to obtain wild genetic resources. But these *in-situ* activities in provider countries are marginal compared to the rest of the plant breeding activity. Plant breeding industry consists in general of multiple of crosses of pre-existing varieties which themselves have been by using different gentic resources. Thus, it is difficult to make a distinction between the initial genetic resource and the final new variety. In the whole process to obtain of a new variety, the breeder is using different sources of genetic resources, making it virtually impossible to identify the precise contribution of each of them.

The plant breeding industry is characterized by free access for breeding purpose to any improved and protected material. It established rules for benefit–sharing according to the provisions of the International Union for the Protection of New Varieties of Plants (UPOV).

In 2004, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), negotiated in harmony with the CBD, has entered into force and fixed common rules for access and benefit sharing for plant genetic resources of 64 plant species / genera of crucial importance for food and agriculture. Genetic resources of these 64 plant species/genera which are under the management and control of the Contracting Parties and in the public domain are included into the Multilateral System established under the ITPGRFA. They are freely accessible for the purpose of utilization and conservation for training, research and breeding for food and agriculture with the exemption of non-food/feed uses. In the case of commercialisation of a product incorporating plant genetic resources for food and agriculture (PGRFA) accessed from the Multilateral System, the recipient agrees to share the new product with others for

[7] Ten Kate and Laird, “Commercial Uses of Biodiversity”, p229
[8] Laird and Wynberg, “Access and benefit sharing arrangements in existing sectors” UNEP/CBD/WG-ABS/6/INF/4/Rev 1, p. 8.
[9] Laird and Wynberg, “CBD Technical Series No. 38 “ABS in Practice: Trends in Partnerships Across Sectors”, p. 57.
[10] Laird and Wynberg, “The Commercial Use of Biodiversity”, UNEP/CBD/ABS/4/INF 5, p.28.

further research and breeding. Where there is a condition limiting further use to research and breeding only, the recipient must pay a percentage of the sales of any commercialised product into a common fund to support the conservation of genetic resources and further development of agriculture.

The Governing Body of the ITPGRFA and the FAO Commission on Genetic Resources for Food and Agriculture are further considering access and benefit-sharing issues in relation to PGRFA of plant species and genera as well as non-food/non-feed uses not included in the MLS under the ITPGRFA.

b. Animal Genetic Resources for Food and Agriculture (AnGRFA, incl. Animal Breeding Sector)

The EU sector of farm animal genetic resources is very diverse:

- A limited number of species are used for food and agriculture production, most of them is represented by many populations (breeds). Genetic variation between breeds is as high as within breeds; existence of variation between individuals within breed enables selection and genetic progress. In many circumstances breeds are overlapping and cannot be clearly dissociated from each other. In many cases the origin of breed cannot be clearly defined. Wild relatives are almost not used in animal breeding.

- Breeds are classified as local (kept in one country only), transboundary regional (kept in several countries in one region only) and transboundary international (common worldwide). Modern high input international breeds have major contribution to commercial food production.

- The majority of local and regional breeds are subject to local and/or national breeding, undertaken by farmers or groups of farmers/cooperatives. The international breeds are subject to intensive selection programmes and are developing dynamically. Their breeding programmes are usually run by breeders associations, farmers' co-operatives and private (international) companies.

- AnGR are privately owned (by farmers or by breeding companies) and are subject to private transaction practices. AnGR kept by pastoral people might be collectively owned with customary law guiding exchange of livestock. Public gene banks are very rare, end have been established for conservation purposes, so have no role in exchange of AnGR (in contrast to PGR).

- A significant international trade (in the form of semen, embryos or live animals for reproduction) is generally limited to international breeds or commercial lines. The gene flow essentially takes place between developed countries; there is a growing importance of the flow of highly performing breeds from developed to developing countries. There is currently hardly any gene flow from local breeds to commercial breeds. The use of wild relatives is almost negligible for farm animal genetic resources.

The current legal forms of AnGR exchanges and utilisations are the following:

- The possibility to attach IPRs to new animal breeds or lines is limited worldwide (impossible in Europe, while poultry lines can for example be protected in the US), but patent for biotechnological inventions based on AnGR can now be obtained almost worldwide11;

- With regard to animal breeding, the flows of genetic resources take the form of semen or breeding males sales or embryos or live animals for reproduction purposes, without any restriction on potential further uses as a genetic resource (such as breeding, biotechnology inventions…) ;

- Commercial trade of AnGR is subject to an established regulatory framework (EU - zootechnical legislation). These harmonised principles are directed to ensure free trade of breeding animals and their genetic material, sustainability of breeding programmes and preservation of genetic resources. For example, harmonised certificates exist for intra-Community trade of breeding animals, semen and embryos with detailed information on the origin and genetic values.

[11] Including the EU according to the Directive 98/44/EC on the legal protection of biotechnological inventions.

- With regard to research, exchanges of AnGR are generally covered by classical scientific cooperation contracts (where each party keeps the property of its inputs in the project and where they share the scientific results, publication and potential IPRs).

The FAO Global Plan of Action for Animal Genetic Resources provides a technical and operational framework for assisting countries in particular in the development of national strategies for the management of animal genetic resources, and supporting effective action in the sustainable intensification, conservation, characterization and access to AnGRs. The FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), being the most relevant forum for farm animal genetic resources stakeholders and issues, addresses access and benefit-sharing for ANGRFA as part of its MyPoW .

The FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) also addresses, as part of its MyPoW access and benefit-sharing for aquatic genetic resources for food and fisheries, forest genetic resources and genetic resources of micro-organisms and invertebrates for food and agriculture.

4. **Fragrance and cosmetics**

Purpose:

Marketable products for natural personal care.

Main forms of utilization of genetic resources:

The natural personal care industry increasingly seeks raw material for product development. Genetic resources are used in relation to extraction, identification and synthesis of new compounds. Botanicals, marine organisms and vitamins provide active compounds that can contribute to a products efficacy and replace petrochemicals and synthetic ingredients. Nevertheless, most of the fragrance and cosmetic industry is based on the use of biological material and products, which are exchanged according to trade rules principles.

Typical acquisition of genetic resources:

The "natural" characteristic of the products is a major asset in sales. For this reason, the fragrance and cosmetic sector is dependent on reputation and image to gain market shares. Even if most of their activity is not subject to ABS negotiations, the fragrance and cosmetic sectors ask for legal certainty for their activities.

As a result, the natural personal care industry and botanicals seems to develop business partnerships with their suppliers and they link the benefits more to the supply of the raw materials, for example by paying premium prices and capacity building through job creation provision of equipment and training to enhance the supply system. Again, there is growing evidence that some companies interest in corporate responsibility to meet consumers growing demands for ethical goods12. The case study of Aveda's sourcing partnerships in Western Australia for Sandalwood is a good example of an enhanced corporate responsibility partnership[13].

5. **Non-commercial research and other research activities**

Purpose:

Biodiversity research, including research on genetic resources, plays a key role in developing critical knowledge for the effective implementation of the CBD and the achievement of its three objectives. In that respect the EU wants to underscore the eminent importance of simplified access to genetic resources for non-commercial research (such as

[12] For example the Union for Ethical Biotrade Verification Framework, http://www.ethicalbiotrade.org/verification/verifiers/

[13] Laird and Wynberg, "CBD Technical Series No. 38 "ABS in Practice: Trends in Partnerships Across Sectors", p. 75.

taxonomic work), while recognizing that steps to clearly identify non-commercial intent is important for generating confidence and trust with providers of genetic resources. [14]

Main forms of utilization of genetic resources:

It is difficult to characterise "research" as a user sector of genetic resources as research on genetic resources includes a range of institutions, processes and activities. While this user sector is mainly characterized through its intent, namely not-for profit research on a genetic resource, it overlaps with other commercial uses. Areas where not-commercial research is untertaken are e.g. taxonomic research, the development of biodiversity inventories or biodiversity assessments. It is critical to underscore the eminent role of research on genetic resources with non-commercial intent.

Discussions on the utilisation of genetic resources for "research" should also give recognition to the special role of botanical gardens – or other ex-situ collection organizations such as museums and zoos- that identify, collect, preserve/conserve and exchange genetic resources. As such, ex-situ collection organizations make an important contribution to research on genetic resources and facilitate further research on genetic resources by others.

Typical acquisitions of genetic resources:

It has to be considered that a vast number of applications for access to genetic resources come from ex situ collections wishing to use genetic resources for non-commercial conservation or education related purposes, such as biodiversity inventories and ecological assessments and for increasing taxonomic knowledge. Benefits generated by research activities with non-commercial intent are almost always non-monetary and generally arise from the comparative use of a library of specimens (such as taxonomic tools, phylogenies, vegetation maps and conservation assessments) and from institution-level capacity-building activities (such as technology transfer, staff exchange, student supervision and training courses). Only very rarely are benefits attributable to individual specimens. So far there are some helpful activities on compliance of researchers/ ex situ collections and public funding agencies in place. Research activities with non-commercial intent have developed policies, strategies and instruments to promote ABS implementation in user countries. The main work has been so far on voluntary codes of conduct and information policy.

As regards Botanical Gardens, they have developed a set of principles on access to plant genetic resources and benefit sharing for participating institutions. These principles state that participating institutions should share fairly and equitably with the country of origin and other stakeholders, the benefits arising from the use of genetic resources and their derivatives (including non-monetary benefits) and in monetary benefits the case of commercialisation. In the Common Policy Guidelines for Participating Institutions15, the benefits set out in paragraph 9.2.2 are largely focussed on non-monetary benefit sharing such as sharing of research results, access to collections, augmentation of national collections, transfer of technology, training, institutional development and joint research and development. However, it includes monetary benefits, such as royalties, in the case of commercialisation.

These instruments, i.e. the International Plant Exchange Network (IPEN), the Principles on Access to Genetic Resources and Benefit-Sharing and MOSAICC (International Code of Conduct concerning micro organisms) present model systems which respond to ABS provisions and help to document transparently the transfer of plant genetic resources.

Gelöscht:

What are the ranges of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

It is critical that the international ABS regime provides the flexibility to accommodate differences in the current or future utilisation of genetic resources in and between different user groups. If this is not achieved, the international ABS regime risks preventing potential users of genetic resources from seeking access to those genetic resources that fall within the scope of the international ABS regime. This would run counter to the CBD, its objectives and provisions relevant to access and benefit-sharing.

One important option for taking into account different characteristics of groups or sectors utilising genetic resources while disseminating best practices in ABS across sectors is the development of sectoral model clauses for potential inclusion in Material Transfer Agreements (MTAs). Such optional model clauses could enhance legal certainty for both

[14] For more information on definitions on non-commercial research see OECD (1994). "Main definitions and conventions for the measurement of research and experimental development (R&D)".

[15] http://www.kew.org/conservation/agrbs-policy.pdf

providers and users of genetic resources and support the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

They should primarily be developed through sectoral processes in a bottom-up way with the involvement of stakeholders.

Elements that could serve as a starting point for inclusion in optional sectoral model clauses include:

- Model clauses stipulating that access for research with non-commercial intent could be linked to an obligation to make the resulting knowledge publicly available[16];
- Model clauses on the settlement of disputes arising between parties of a MTA;
- Specifying notions of what constitutes an "utilisation" of genetic resources in the sense of Article 15.7 CBD in specific user chains and sectors using genetic resources.
- Identification of sectoral reference points that are characteristic for research and product development based on genetic resources in specific chains of users of genetic resources. E.g., identifying the typical boundary between non-commercial and commercial research.
- Specifying sectoral notions of non-monetary and monetary benefit-sharing.
- Confidential elements will generally be negotiated for individual contracts and do not seem to lend themselves for inclusion in optional model clauses.

EU available studies on the issue of sectoral approaches:

Holm-Muller, Richerzhagen and Tauber. 2005. "Users of Genetic Resources in Germany. Awareness, participation and Positions regarding the Convention on Biological Diversity", BfN-Skripten 126.

Sukhwani. 2008. «Caracterización del uso de los recursoss genéticos por parte de los distintos sectores de la industria y la ciencia". Ministerio de Industria, Turismo y Comercio; Oficina Espanola de Patentes.

FinaEnviro. 2006. Evaluation économique de l'utilisation des ressources génétiques en France. Rapport technique du Ministère de l'Ecologie, de l'Energie, du Développement Durable et de l'Aménagement du Territoire (in French only).

[16] This leaves room for properly negotiated agreements with a different content. An MTA could, for instance, grant exclusive access to research material for a limited time-span.