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Review of the Experience of Implementation by UK Stakeholders of Access and Benefit Sharing Arrangements under the Convention on Biological Diversity

defra
Department for Environment
Food and Rural Affairs

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This publication is also available at
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Acronyms and Abbreviations

ABS	Access and Benefit-Sharing
CBD	Convention on Biological Diversity
CHM	Clearing House Mechanism
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP	Conference of the Parties
Defra	Department of Environment, Food and Rural Affairs
DTI	Department of Trade and Industry
DfID	Department for International Development
DUS	Distinctness, Uniformity and Stability
EC	European Community
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FCO	Foreign and Commonwealth Office
FIELD	Foundation for International Environmental Law and Development
GRFA	Genetic Resources for Food and Agriculture
GSPC	Global Strategy for Plant Conservation
IPRs	Intellectual property rights
ITDG	Intermediate Technology Development Group
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MOSAICC	Micro-Organisms Sustainable use and Access regulation International Code of Conduct
MoU	Memorandum of Understanding
MTA	Material Transfer Agreement
NGO	Non-Governmental Organisation
OTs	Overseas Territories
PIC	Prior Informed Consent
PBRs	Plant Breeders Rights
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UKNCC	United Kingdom National Culture Collection
UKPGR	UK Plant Genetic Resources Group
UPOV	International Convention for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization
WIPO IGC	WIPO's Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore
WSSD PoI	World Summit on Sustainable Development, Plan of Implementation
WTO	World Trade Organization

Executive Summary

1. Genetic resources contained in biological material are no longer "the common heritage of mankind". Instead, since the Convention on Biological Diversity (CBD) was signed in Rio de Janeiro in 1992, the rights of States over their natural resources extend to their authority to determine access to genetic resources. The Convention covers for the first time the issue of "access" to "genetic resources" and requires "the fair and equitable sharing of the benefits" derived from their utilisation.

2. Genetic resources (of plant, animal, fungal or microbial origin) are essential to many areas of scientific research and industry. They are used in products such as pharmaceuticals, botanical medicines, biotechnologies, agricultural and horticultural products, personal care products, flavours and fragrances. Some genetic resources also have national strategic importance for food security and defence. UK academic and industry sectors are major *users* of genetic resources. In addition, a number of important *ex-situ* collections (holding material outside its natural habitat) and *in-situ* collections (holding material in their natural habitat), are based in the UK, and could *provide* or supply those resources.

3. A decade after ratification of the CBD by the UK in June 1994, it was decided that a review of the experience of UK users and providers of genetic resources with implementation of the core access and benefit-sharing (ABS) provisions needed to be undertaken – the Terms of Reference are at Annex 2. About 100 countries have enacted specific legislation, regulations or other measures pertaining to ABS. UK organisations (public and private) ought to respect those requirements. Developing countries, non-governmental organisations (NGOs) and the media are well aware of the issue of "misappropriation" or "biopiracy" (i.e. when material is "illegally" acquired - without the consent of the providing country). There is a steady and growing stream of publicity focusing on the alleged failure to comply with ABS requirements, which reflects adversely on the reputation of organisations in developed countries.

4. This review represents the second part of a two-stage process. The first stage, a UK Policy Review on Genetic Resources for Food and Agriculture was carried out by Claire Wilding for Defra in 2002.[1] The aim of the current review is to report on the efforts and experiences with implementation of ABS arrangements under the CBD of stakeholders, both providers and users, based in the UK, of genetic resources of all types (plants, animal, fungal and microbial but not human).

5. The review is based on a wide consultation, held chiefly through a questionnaire, with stakeholders. Of the 600 stakeholders identified and approached, 127 relevant responses were received (21% response rate).

[1] Available at www.defra.gov.uk/science/geneticresources

6. Respondent UK stakeholders included the most relevant public and semi-public sectors: research institutions; universities; botanical gardens; zoos and aquaria; culture collections; and private sector industry: pharmaceutical; cosmetics; agribusiness (plant breeding and crop protection through plant breeding); ornamental horticulture; livestock production; wildlife traders; providers and potential providers of material from *in-situ* conditions.

7. This is the first exercise of its kind conducted by Defra and it is a significant step forward to work closer with the stakeholders involved in ABS. The outcome of the review is not a full and comprehensive statistical account but rather an identification and an initial analysis of the most salient issues, problems and needs noted by stakeholders. It will help Defra get a broad picture of the situation regarding ABS in the UK and it will form the base for future work. In particular, the findings in the review are intended to inform national policy development by Defra, including its positioning in ongoing negotiations within the CBD on a future international regime on ABS and the approach to the implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture.

8. Main conclusions

- On the importance of genetic resources: the use of genetic resources in both the private and public sectors appears to be increasing, possibly owing to the advancement of genomic science and new technologies. However, this does not necessarily imply that this growth will be satisfied through genetic resources obtained from biodiverse developing countries (there seems to be some evidence to the contrary).

- On the level of awareness of the CBD and ABS provisions: respondent organisations seem generally well aware of them, however the majority appeared to lack detailed understanding. Large organisations seemed generally more knowledgeable and experienced on ABS.

- On acquisition of genetic resources: large organisations appeared to be more familiar with requirements under the CBD (e.g. prior informed consent requirements, and the use of policies and agreements for ABS).

- Although the rationale for the CBD is generally perceived as positive, difficulties experienced with the implementation of its ABS provisions are often perceived as negative.

-The use of intermediaries when acquiring resources was widespread among respondents and many relied on others to comply with ABS requirements. Whether intentionally or not, the use of intermediaries can result in bypassing or ignoring national and local ABS regulations.

- The results of compliance with foreign legislation and regulation on ABS are inconclusive. However, it appears that some UK stakeholders fall short of meeting the full requirements of ABS.

- On supply of genetic resources: the effective coverage of ABS issues in the national legal systems in Great Britain and Northern Ireland is generally covered by well established laws of, *inter alia*, property, trespass and intellectual property and this appears adequate for current requirements.

- It is possible that *ex-situ* collections may play an even greater role as potential providers of material in the future. *In-situ* sources that can provide genetic resources will, in particular, benefit from guidance on benefit-sharing. Among providers or potential providers, the Overseas Territories, some of which are very rich in biodiversity, might benefit from assistance.

9. Main recommendations

In order to improve awareness and compliance with ABS provisions and any implementing national (foreign or domestic) legal requirements, it is recommended that Defra should facilitate the understanding of these instruments and provisions (Recommendations 1 and 2).

Defra should also promote the use of the voluntary Bonn Guidelines on ABS (adopted by the CBD in 2002) as well as identify and encourage the dissemination of best practice among organisations (Recommendations 3 and 4).

Organisations holding *in-situ* material should be encouraged to consider ABS arrangements, in particular benefit-sharing. UK provisions relevant to ABS should be reviewed in the future (Recommendations 5 and 6).

Defra should consider collaborating with FCO regarding Overseas Territories and the possible role of missions abroad (Recommendations 7 and 8).

Defra should engage stakeholder organisations by setting up a pool of specialist industry and institution contacts and a network of stakeholders to improve communications and consultations (Recommendations 9 and 10).

Defra to focus its engagement and cooperation with relevant international fora (e.g. WIPO, UPOV and WTO TRIPS) as a means of informing its policy development and its involvement with the CBD and ITPGRFA (Recommendation 11).

Stakeholders themselves are recommended to take action to improve implementation (Recommendation 12).

The full list of Recommendations is in pages 60 to 63.

Chapter 1 - Introduction

1.1 The Project: rationale and objectives

This review represents the second part of a two-stage process. The first stage, a Review of UK Policy on Genetic Resources for Food and Agriculture (the Wilding Report) was carried out by Defra in 2002. That review included, amongst other things, a commentary of the current state in the UK of genetic resources for food and agriculture (GRFA: plant, animal and microbial); a description and analysis of current policy; and recommendations for a new over-arching policy on conservation and sustainable use of GRFA linking biodiversity and agriculture. The Wilding Report is available at www.defra.gov.uk/farm/geneticresources

The second and present stage, as stated in the Wilding Report, is a review of the experience of UK users and providers of *genetic resources*[2] with implementation of the core provisions (Article 15) of the Convention on Biological Diversity (CBD) on access to genetic resources and benefit-sharing (ABS). The review has been undertaken ten years after the UK ratified the CBD in June 1994.

The Third Conference of the Parties to the CBD (COP 3) in November 1996 had already "invited governments (…) to conduct analyses of ongoing experiences of legislative, administrative and policy measures and guidelines on access, including regional efforts and initiatives, and to disseminate these widely to assist Parties and stakeholders involved in developing and implementing measures and guidelines on access."[3]

In addition, the role and experience of the main actors working with genetic resources (users and providers of genetic resources) has received limited attention to date. The Fifth Conference of the Parties to the CBD (COP 5) recognised, in May 2000, the need "for more information regarding, among others, user institutions, the market for genetic resources, (…) and

[2] The Convention on Biological Diversity defines 'genetic resources' as 'genetic material of actual or potential value.' In turn, it defines 'genetic material' as 'any material of plant, animal, microbial or other origin containing functional units of heredity.' These definitions may have different interpretations. For the purposes of the current review, we took 'genetic resources' to mean biological material (excluding human material of any kind), the *genetic* attributes of which are intended to be used. Accordingly, the questionnaire considered **living or preserved** whole organisms, their parts and derivatives containing DNA, and DNA (or RNA) itself, where there is intent to use the genetic material, and also propagating or reproductive material (e.g. seeds, spores, eggs and sperm). Thus **genetic resources include**: plants, animals, fungi, bacteria, protista and viruses kept for display, research, breeding or commercial purposes, and material such as germplasm, blood, embryos, eggs, cells, animal tissue, plant cuttings, museum and herbarium specimens and DNA samples. Genetic resources **do not include**: material such as timber, fur and cut flowers (which are used as commodities) and material such as oils and resins (which do not contain genetic material)

[3] Decision III/15 para. 4.

intermediaries".[4] The call for further information about the main players, and private sector in particular, was also echoed at subsequent meetings.[5]

Hence, the main driving force for the present review was to gather information about the main providers and users of genetic resources in the UK in the most relevant public, semi-public and private sectors ("stakeholders") and their experiences with ABS arrangements.

In addition, given that developing countries, NGOs and the media are increasingly aware and sensitive to ABS issues, it was important that Defra evaluated the situation in the UK - the issue of "missapropriation of genetic resources" or "biopiracy" (i.e. when the material is "illegally acquired" or without the consent of the relevant national authority) has featured several times in national media; consequently, the risk of any such cases damaging the reputation of British organisations should be addressed.

A number of UK-based NGOs have played a significant role on ABS issues at the national and international level. This was done mainly through awareness-raising and by providing expertise for capacity-building and training, as well as producing reports and case studies. Given that this review focuses on users and providers of genetic resources, NGOs have not been invited to participate in the survey However two organisations (ITDG – Intermediate Technology Development Group, and FIELD – Foundation for International Environmental Law and Development) have been consulted at different stages of this exercise.

This review seeks to ascertain for the first time, the extent to which ABS provisions of the CBD are known and understood in the UK; to what degree the Bonn Guidelines are influential; and what experiences with ABS requirements stakeholders have had.[6] Chapter 2 provides a contextual description of each stakeholder group covered and reports on the importance and demand of genetic resources by each group. Chapter 3 covers the awareness of stakeholders about the CBD and the Bonn Guidelines. Chapter 4 reports on stakeholders' views and experiences when accessing material and, similarly, Chapter 5 deals with those stakeholders that supply or could supply material. Chapter 6 sets out conclusions and recommendations for Defra and stakeholders. Annex 1 details the description of sectors in Chapter 2. Annex 2 includes the ToR of the project and review. Annex 3 lists the main bibliographical references.

The outcome of the review is not a full and comprehensive statistical account but rather an identification and an initial analysis of the most salient issues, problems and needs noted by stakeholders. It attempts to identify best practices. The conclusions and recommendations are intended to inform

[4] Decision V/26, para. 12.
[5] Second meeting of the Panel of Experts on ABS in 2001 and COP Decision VI/24D, para. 6.
[6] In common with most of the developed countries, the UK gives effect to its CBD obligations by administrative measures and has not enacted specific legislation on ABS. However, many biodiversity-rich countries have more specific laws and regulations in place.

national policy making and development in Defra, including its position in ongoing negotiations within the CBD on a future international regime on ABS.

1.2 Process, methodology and coverage

The questionnaire covered organisations' characteristics (e.g. whether it held a collection and of what type, whether it uses genetic resources and how, etc); experience with the CBD and Bonn Guidelines; extent of and experience with acquisition and supply of material; access and supply agreements; and further comments. The terms of reference (see Annex 2) and the questionnaire on which the review is based are available at www.defra.gov.uk/farm/geneticresources

An interdepartmental meeting (the 'Ad Hoc ABS Review Group') which involved all interested Whitehall Departments, the Devolved Administrations and public bodies with expertise, was convened to give advice. The Ad Hoc Group first met on 10 September 2003 to discuss the ToR and questionnaire. It met a second time on 27 October 2004, to comment on the final product; the review, and, especially its recommendations.

A database of potential stakeholders was prepared after consultations with Government Departments and trade associations as well as internet research. This entailed identifying the main stakeholders based in the UK from the most relevant public, semi-public, and private sectors. Stakeholders approached included:

- research institutions;
- universities;
- botanical gardens;
- culture collections;
- zoos and aquaria;
- industry: pharmaceutical; cosmetics; horticulture (ornamental); wildlife trade; farm animal breeding/livestock production; plant breeding; natural and traditional medicine; biotechnology other than pharmaceutical and agriculture (i.e. industrial and environmental biotechnology such as bioremediation); and,
- providers and potential providers of material from *in-situ* conditions (i.e. in their natural surroundings).

The review is based on a wide consultation, held chiefly through a questionnaire, with stakeholders. Of the 600 stakeholders identified and approached, 127 relevant responses were received (21% response rate). Prior to the formal consultation, an initial piloting and communication with some potential stakeholders took place.

Unfortunately, no responses were received from the botanical medicines and natural products sector (including Chinese medicine) and other biotechnology (industrial applications of biotechnology other than pharmaceuticals and crops, e.g. bioremediation); consequently, these sectors have not been taken into consideration for the purposes of this review. The number of replies from

the cosmetics industry, 4 relevant, was very low (5% of cosmetic companies approached) but nevertheless, bearing in mind this limitation, their responses were judged useful and they have been included in the review.

Once all the completed questionnaires were received and had been analysed, some 20 communications and interviews with different people were held since it was felt that further information and clarification would be helpful. In addition, research on the various sectors was conducted to provide background information. The draft review was circulated for comments to selected reviewers, including representatives of the stakeholder groups approached.

The survey was voluntary and not all sections of the questionnaire were answered by all organisations. Consequently, the data are not necessarily authoritative and certainly not representative. However, they are believed to be usefully indicative, particularly since the respondents included a wide range of stakeholder groups and were often the main institutions and companies in each group. Furthermore, the survey is not the only source of information for this review. Numerous communications as well as interviews have also taken place and a literature review has been used to double check and back-up the findings. The findings from the questionnaire appear largely consistent with the information obtained from these other sources.

Overall, this is the first exercise of its kind conducted by Defra and it is a significant step forward to work closer with the stakeholders involved in ABS. It will help Defra get a broad picture of the situation regarding ABS in the UK and it will form the basis for future work.

1.3 The international framework: The Convention on Biological Diversity (CBD) and its provisions on access to genetic resources and benefit-sharing (ABS)

Biological diversity (or biodiversity) can be defined as the variability among living organisms and includes diversity within species, between species and of ecosystems. Genetic material contained in organisms (plants, animals or microorganisms) are essential to many areas of scientific research and industry. They are used in products such as pharmaceuticals, botanical medicines, biotechnologies, agricultural and horticultural products, cosmetics and personal care products, flavours and fragrances. Some genetic resources also have national strategic importance for food security and defence.

The United Kingdom is not amongst the most biodiverse countries in the world (although some of the Overseas Territories are home to rich biodiversity) but uses, such as those listed above, have been made of UK genetic resources. In addition, its academic and industry sectors are major *users* of genetic resources/biological material. Furthermore, a number of important *ex-situ* collections (material held outside its natural habitat), some of them of world-wide renown, are based in the UK.

The United Nations Convention on Biological Diversity (CBD) is one of the three Conventions that resulted from the process started at the Rio Summit on Environment and Development in 1992.[7] Unlike earlier treaties which dealt with specific aspects of biodiversity (e.g. certain species, habitats or geographic areas), the CBD is comprehensive in its approach and scope. The three objectives of the CBD are the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

The CBD was signed in Rio de Janeiro in 1992 and entered into force on 29 December 1993. As of December 2004, it has been ratified by 188 countries, attracting the greatest support of any international convention. The UK was an active negotiator of the CBD and ratified it on 3 June 1994. The European Community (EC) and all its Member States are Parties to the CBD and, consequently, legally bound to implement it.

Importantly, the CBD recognises the sovereign rights of States over their biological resources, specifically including the authority of national governments to determine access to genetic resources. At the same time, access must be on mutually agreed terms (MAT), and subject to the prior informed consent (PIC) of the State providing such resources. Also, countries must endeavour to create conditions to facilitate access to genetic resources by other countries 'for environmentally sound uses'.

Parties to the Convention also agree to take measures aimed at sharing in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources (plants, animal and microbial but not human) with the Party providing such resources. The sharing of benefits in exchange for access to genetic resources is generally seen as an issue of equity and fairness, designed so that biodiverse countries can reap the benefits of their biological richness, providing them with the resources and the capacity to share the costs of conservation.

The Convention, and relevant implementing national legislation of its Parties, requires prior informed consent and benefit-sharing for *both* commercial and non-commercial purposes. In cases where genetic resources are used for scientific, non-commercial purposes only - for example, in the case of access for taxonomic research - benefits will usually be non-monetary, such as exchange of information and training. Similarly, benefits that may arise in the commercial field, whether or not a product reaches the market, may include those of a non monetary nature, such technology transfer and training (capacity-building).

As an international treaty, the CBD is only binding on sovereign Parties, i.e. sovereign states and regional economic integration organisations such as the EC. To give effect to their international obligations, governments may

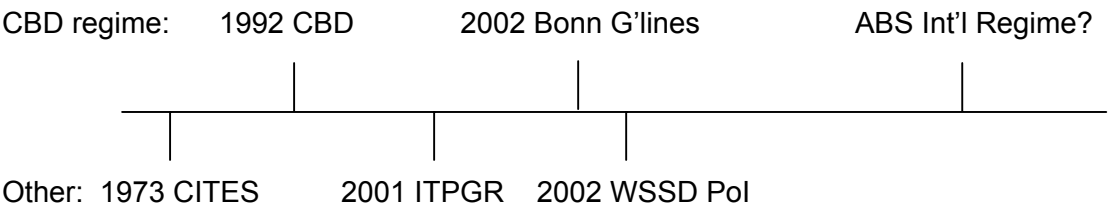
[7] The other two Conventions are the 1992 Framework Convention on Climate Change and the 1994 Convention to Combat Desertification.

introduce laws and regulations which apply to individuals and organisations (public or private, national or foreign, from a state Party or not) operating in that particular country. To date over 100 countries, primarily developing ones, have either enacted or are designing national laws and regulations that include provisions on access and benefit-sharing. [8]

The CBD does not specify how requirements pertaining to access and benefit-sharing can be put in operation. In practice a number of arrangements (written or not), some even prior to the CBD, have dealt with these issues.

Private entities exchange or pass on biological material through, among others, written material transfer agreements (MTAs). The Bonn Guidelines are a significant tool in providing elements and examples which could be included in MTAs.

Box 1 – Timeline: Main relevant international instruments



1.3.1 The Bonn Guidelines

The Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization agreed in Bonn, Germany, (therefore known as "the Bonn Guidelines") are a very significant contribution to the development and clarification of the ABS provisions of the CBD. The Bonn Guidelines concluded a negotiation process that started at the Fourth Conference of the Parties (COP 4) to the Convention in 1998, with the aim of exploring options for access to genetic resources and benefit-sharing on mutually agreed terms and ended with their adoption at the Sixth Conference of the Parties (COP 6) in April 2002.

This negotiation drew from existing practice such as codes of conduct, voluntary policies and material transfer agreements. Among those, it is worth

[8] China Williams, Kate Davis and Phyllida Cheyne. *The CBD for Botanists: an introduction to the Convention on Biological Diversity for people working with botanical collections*. RBGKew, 2003, pp. 61-62. See also Kerry ten Kate and Sarah Laird, Royal Botanic Gardens, Kew, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, Earthscan Publications Ltd, London, European Communities, 1999, p.14

noting, are initiatives such as the “Principles on ABS and Common Policy Guidelines for botanical institutions”, a project coordinated by the Royal Botanic Gardens Kew; and MOSAICC (Micro-Organisms Sustainable use and Access regulation International Code of Conduct) which among its 12 partners, included 3 organisations based in the UK: CABI, RBG Kew and the World Federation of Culture Collections.

The purpose of the Bonn Guidelines is to assist Parties, Governments and other stakeholders in developing and drafting legislative, administrative or policy measures as well as contracts and other arrangements for access and benefit-sharing. *Inter alia*, the Guidelines identify roles and responsibilities of different actors regarding ABS and enumerate possible elements for inclusion in material transfer agreements, providing a list of possible monetary and non-monetary benefits.

The Plan of Implementation agreed at the World Summit on Sustainable Development (WSSD PoI) at Johannesburg in September 2002, called upon signatory states “to negotiate within the framework of the CBD, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources” (paragraph 44(o)). Equally, it also called on signatories “to promote the wide implementation of and continued work on the Bonn Guidelines” (paragraph 44(n)).

Chapter 2 – Importance of Genetic Resources

2.1 Introduction

In spite of many years of international negotiations on access to genetic resources and benefit-sharing issues, there is still a significant lack of knowledge on the actual market and trade in genetic resources, the importance of genetic resources for users and providers, and future trends regarding access and use. This has been acknowledged repeatedly by the Secretariat of the CBD in its papers and by decisions taken by the Convention's Sixth (2002) and Seventh (2004) Conferences of the Parties (COP6 and COP7).

The groups of stakeholders responding to this survey have diverging interests and different perceptions of the value of genetic resources. Their views of access and benefit-sharing arrangements across the sectors have raised different concerns that need to be addressed and reconciled in access and benefit-sharing systems.

This chapter gives a brief description of the groups of stakeholders followed by the responses of organisations on the importance of genetic resources to their work.

Annex 2 provides further contextual background as well as numerical data. However, market data included in Annex 2 is purely indicative: figures relate to economic activity and not necessarily and solely to the value of the genetic resource component. Ascertaining such detail would be a massively complex task, which has never been undertaken and was not the object of this survey.

All the stakeholders described in this chapter *use* genetic resources to a certain extent, whether it is to develop a product or for academic scientific research such as classification of species (i.e. taxonomy/systematics). Some of these stakeholders may also *supply* or *provide* genetic resources that they hold in *ex-situ* collections to third parties, as discussed in Chapter 5. Finally, another group of stakeholders (providers and potential providers of genetic resources) described in Chapter 5 do not use genetic resources but manage land with biological resources of potential interest (e.g. nature reserves). Such material held in *in-situ* conditions can be supplied to third parties.

Of the 127 stakeholders that replied on these specific issues, two thirds considered genetic resources to be "crucial" to their work, with only 3% considering them of little importance or irrelevant.

Box 2 – The Potential of Biodiversity

It is generally understood that the potential of large areas of tropical rainforests, coral reefs, oceans, soils and other remote or largely scientifically unexplored areas remains virtually untapped. Hiding within the undiscovered organisms are cures for diseases, new food sources, means to clean polluted environments and better ways to manufacture products used daily in modern society.

This is primarily the issue addressed by access and benefit-sharing in the CBD: the exploration and use of those biological resources could and should serve as an incentive to conserve them and their habitats, as well as providing monetary and technological resources and expertise to do so. The intention of this so-called "grand-bargain" envisaged in the CBD is to allow biodiverse countries to reap the benefits of their biological richness with contributions to the cost of conservation. However, unless trust between these blocks of partners exists, that trade-off will not be achieved.

Natural products provide unique and extremely broad biochemical diversity, distinct from that found in synthetic or combinatorial chemical libraries currently available, and they exhibit an extreme range of activity.

It has been estimated that for the period 1983-1994, 78% of the antibacterial agents and 61% of the anticancer agents approved for use were derived from terrestrial natural products. By comparison, the marine environment remains relatively unexplored. Over the last quarter-century more than 10,000 compounds have been reported from marine-derived organisms. However, in spite of this potential, by the year 2000 no compound isolated from a marine source had ever advanced to commercial use as a potential anticancer agent.

Fungi provide another example of the potential of biodiversity yet to be explored and their components discovered and used. This group of organisms rank second only to insects in estimated species biodiversity. There are approximately 72,000 recognised species of fungi, out of an estimated 1 to 1.5 million in total: less than 5% of fungal species have been described to date. Given that a quarter of all known biologically active natural products are derived from fungal sources, the world's undescribed fungi can be viewed as a massive resource for potential new medicines. Similarly, it is believed that less than 1% of bacterial species are currently known. Despite the more intensive investigation of terrestrial flora, it is estimated that only 5-15% of the approximately 250,000 species of higher plants have been systematically investigated, chemically and pharmacologically.

But could the chemicals in natural products ever be made redundant by new technologies and advances in modern chemistry? Chemists working in the fields of either natural products or of 'combinatorial' chemistry tend to demonstrate a prejudice in favour of the value of their own discipline and source , i.e. beauty is in the eye of the beholder.

Source: Biodiversity- New Leads for the Pharmaceutical and Agrochemical industries, Wrigley et al (eds.), the Royal Society of Chemistry, Cambridge, 2000.

2.2 The groups of stakeholders

This chapter is mostly introductory and describes in general terms the thirteen groups of stakeholders that responded to the questionnaire. Background to each sector is given followed by information from the questionnaire on the importance of genetic resources.

Organisations which are largely in the commercial sector are dealt with first, in detail, (in the following order: plant breeding, horticulture, livestock production, pharmaceutical industry, cosmetic industry and wildlife traders). Organisations for which research, often academic, is a main activity area and are often public or semi-public, follow (these include: research institutions and universities, botanical gardens, zoos and aquaria, and culture collections).

2.2.1 Agricultural Business

Agricultural business or "agribusiness" uses genetic resources for plant breeding and also for crop protection. Crop protection can be achieved not only through the use of chemicals (e.g. pesticides, herbicides and fertilisers) but also through plant breeding (e.g. genetic resistance to pests and diseases).

Although crop yields have improved through better pest management, mechanisation and fertiliser use, extensive evidence suggests that yields have benefited the most from plant breeding, which has resulted in improved hybrids and varieties. Furthermore, crops have benefited from genetic improvements in relation to their suitability for specific end uses, their ability to resist pests and diseases, as well as to their amenability to intensive mechanisation and extended cultivation periods.

None of the major food crops (i.e. maize, oilseed rape, potatoes, sugar beet, wheat and barley) grown in the UK is native to the country. Therefore, the majority of breeding companies have to use *ex-situ* collections, worldwide, either for accessions for use as potential parents in breeding programmes or for information relating to pedigree, characterisation or known genetic traits. In some instances, collaborative characterisation work of mutual interest is done by a reciprocal arrangement whereby in return for supplying the genetic material the provider receives the data obtained by the user - an early and established example of access and benefit-sharing.

The survey reveals that there is a general recognition in the plant breeding sector of the value of biodiversity - scientifically, environmentally and culturally. Respondents often acknowledged that genomic science has increased the ability to analyse and interpret genetic diversity. In addition they noted that there is an increasing demand for new varieties and specialised food/feed and non-food uses of plants.

Consequently, companies responding in this sector, including several larger companies, considered genetic resources to be "crucial", "very important" or "important" for their work. The large majority of respondents from this sector

thought that the demand for genetic resources had increased in the last 10 years, although a significant minority considered that demand had not changed. Responses indicated that the demand for these resources will either increase or remain the same, but not decrease, in the next decade.

In the UK, the genetic resources used in this sector, i.e. crops, have been covered by the CBD since 6 June 1994 (date of ratification of the CBD by the UK). However, since 29 June 2004, the date of entry into force of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) to which the UK is also bound, 36 food crops and 29 forages are covered specifically by this other international regime. For the specific uses of the crops and forages listed in the ITPGRFA[9], a standard MTA will apply to access, use and benefit-sharing.

Box 3 - Developing New Crop Varieties

The essence of plant breeding is the discovery or creation of genetic variation in a plant species and the selection from within that variation of plants with desirable traits that can be inherited in a stable fashion. Plant breeders' final selections of superior plants will form the basis of one or more plant varieties. They use all available technology both to create genetic variation and to select from within that variation.

A new variety is created when selected parent plants are crossed to combine desired characteristics. The breeder has to combine a range of traits in one plant, such as high yield, quality and resistance to disease.

Creating a new variety may take some years, so breeders have developed ways to enhance the speed, accuracy and scope of the breeding process, using artificial growth facilities and modern laboratory techniques.

Techniques include parallel selection programmes in the northern and southern hemispheres that allow two generations to be produced each year. Recent laboratory procedures also enable breeders to operate at the level of individual cells and their chromosomes - producing varieties through practices such as protoplast fusion, embryo rescue and assisted pollination, double haploid breeding, genomics, marker assisted breeding, genetic modification and proteomics.

Over the past decade or so, scientists have been able to identify the individual genes that determine particular characteristics in a plant. Just as importantly, they can now transfer these genes between plants, which means that novel features can be introduced into crop species. It is unlikely that biotechnology will solve every agronomic problem, but it can offer farmers new options.

[9] Article 12.3 (a) states: "Access [to the Multilateral System] 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 (…)".

Developing a new variety is a long process, up to 12 years for a cereal variety from the first cross to the variety coming on to the marketplace. It is even longer for some crops, such as potato. The time is spent selecting plants with the desired attributes, assessing them for yield, disease resistance and end use quality and then purifying and multiplying seed of the most promising for entry into official trials.

Plant breeding involves a major investment in people, technology and facilities, with no guarantee of success. The cost of maintaining a typical wheat-breeding programme is estimated at £1.5 million per year and costs are increasing, as customer requirements become more demanding.

Before any new crop variety can be placed on the market it must undergo statutory testing under a process known as National Listing. Successful varieties are placed on a National List of varieties approved for marketing.

Official trials are conducted, in most cases for a minimum of two years, to test each new variety for a range of characteristics, which together determine its distinctness, uniformity and stability (DUS) and its value for cultivation and use (VCU) to growers, and the rest of the food chain. National List trials are extremely rigorous and may be followed by three years of further commercial evaluation.

Source: British Society of Plant Breeders website (www.bspb.co.uk) and Defra.

2.2.2 Horticulture

In this review, the horticulture sector refers to the industry of growing plants and flowers as ornamentals and does not include vegetables or fruit (covered in the agribusiness sector). However, cut flowers are not a genetic resource as defined in this review (see footnote 1 in the Introduction).

The majority of material used for breeding is already on the market or available from genebanks and botanic gardens. Usually, there is sufficient genetic variation within an individual company's stock so that new varieties can be developed from available germplasm.

However, a minority of horticulture companies focus on the development of new lines of ornamental plants, relying very heavily on new material. Indeed, in order to accommodate the growing demand for ornamentals, there is a need for ever greater diversity and variability for breeding purposes. This strong trend is expected to continue for some years.

The extent of wild material actually collected by this sector could not be ascertained through the survey, nor could the importance of 'plant hunters' to the UK. One respondent from a major organisation explained that in the case of plant imports, almost 100% of material comes through other EU countries in order to avoid "more strict customs officials". Once the material is introduced into the EU it is usually brought to the UK without further controls, in accordance with the EU principles of free movement of goods and people. However, this does no more than reflect the normal situation, that trade occurs through the points where the flow is fastest and least hindered. It is therefore important that CITES controls (see next paragraph) are applied

evenly across the EU Member States. However, there might be significant trade of propagated material which includes new species or wild specimens which it is claimed have been propagated. In addition, a wide range of imports are not covered by CITES and, consequently, there is no reliable data on such imports.

The international trade in endangered/threatened plant species and material, is regulated by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), implementing European Community legislation and by various phytosanitary regulations. In general, whilst there is very little awareness of the CBD, some of its benefit-sharing aspects are effectively covered by the UK Plant Varieties Act of 1997 in line with 1991 UPOV (International Convention for the Protection of New Varieties of Plants).[10]

2.2.3 Livestock production

The large majority (67%) of respondents from the farm animal production sector have experienced an increase in demand for genetic resources and an even larger majority expects an increase in demand over the next 10 years. Studies[11] suggest that in the dairy, pig and poultry sectors, breeds that are currently mainstream will remain globalised with regular exchange of material, and with breed development in the hands of private breeding companies supplying multinational markets. Beef and sheep breeds are less globalised but the mainstream breeds still have a strong international presence. Respondents also noted the changing demands of the market and the increasing capability to use genetic resources through genomics and application of quantitative genetics: this is where exotic and non-mainstream breeds from developing countries may, particularly in the future, have a role to play in cross-breeding.

There is a growing, though not dramatic, interest by industry in the diversity of breeds, their conservation and use. In particular, there is a growing interest in rare breeds, including those native to the UK, some of which could have commercial potential. Non-governmental organisations funded through charitable donations are very active in the conservation of the UK's breeds at risk. Nevertheless, some involved in mainstream animal breeding felt that the current interest might just be a short-term trend. In any case, the need to conserve national rare breeds has resulted in the development and expansion of national collections, both on farms and *ex-situ*, which still need further enhancement.

The international trade in farm animals and their genetic resources is covered by numerous sanitary and health certification standards. The benefit-sharing aspects of exchange are not expressly regulated at international level but rather through *ad hoc* sector-by-sector rules and best practice. The

[10] See Box 7 on Benefit-Sharing and Intellectual Property Rights.
[11] UK Country Report on Farm Genetic Resources 2002. The UK's Official Contribution to the First Report on the State of the World's Animal Genetic Resources for Food and Agriculture. Available from www.defra.gov.uk/farm/geneticresources

implementation of the CBD in the sphere of animal genetic resources is far less developed and defined than it is in the plant sectors. The UK Policy Review on Genetic Resources for Food and Agriculture of 2003 called for a comprehensive and coordinated policy on the conservation and sustainable use of plants, animal and microbial genetic resources. In the light of the adoption of the ITPGRFA, discussions have begun under the auspices of the FAO on the possible need for and content of a policy and/or regulatory framework on access and benefit-sharing in the area of animal genetic resources for food and agriculture.

2.2.4 Pharmaceutical industry

The pharmaceutical industry is the biggest sector in terms of sales, using genetic resources and adding value to them, by generating a range of products. Being the largest sector affected by ABS rules it has also been the target of criticism for misappropriation of genetic resources. The CBD is therefore one of many factors the sector has to consider – the industry is recognised as one of the most highly and globally regulated.

It appears that the pharmaceutical industry generally perceives the CBD as negative, owing, in essence, as we shall see subsequently, to its lack of clarity and the unrealistic expectations of some partners and governments.

By a small margin, respondents thought genetic resources were “crucial” for their business, and whilst almost two thirds considered the demand for genetic resources had increased in the last 10 years, the remaining third of respondents thought demand had stayed the same.

Regarding future demand for genetic resources, the results were inconclusive. As a top senior manager explained in an interview, this might be a consequence of the importance of genetic resources in technology being “cyclical”. In other words, depending on how technology advances and delivers there is less or more need to access biological resources. Expectations on technology might prove unrealistic and indeed it seems that the new technological advances for drug development forecasted in the early 1990s have not delivered as much as anticipated (see Box 4).

The whole drug discovery process is expected to be significantly revisited to improve productivity and innovation, which will have an impact on bioprospecting and drug discovery. Companies are partnering with other companies, merging R&D centres (consequently enhancing their ‘genetic libraries’, which will result in a reduced need to acquire new material). A growing number of firms- have also outsourced R&D efforts abroad (where acquisition of genetic material takes place).

In addition, small companies, will become even more specialised, some focusing on “tools” (chemicals and technologies, such as diagnostics), others on discovery, all relying heavily on the big companies as customers.[12]

[12] Ernst & Young, 8th Annual European Life Sciences Report, 2001.

Contracting and outsourcing to smaller but specialised companies covering research, clinical trials, manufacturing and even sales and distribution, is rising[13] (in 2003 its value was calculated as $10 billion).[14]

Outsourcing and subcontracting means that more intermediaries will be acquiring genetic material for the larger companies. Those intermediaries (e.g. biotechnology companies, universities, discovery companies) will then deal with the policy and legal requirements that regulate access to genetic resources. This may have important repercussions for benefit-sharing as covered in material transfer agreements as we will see in the next chapter.

Box 4 - Drug Discovery

Creating a drug is not easy. Once a potentially treatable disease is chosen, a target molecule (usually a protein), contained in biological material, has to be identified and can be modified with a drug to produce the desired effect. Next, chemical compounds are made after advanced screening and the identification of the active agents and chemical structure. The new compounds are tested against the target. The most promising of the "hits" are selected and optimised to suit a profile of "drug-like" properties. These optimised hits become "leads" that are tested, first in animal models of the human disease and then, if all goes well, in humans.

There are four drivers for successful drug development. First, revolutionary new technologies, such as genomics, proteomics, bioinformatics, high throughput screening, combichem and electronic data transfer. Second, molecular diagnostics where disease and patient variations are mapped. Third, informatics where all that data available is transformed into useful information. Fourth, there is the growing impact of consumers on healthcare systems.

Expectations were high in the 1990s when two much-hyped technologies - combinatorial chemistry and high-throughput screening –were used together for drug discovery. They promised to speed up the development of new drugs by exploiting automation: the ability to generate and test many new compounds quickly would, it was hoped, increase the rate at which new leads were produced. The approaches looked promising, in that they generated lots of hits. But while the quantity improved, the quality did not. The number of new leads going into clinical testing did not increase, and enthusiasm for the new technologies waned.

The pharmaceutical industry is under great pressure to decrease the 12-15 years currently needed to discover and develop new medicines. The technology needed to do this is seen to be a combination of genomics (the study of genomes[15] including genome mapping, gene sequencing and gene function) and high-throughput mechanism based screening. The starting point for drug discovery is now at the gene level. Today genomics has become commonplace and the technology is available to all.

[13] Id.
[14] Ernst & Young, "Defining Issues in the Pharmaceutical Industry".
[15] The genome is the genetic endowment (i.e. entire genetic information: chromosomes, genes and DNA) of an organism. When expressed this will result in observable characteristics, that is the phenotype.

The challenge will be to take all relevant disciplines such as functional genomics, proteomics and bioinformatics and integrate them into a coherent but still complex drug discovery engine, changing the culture in the R&D organisation in the process.

Sources: Communications with respondents, The Economist 11 March 2004 and Ernst & Young, 8th Annual European Life Sciences Report, 2001.

2.2.5 Cosmetic Industry

The cosmetic industry is probably the second largest industry user of genetic resources, after pharmaceuticals. The differences between both sectors have slightly blurred in recent years due to therapeutic cosmetic products or "cosmeceuticals".

Cosmetics in general often include biological components as the principal efficacious component. However, it is undeniable that there is a significant trend for 'natural' cosmetics, which contain a minimum of biological content, solely for the purposes of marketing. Both small and large companies alike are involved in this phenomenon. As one respondent explained, "consumers are becoming more aware of plants and their values in skincare products. As this awareness increases the demand for these plants in a broad spectrum of products will be sought. The value of product we manufacture will also increase".

The tremendous variation in the role of natural ingredients in product development has led to variations in the ways in which companies seek access to natural materials and share benefits. Some companies subcontract to collectors who gather large numbers of samples for screening; others send staff researchers to the field. Most companies make use of species already available and well-known in the market, and re-formulate existing ingredients, rather than prospect for new species.[16] Only a few companies seem to conduct or commission field collections of samples.[17] However, all companies review literature, databases, material promoted at trade shows and use speciality extract suppliers and other intermediaries, as a source of leads for a new product or ingredient development.[18]

While opposition to animal testing for personal care and cosmetic products is widespread, concerns relating to the environmental and social impacts of sourcing of raw biological material is also evident to a limited extent, in the UK in particular.[19] There is little awareness within most companies of benefit-sharing and equitable partnerships related to the sourcing of raw materials.[20] In parallel with the botanical medicine industry, we are confronted with the paradox of consumers asking for natural products but paying little attention to

[16] ten Kate and Laird, p. 262.
[17] Id.
[18] Id.
[19] ten Kate and Laird, p. 275.
[20] Id.

the impact that the delivery of such products has on the environment and local communities in the areas from which they originated.[21]

Lack of awareness and complexity of the supply chain of raw biological material in this sector might explain why only five companies replied to the survey. It appears that the importance of genetic resources in this sector in the UK has not increased during recent years and that this trend is unlikely to change.

As one company stated: "the use of plant extracts will always play a key role in cosmetics; however, while the overall usage remained the same, differentiation in terms of new plant extracts increased, i.e. one extract is replaced by a newer/more up to date version."

2.2.6 Wildlife Traders

Wildlife traders have been largely overlooked as a sector involved in ABS until very recently. In fact, there are important synergies between CBD ABS and CITES, which the Vilm Expert Workshop on CITES-CBD Cooperation in April 2003 considered in depth. The years of practical experience with implementation of CITES, especially its permit system, coordination of national authorities and capacity-building, could be very beneficial to the still nascent regime on ABS.

Trade in live animals forms a significant component of wildlife trade overall. Live animals may be imported for use as pets, for keeping or breeding by specialist keepers, for use in the bio-medical industry and pursuits such as falconry, as well as other commercial interests. In recent years, advances in husbandry techniques and improvements in equipment have made captive breeding not only possible on a larger scale, but also more profitable. Technology has resulted in greater availability of facilities for keeping live specimens, which has made the keeping of exotic species more accessible to the general public. In some cases, specimens obtained in the wild need be imported in limited numbers in order to provide sufficient founder stock for *ex-situ* captive breeding operations. In turn, this can supply the demand of developed nations. Captive breeding may then become independent of wild-taken material and further imports may cease or be significantly reduced.[22]

This shift to captive breeding in developed countries has had, in some cases, a significant negative effect (i.e. decrease) on exports of wild-caught stock from countries rich in species but often poor in other resources. The implications, both positive and negative, of such a shift is an issue of much discussion within CITES. Developing countries might see captive breeding in

[21] Id.

[22] For those species regulated under the provisions of CITES, for a specimen to be defined as captive bred (and so qualify for some exemptions under the Convention), it is a requirement, amongst other things, that breeding stock is not supplemented by wild-taken specimens (albeit with some specific exceptions). The availability of wild-taken specimens may also be limited by the application of import suspensions under the EC CITES Regulations or by export bans or quotas from countries of origin and by consumer preference.

the developed world as another way of using their genetic resources with a deleterious effect on their economies and biodiversity conservation. *Ex-situ* production of animals may not necessarily provide any direct benefits to *in-situ* conservation of the species.

This is a highly political issue. According to one respondent from a major organisation, captive breeding has been largely driven not by economic factors (wild-caught material is often considerably cheaper) but as a result of lobbying by "protectionist" NGOs. Measures to enable the sustainable trade of regulated species and achievement of conservation goals might need to be re-balanced in the wider policy framework.

In the UK, the vast majority of the more popular and highly priced species (birds, reptiles and amphibia) are now bred in captivity in the UK or within the EU (for which import documentation into the UK is not usually a requirement). Thus, several respondents stated that "most of the species bred are well established in captivity from previous imports sanctioned under CITES. We only need to keep 'fresh blood' coming in small numbers". Responses concerning the general demand for genetic resources are similar to those relating to zoos and aquaria, though for different reasons: the majority did not record any increase in demand in the recent years but a few expect a slight increase in the near future. Nevertheless, the UK continues to import significant numbers of wild-taken specimens of some taxa.

2.2.7 Research Institutions and Universities

Within the public sector or organisations mostly funded with public money, research institutions and universities are the most prominent users of genetic resources. In the UK, the Government is the lead investor in basic scientific research. Through education policy and as an employer/funder of thousands of scientists in public research laboratories, the Government influences the funding available for science.

Traditionally, all these organisations were involved in basic research or academic research for publication (i.e. a way of benefit-sharing). As the benefits of this type of research are generally shared among peer groups and academia, there is and there should continue to be, a general trust among organisations. Consequently, the terms mutually agreed (tacitly or explicitly) when biological material was collected need not be too extensive.

However, academic and research institutions do not only carry out academic research but may undertake research for commercialisation, and are under increasing pressure to generate income, protect intellectual property rights (IPRs), etc. In fact, some highly specialised organisations make important contributions to discovery and development of commercial products by industry (pharmaceutical, agricultural, etc). In addition, these organisations often act as intermediaries for industry by collecting material. In both cases, organisations should endeavour to clarify the providing country with details of the likely final use of their research and location of the material. These organisations should therefore develop policies on ABS and MTAs, perhaps

using framework organisations like the Research Councils, to develop common solutions.

According to 80% of the universities that responded, the demand for genetic resources has increased in the last 10 years. The same ratio of responses indicated that it is expected that this trend will continue. Research institutions and culture collections also recorded an increase in the use of genetic resources (but less significant than universities), and the majority also expects an increase in the near future.

2.2.8 Botanic Gardens

Botanic gardens worldwide play major roles in science, horticulture and education. In recent decades they have also become important centres for biodiversity conservation by integrating conservation and sustainable use. In the UK, most botanical gardens are engaged in conservation, research or education activities. Among these, several collections are currently participating in the Global Strategy for Plant Conservation initiative under the CBD, which provides a specific and common conservation framework, including objectives and targets for plant collections up to 2010.

Botanic gardens responding to this review recognised an increased interest of the public in plants as a result of greater awareness (popular gardening programmes on television have doubtless played a role). In consequence, many gardens have experienced significant increases in public attendance and enthusiasm for growing and learning about unusual plants. However, a number of respondents believed that public interest in plant collections might already be peaking.

In addition, there are more organisations involved in plant science (of living collections in particular) and conservation than in the past.

After a significant increase in the last decade, the overall future demand forboth plant material held in these collections and these collections' demand for new plant material is not expected to be high - respondents predicted a slight increase or that both demands stay the same.

However, some respondents also noted increased interest in research of biochemical compounds contained in material held in these collections. It is possible that this interest by research organisations and private companies is due, as another respondent commented, to the difficulty in obtaining plants from certain countries. Indeed, as we will see in Chapter 4 on Acquisition, it appears that the demand for plant material from the large collections it is likely to increase. In the coming years it seems quite possible that *ex-situ* collections in general, may play an even greater role as potential providers of material.

2.2.9 Zoos and Aquaria

Zoos and aquaria exhibit collections that primarily consist of living wild animals, of one or more species. Although historically these organisations were mere collections for public display, nowadays education, conservation and research play a very important role.

Many of the UK organisations and almost all respondents from this sector, are involved in conservation breeding programmes and support projects for reintroduction of species into the wild. Many zoos and aquaria are also committed to research for the better understanding of the natural world and environmental education.

There is little practical need to acquire new genetic material from the wild. Respondents noted that although the exchange of animals for conservation efforts are expected to increase, the demand for new material (e.g replacement and extension of displays) is very small and it is not expected to increase. Many recognise that they are not likely to develop new species programmes in their collections. Supply of animals comes from their own managed breeding programmes and also from exchange with other collections nationally and internationally, often as part of international conservation programmes.

2.2.10 Culture Collections

Culture collections have, and will continue to be, centres of research in areas of taxonomy and preservation of the specialist groups of organisms within their remit and/or expertise. With the advent of new molecular biological technologies and the need for applied research to address current topical industrial and environmental problems (e.g. industrial pollution, oil spills and water treatment), institutions with culture collections are now exploring new areas of research and development as an interface with industry and academia.

Culture collections also recorded an increase in the use of genetic resources, and the majority expect an increase in the near future. Once again, organisations responding remarked that new molecular tools have facilitated gene discovery from novel germplasm for use in breeding and drug discovery, and that the use of, and better understanding of, diagnostic work and genomics has resulted in a greater awareness of the potential of genetic material. New areas of research potential are, consequently, becoming evident. Some organisations have also reported a greater interest in UK native species.

Chapter 3 – Awareness of the CBD and ABS

3.1 Awareness of the CBD and its ABS provisions

Like all international conventions the CBD is, essentially, a treaty between sovereign States, but it is of central importance to business and research organisations using biological resources. The provisions of the Convention, and national laws that implement them, set the scene for any organisation or individual seeking access to samples of plant, animal or microbial origin for scientific research or for commercial development.

From the outset of the negotiations that led to the signature of the CBD in 1992, the pharmaceutical and agribusiness sectors were identified as the largest and most important users of genetic resources. Consequently, before and during the actual negotiations of the CBD, in particular on the ABS provisions, these two global sectors were represented and consulted in expert meetings. This appears to have been reflected in the high level of awareness of the CBD and ABS issues amongst these sectors in the findings of the survey. However, for some sectors, including cosmetics, wildlife traders and livestock production, this review was the first time they had been formally consulted on these issues by Defra since the CBD came into force. Other sectors, including some botanical gardens, zoos, research institutions and potential providers of *in-situ* material (e.g. major landowners) had already been approached on some of the issues for the setting up of Defra's web-based National Focal Point for ABS (www.defra.gov.uk/science/geneticresources). Others were aware of the CBD as a result of their participation in UK networks such as PlantNetwork or the UK Plant Genetic Resources Group (UKPGR).

Box 5 - Summary of provisions in the CBD on access to genetic resources and benefit-sharing (ABS)

- Art. 1 Objectives of the Convention: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources.
- Art.15.1 Sovereign rights of States over their natural resources; the authority of national governments to determine access to genetic resources.
- Art.15.2 Endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the CBD.
- Art.15.3 Articles 15, 16 and 19 only apply to genetic resources acquired "in accordance with this Convention": i.e. not to those obtained prior to its entry into force or from non-parties.

- Art.15.4 Access, where granted, to be on mutually agreed terms and subject to the provisions of Article 15.
- Art.15.5 Access to genetic resources to be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
- Art.15.6 Endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
- Art.15.7 Take legislative, administrative or policy measures, as appropriate, . . . 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 resources. Such sharing to be upon mutually agreed terms.
- Art.16.3 Access to and transfer of technology using genetic resources to countries providing the genetic resources.
- Art.19.1 Effective participation by providers of genetic resources in biotechnological research on the genetic resources they provide.
- Art 19.2 Priority access on a fair and equitable basis by countries (especially developing countries) providing genetic resources to the results and benefits arising from biotechnologies based on them. Such access to be on mutually agreed terms.

3.1.1 Results from the survey

According to the survey, more than 80% of the 127 respondents are **aware of the CBD**. However, about 30% of the total number of respondents claim that the CBD does not affect them or do not see the relevance of the CBD to their work. 15% did not answer the question. General awareness of the CBD was significantly higher in botanical gardens, zoos, research institutions, universities, culture collections, and pharmaceuticals and agribusiness. Organisations in cosmetics, horticulture and wildlife trade appeared to have lower awareness.

55% acknowledged being **aware of the provisions on access to genetic resources and benefit-sharing**. Universities, research institutions and botanical gardens appeared more aware (60 - 80%) than any other group. The majority of respondents from the pharmaceutical, agribusiness, horticulture and livestock production industries and also *in-situ* providers, considered themselves aware of ABS provisions. However, only a minority of zoos, aquaria and cosmetics acknowledged familiarity with ABS issues of the CBD.

*Respondents' general awareness of the CBD does not necessarily imply the **understanding of its provisions**. From the questionnaires received it appears that a large proportion of organisations have only a basic grasp of the relevance and implications of the CBD to their work. As one major research institution commented, "knowledge has been patchy and the interaction between the CBD and other relevant national regulations is unclear" (e.g. regarding plant health, export, etc).*

The majority of respondents appeared to lack detailed knowledge of the CBD and many of the responses appeared to indicate confusion or misinterpretation. Some respondents thought that the CBD provisions on ABS only apply to commercial activities, or to genetic resources that are commodities and that, consequently, only commercial benefits need to be shared. Others believed that the CBD only applies to endangered species or species taken from the 'wild' and not material obtained from ex-situ collections. A frequently expressed view was that the CBD does not affect organisations that do not collect genetic resources directly (i.e. if they use intermediaries or get material from ex-situ collections).

40% (50) of respondents have actually developed a specific **ABS policy** or an environmental, international or ethical policy covering ABS. Of the remainder, 30 are currently preparing or plan to develop in the near future, a policy on these issues. Groups of organisations that have been more proactive in developing their own specific ABS policies comprise: pharmaceuticals, botanical gardens, culture collections, agribusiness and research institutions.

Nearly a third (42) of respondents stated they have heard of the **Bonn Guidelines** and 10 have actually used them to inform or draft their own policies. Those organisations alert to the Guidelines found them helpful when negotiating MTAs. Other respondents indicated that they had not found it necessary to update their policies in the light of the Bonn Guidelines, since they were already consistent with the terms of the guidelines. Some respondents raised concerns that the Bonn Guidelines were not sufficiently specific; that a sectoral approach would be more appropriate; or, suggested that their voluntary nature does not help to create a level playing field (i.e. some use the Guidelines while others do not, or some use them with greater precision than others).

Organisations from the agribusiness sector, which is the most familiar with the Guidelines, were consistent in expressing that, in spite of the Guidelines being rather general, they are helpful to some degree. However, this particular sector considers that the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is better adapted to the characteristics of its trade. In any event, both instruments enshrine the same principles of access and benefit-sharing, and the voluntary Bonn Guidelines could be used when developing ABS policies either pursuant to the CBD or the ITPGRFA.

Box 6 – Stakeholders' Perceptions of the CBD

Main positive views of the CBD include:

- Increased recognition of the value of biodiversity, scientifically and environmentally
- All respondents agree with the principle of international equity and having fair relationships between developed and developing countries
- Agree with the ultimate goal of promoting conservation of these resources

- Agree that the CBD has improved awareness about international, conservation and ethical issues.

However, the CBD and its implementation is generally perceived as a negative externality or at least is cause of concern equally for the small and big player. Negative views on the CBD can be summarised as follows:

- Lack of clarity in the CBD and national access and benefit-sharing measures;
- Difficulty in keeping up with the different measures adopted by countries
- Bureaucracy and delay involved in access procedures
- Lack of understanding of product development process and R+D inputs
- Unrealistic expectations from some governments and provider country institutions
- ABS provisions make you pay again for something that was already purchased
- Belief that the CBD and access legislation create an additional disincentive to conduct natural products research, already under pressure from new technologies and market trends
- Regulations and policies on ABS if not universally applied create an unlevel playing field
- Policies on ABS and MTAs create a disincentive to exchange material among research organisations
- In spite of the CBD and ABS policies, guidelines and laws it is actually extremely difficult to implement the CBD provisions on ABS
- Sometimes the lack of trust in the partner or supervising national authority providing the material, in spite of a body of laws, guidelines and policies in place, impedes MATs being successfully negotiated
- Link to conservation is not strong enough – i.e. too hard to do biodiversity research – easier to log the forests

3.2 Complexity of the existing international framework and of the concept of biodiversity

Much of the lack of detailed knowledge of the CBD and its provisions on ABS is, arguably, understandable. The CBD is a complex agreement and its text can be ambiguous. This is almost undoubtedly a reflection of the fact that biodiversity itself is a complex topic and covers an enormous range of interrelated and multifaceted issues. Large gaps in scientific knowledge[23] and the difficulties of economic quantification leads to a great diversity of political approaches, difficult to reconcile in the short term.

The numerous overlapping international instruments may also lead to some confusion among stakeholders. These can be overwhelming and range from habitat protection, to sustainable management practices, to intellectual property rights (IPRs).

Unlike the other Rio Conventions, the CBD entered a legal field crowded with global agreements. Legal instruments are particularly prolific in relation to the

[23] With 1.7 million classified species and estimates of unknown species ranging from 10 million to 100 million it is practically impossible to have all the facts and data.

CBD's first objective (conservation). Zoos, aquaria, wildlife traders and livestock producers are generally well aware of the 1973 Convention on the International Trade of Endangered Species of Wild Fauna and Flora (CITES) as they deal directly with many of the species covered by it. Other international and EC instruments govern aspects of other sectors related to the second objective of the CBD on sustainable use (for example, import/export requirements, health and environmental regulations for the animal breeding sector). Regarding its third objective (ABS), the CBD provisions overlap to some extent with a number of international regimes. On access to agricultural resources there is the International Treaty on Plant Genetic Resources for Food and Agriculture with which the agribusiness sector is rapidly familiarising itself since it came into force in June 2004. Regarding aspects of benefit-sharing, treaties such as the UPOV Convention (International Convention for the Protection of New Varieties of Plants), WTO TRIPS (Trade-Related Aspects of Intellectual Property Rights) and various WIPO's (World Intellectual Property Organization) instruments already cover issues related to intellectual property rights.

Ten years after its entry into force, the CBD, and in particular its provisions on ABS, have proved very difficult to implement. Beyond establishing general principles of national sovereignty, the CBD's terminology and implementation is extremely complicated and actual action required has proven very difficult to specify. In spite of many countries enacting law covering ABS issues, in some cases such national legislation has proved too complicated, unclear or cumbersome. The development of standard procedures and rules has proved a significant challenge. Consequently, it is difficult to raise awareness by explaining what those procedures and rules are, other than in general terms. As one representative from a multinational agribusiness company explained "although we have a policy to comply with the CBD, to respect the sovereign rights on genetic resources of the Parties and not to access such genetic resources without prior informed consent of the national authority, the absence of national legislation in some providing countries and clear guidelines or obligations, make the drafting of written and more detailed policies in this area impractical".

There is a feeling of frustration among those organisations that acknowledge the objectives of the CBD but experience real difficulties in implementing the detail of its ABS provisions in policies and ABS agreements (e.g. MTAs). The Bonn Guidelines notwithstanding, another representative noted that the absence of clear benefit-sharing guidance has tended to deter both potential donor organisations and industry, as the liability is initially unquantified (it could be later specified in an MTA if the parties agree to negotiate one) and the bureaucracy onerous because of the uncertainty on what exactly is required. It appears that with very little practical guidance and best practice available negotiating MTAs is proving a real challenge.

3.3 Conclusions

Those organisations most knowledgeable of the CBD and Bonn Guidelines are generally large, more actively involved and experienced in the use and trade of genetic resources. The dissemination of best practice needs to be encouraged from the large organisations to the small and medium ones. This will contribute to achieving a more level playing field. Options on how to encourage best practice and its dissemination should be considered.

In general terms, there seems to be some confusion in understanding how the various related instruments apply and relate to each other, including the voluntary Bonn Guidelines and the CBD, relevant sectoral guidelines, policy or legislation (e.g. health, environment, alien species) and international treaties such as the ITPGRFA, CITES, UPOV Conventions and WTO TRIPS. Work is needed to explain the relationship and implications of these overlapping instruments.

The ABS provisions of the CBD are in themselves insufficient to be implemented by practitioners given that they are a framework for action rather than precisely defined obligations. The Bonn Guidelines, adopted within the CBD in 2002, whilst are not intended to be a substitute for national legislation or regulation, are the most detailed and practical instrument developing the CBD ABS provisions. Given that the Guidelines are a recent development, experience with their use is rather limited, not only in the UK but world-wide. Their use should be strongly encouraged in order to best fulfil the requirements laid out in the CBD and, very often, implementing national legislation. In addition, experience with practical use will be crucial information for the negotiations on an international regime on ABS which are about to start.

Chapter 4 - Acquisition

4.1 Introduction

The CBD establishes rights and responsibilities for Parties, i.e. States. Thus, Parties are directly bound to the CBD provisions and are required to give effect to their obligations within their territory. Private actors are only legally bound to the CBD when governments, in exercise of their sovereign rights, implement CBD provisions through national legislation, regulation or administrative measures.

In particular, Article 15 of the CBD stipulates that access to genetic resources is subject to the prior informed consent (PIC) of the Contracting Party providing those resources; that such access, when granted, is to be on mutually agreed terms (MAT); and that those terms must include the sharing of the benefits arising out of the commercial and other utilisation of those genetic resources.

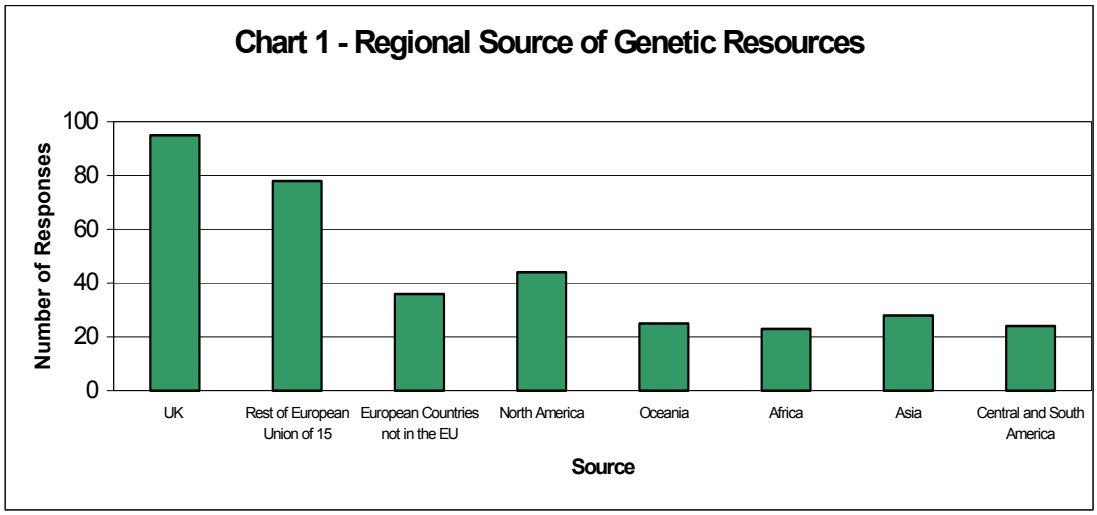
National law may then specify access requirements in detail, in particular it may clarify the ownership of genetic resources and grant rights to landowners or holders of intellectual property. Those rights will determine the role of those players in ABS negotiations. However, many countries, including the UK, have not enacted specific law to implement ABS requirements. This does not mean, though, that there is no applicable law on ABS. For example, property law and contract law will generally be of relevance when collecting material and negotiating mutually agreed terms. In addition, there is often environmental law with implications for ABS (e.g. on access to, and permitted activities on, protected areas).

Whilst there is no definition of “prior informed consent” (PIC), before any biological resources are obtained from *in-situ* conditions (i.e. in their natural environment), the consent of the relevant national authority/ies of the providing country must be sought where required by its national law. The consent to collect material from the “wild” (i.e. in *in-situ* conditions), is often granted by means of a permit. The terms of access, use (including any further supply of the material) and benefit-sharing need to be negotiated and mutually agreed between the parties/partners. This can take many forms from a memorandum of understanding (MoU), to an exchange of letters, to a material transfer agreement (MTA) which can be equal to a contract. If the first recipient later passes on that material to another recipient, the terms of the original transfer should be observed (e.g. the original MTA could require that an equitable share of the benefits derived by the second recipient should go back to the providing country). There is no definition either of what is meant by “equitable share” but it is reasonable to expect that parties should operate on the basis of best practice and good faith, ensuring transparent mutually acceptable terms.

Material can also be obtained from *ex-situ* conditions (i.e. outside its natural environment such as from a genebank or a microbial collection), in which case the consent of the national authority should also be obtained. Current best practice (e.g. Bonn Guidelines) recommends that the consent of the body governing the *ex-situ* collection should be obtained.

4.2 Access to genetic resources: general findings

127 organisations replied to this section of the questionnaire and identified the different sources of the material they use and hold. Chart 1, below, shows the world regions that respondents identified as the main sources of material that they have obtained in the last 10 years. One organisation responding could identify several sources for the material held in its collection.



According to the survey, 95 organisations obtained a large proportion of their genetic resources in the last 10 years from the UK (*in-situ* or *ex-situ;* if the source is *ex-situ* the material may well not be native to the UK); 78 organisations acquired their material from EU-15 sources (excluding UK); and 36 organisations obtained material from other European countries outside the EU of 15 Members (before the enlargement to 25).

47 organisations sourced material from North America and 26 from Oceania (Australia, New Zealand and South Pacific). Only 24 accessed biological material from Africa, 26 from Central and South America and 30 from Asia.

Less than 20% of respondents sourced material from Africa, South and Central America or Asia.

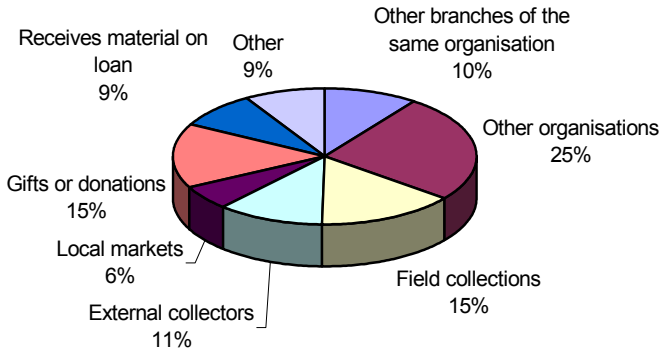
These data show that the large majority of respondents sourced the greatest bulk of their material from developed countries. However, this does not necessarily mean that the material actually originated (i.e. was native or endemic) in developed countries as no differentiation was made between *in-*

situ and *ex-situ* material nor post and pre CBD material (i.e. after or before the entry into force of the CBD in December 1993).

Thus, we do not know whether those developed countries were the actual countries of origin of the material acquired by the British organisations (i.e. the material is found *in-situ* conditions (its natural habitat)) nor whether the material held in *ex-situ* collections in those countries was originally acquired in conformity with the CBD. However, as a very general rule most of the material held in *ex-situ* collections is pre CBD. The next sections explore the issue of UK organisations' compliance with the national laws on ABS of the providing country or countries.

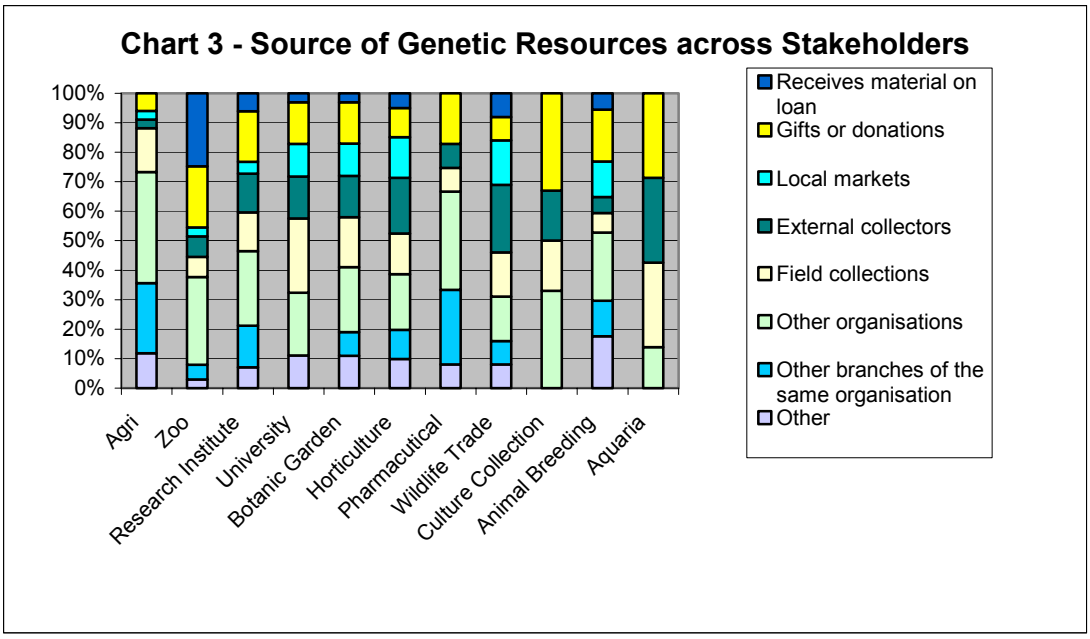
Chart 2 shows the sources of material held by all the different organisations responding to the survey.

Chart 2 - Institutional Source of Genetic Resources



The largest segment shows that a quarter of organisations obtain genetic resources through exchange with other organisations (*ex-situ*) rather than from the wild (*in-situ*). Field collections (i.e. in the wild (*in-situ*)) and material received as gifts or donations are also an important source, followed by exchanges within the same organisation, external collectors and loans. The large majority of material is in fact indirectly acquired, meaning that the responsibility for getting PIC is left to others.

Chart 3 shows the percentage of the different sources of material obtained by the various stakeholder groups in the last 10 years.



Exchange with other organisations is the main source of material for all stakeholders except universities and wildlife traders. The primary source of material for universities is field collections (25% of material held); in fact, 78% of university respondents undertake field collections. Botanic gardens also carry out significant collecting (67% of botanic garden respondents) but its not its main source of material (17% versus 22% from exchange).

Agribusiness and pharma, which generally hold large in-house collections, rely more than any other group on the exchange of material with other organisations and other branches within the same organisation. Culture collections source material in equal parts from other organisations and donations.

Field collectors should comply with any relevant law (including PIC and MAT requirements) when acquiring material, as explained in the next section. Any organisation acquiring material indirectly (via an external collector, other organisations, etc.) should ensure that the material was legally acquired. There is the possibility that some of the material could be obtained without the consent of the national authorities of the providing country, particularly in the case of unsolicited gifts or donations, loaned material and local markets. This presents a dual task. First, the UK as a country with *users* under its jurisdiction, needs to raise awareness about compliance with national legislation of providing countries. Second, the UK, which is also a country with *providers* under its jurisdiction, should also raise awareness about applicable UK legislation, the role of biological diversity in conservation and sustainable development, procedures for obtaining PIC and negotiating benefit-sharing. In both cases, the context of the CBD and the relevance and advantages of the Bonn Guidelines should be explained, as an important and useful tool.

4.3 Obtaining Prior Informed Consent (PIC)

Those organisations responding from all sectors that collect material abroad and are well aware of the CBD and its requirements on ABS, consider that in the last 10 years (since the entry into force of the CBD) it has become more difficult to obtain material. Such increased difficulty might not be necessarily or solely related to the CBD. For example, increasing numbers of species are covered by the provisions of CITES, more stringent mechanisms relating to preventing the spread of animal or plant diseases are in place and enforcement may have become more effective.

Respondents have found difficulties either identifying relevant national authorities or finding out about national law relevant to ABS in providing countries. However, a few praised the CBD website listing National Focal Points on ABS (http://www.biodiv.org/doc/lists/nfp-abs.pdf) for greatly facilitating the process of finding relevant authorities and applicable law.[24] As one representative from a major company put it: "We have had many problems, too numerous to detail. The biggest problems are countries where the authority remains unclear, and samples, often passing *via* universities in the developed world, where the recording of the origin of the samples has been lost (or possibly never existed). Wherever possible, we avoid entering into arrangements in such cases now." Another respondent explains that at the initiation of a research programme, they use 'reasonable endeavours', including checking the CBD web page, dealing with third parties with experience and credibility, and asking donors to confirm as part of the contract that they have the necessary authority to provide samples: further checks would be carried out given success in reaching critical milestones on the path to commercialisation. However, only a minority of respondents seem to take such an approach on a regular basis.

Organisations that are aware of the CBD and face these difficulties might be inclined to take a more practical approach, as a curator from a research institution and culture collection explained. His understanding of the CBD was that its intention is not to prevent or hinder the free and unrestricted flow of materials within the scientific community. Consequently, this organisation's policy on ABS places most of the burden of compliance with the exporter of material and end user (i.e. the provider and the user that commercialises material). Thus, the organisation requires from the provider the disclosure of the country of origin and proof of prior informed consent and mutually agreed terms. In exchange, it offers a benefit-sharing agreement to the provider. This curator acknowledged that in the last year and a half, none of close to 200 providers of material to his collection have actually showed proof of PIC and MAT. The curator of this collection confirms that in his experience, providers do not know how to obtain the documentation associated with the CBD, or cannot be bothered accessing and completing it and/or have little intention of reading or complying with that paperwork. He also wonders who would police the practices associated with the CBD. In any case, given this context of

[24] More recently a list of National Competent Authorities has been added. See http://www.biodiv.org/doc/lists/nfp-abs-cna.pdf

perceived non-compliance, he expressed concerns that if his collection was to fully implement the undertakings of the CBD, his collection would soon be out of business.

One agribusiness multinational that collects material worldwide commented: "The CBD provides that legislative measures must be taken by Contracting Parties to facilitate access to genetic resources. However, very few countries have taken such measures. In general, we have avoided sourcing from countries, which have not put legislation in place. At the moment, therefore, the CBD is counterproductive: few countries are in a position to receive income, and the genetic diversity is not being explored and used. Given that a key aim of benefit-sharing is to preserve diversity, the fear is that the lack of funding means that diversity is being lost. Much of the problem seems to be that the CBD provisions are not sufficiently clear on the obligations of sourcing or receiving entities, so the exposure being assumed is uncertain, and there is a fear of undertaking commitments that will prove to be undeliverable once the obligations become clearer." Very similar views and concerns have been expressed by the pharmaceutical sector.

For these reasons, among others, the agribusiness sector has strongly supported the International Treaty on Plant Genetic Resources for Food and Agriculture, which takes account of the specific needs of the food and agriculture sector. This is a new Treaty which entered into force in June 29 2004. It establishes a multilateral system for access and benefit sharing, which provides for facilitated access to genetic resources and a multilateral approach to benefit sharing. It will be implemented through a standard MTA, to be adopted by the Treaty's Governing Body.

4.4 Use of genetic resources vs. biological resources and implications on material and intellectual ownership of the resources

The ABS provisions of the CBD clearly relate only to "genetic resources" and not to "biological resources". This differentiation is important as the use to which the material acquired is subject to, determines whether the ABS provisions apply.

Several respondents from the horticulture, agribusiness and wildlife trade industry expressed concerns and had questions about the ownership of material. These sectors trade biological material on a regular basis. Once the material is acquired, often by purchase, they assume that complete ownership of the material, and the rights to use the genetic resources within it, is transferred. Those working in these sectors find it difficult to understand that in spite of the 'purchase' and transfer of physical material, the right to use the genetic resources might still belong to the authorities of the providing country. If this is the case, they also wonder how far down the line ('downstream') the national authorities have control over the resource. For the great majority these were issues that needed clarification.

For some sectors, biological material is perceived as a commodity which may have little economic value per unit but is subject to significant trade. However, for other sectors, it is a resource which is only needed once but contains genetic information of great potential, including economic value (e.g. when results in a drug or cosmetic). The ABS provisions of the CBD have been conceived with the second interpretation in mind (i.e the use of the "genetic resources").

It seems that those sectors that value living biological material as a commercial commodity and regularly trade with it (an advantage if carried out in a sustainable and controlled manner), are increasingly reducing such trade. Instead, those sectors seem to obtain biological material once (or not regularly) in order to produce offspring in *ex-situ* conditions (i.e. captive breeding or propagation), and consequently, are becoming less dependent on the providing countries for supply. In such case, those sectors no longer use "biological material" as such, but use the "genetic resources" contained therein (e.g. genomic information to artificially replicate an organism or living material). Such use would be equivalent to those undertaken by industries like the pharmaceutical and plant breeders (agribusiness and horticulture). The ABS provisions on "genetic resources" of the CBD clearly apply in that case, in particular the requirement for benefit-sharing with the providing country.

Thus, whenever the "genetic resources" are used, the benefits derived from that use (commercial or not; monetary or non-monetary) should be "equitably shared" with the country providing those resources. This is what the CBD says and many national laws and regulations have implemented this "benefit-sharing" requirement. For example, if any intellectual property rights are obtained over the genetic resource or over an invention directly based on the genetic resource, the owner of the IPR would remain so, but may be required to negotiate the sharing of part of any resultant economic benefits. This is an extremely complex and sensitive issue but stakeholders would benefit if, as appropriate, best practice is shared globally.[25] Transparency would help raise awareness, harmonize terms and conditions and build trust among potential partners worldwide.

4.5 Policies on ABS and use of Material Transfer Agreements (MTAs)

Few of the organisations approached have developed policies in response to the CBD, and very few of them, private enterprise in particular, have made those policies available on their websites.

Several organisations replied that it is their policy to comply with the CBD but many have expressed their frustration when trying to implement it. Many respondents have also declared (backed up by written policy or not) that they only work with 'reputable' or 'legitimate' suppliers or sources, thus relying on

[25] In addition, the EU has agreed a proposal for a mandatory requirement to disclose the country of origin or source in patent applications. This will help providing countries monitor compliance with their ABS rules.

the supplier to be fully aware of pertinent legislation and abide by it: but they do not check the paperwork. Others subcontract organisations or individuals (intermediaries) to obtain the material for them and expect them to observe the applicable law to ABS. Several only rely on commercially available material, assuming, rather than positively checking, that it has been obtained legally.

A typical response was: “we deal only with bona fide organisations and never knowingly deal in genetic resources from unknown sources.” There is generally a strong element of trust in the supplier. Few organisations seem to seek written proof from intermediaries that the genetic resources were obtained lawfully.

Some botanical gardens have the policy of working only with organisations that abide by the terms and the spirit of the CBD. This is not the case in the horticulture industry, which generally relies on nurseries, *ex-situ* collections and even plant collectors, but seems to be less aware of the CBD. On the other hand, the vast majority of horticulture material exchanged is commercially available worldwide and was acquired before the CBD came into force.

Big pharmaceutical companies are among the most aware of ABS requirements. The CBD seems, nevertheless, to have had some negative impact in the sector. Some of these companies have changed their strategies by getting less involved in the acquisition process of raw materials (i.e. relying on suppliers or synthetic compounds or outsourcing the collecting and screening process) or sourcing from, and working with, less problematic partners or countries. For example, one company explained: “we deal mainly with commercial and academic organisations in the EU or USA who are aware of these issues in their own countries, and who export genetic material on a regular basis”. In the UK, many of the pharmaceutical companies are actually subsidiaries of multinationals based in the US or other European countries. In such cases, biological material is generally passed on from either the main offices or specialised branches or laboratories responsible for R+D.

The great majority of respondents stated that they enter into some sort of formal arrangement when acquiring biological material. This might not be ABS-related in all cases – for example, the acquisition of animals from wild populations for the zoo sector is generally covered by written agreements, which follow the guidelines of the UK Federation of Zoos and the World Zoo Conservation Strategy. Among other issues, these guidelines ban illegal and unethical trade (which threaten the numbers of wild populations), unethical animal transport and so on.

A small subset of actors but among them many of the larger organisations that have had to deal with terms and conditions of access over the last ten years or so (*ex-situ* collections, research institutions, pharmaceutical and seed industry), generally try to make use of material transfer agreements (MTAs) in line with the CBD requirements on ABS. MTAs can specify the

terms and conditions of the acquisition and use (including further supply) of the material.

Although organisations regard entering into agreements as desirable or even inevitable, and benefit-sharing with the partner is often regarded as "business-as-usual", some organisations resent having to share benefits with the government instead of the partner in the source country. Several organisations complained that procedures are much simpler when the benefit-sharing process only involves the partner (as opposed to the government) in the source country: often, organisations work with close collaborators where there is a good relationship. A scientist-to-scientist relationship is perceived as generally easier as there is trust and it is often the non-monetary benefits that scientists in developing countries are interested in (e.g. training and equipment). Those sorts of benefits are also much easier to negotiate and distribute than, for example, potential royalties, which materialise 10 or 15 years down the line, as in the case of a drug for example. The participation of authorities is clearly seen as a burden as it may translate into further procedures, delays and much more difficult negotiations, partly due to overly high expectations of returns. But crucially, it is the involvement of the national authorities in the relationship between the provider and the user that guarantees the linkage between benefit-sharing and conservation as envisaged in the CBD, as well as ensuring that those resources are not over-exploited. The government of the providing country has the responsibility to ensure that such distribution is "fair and equitable" and used to protect biodiversity.

Box 7 - Benefit-Sharing and Intellectual Property Rights (IPRs)

Benefits derived from the use of genetic resources can take many forms and are often of non-monetary nature. Among the monetary benefits, intellectual property rights (IPRs) are the most complex ones and benefit-sharing should be covered by ABS agreements. There are two main intellectual property rights used in this context: patents and plant breeders rights.

Patents

The World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) sets the international framework for conventional IPRs. Article 27(1) of TRIPS states that: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

Article 27(3)(b) allow for the exclusion from patentability: "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.(…)"

Under the Patent Rules in the UK, an application for a patent can be filed for inventions which involve the use of or concerns biological material.

Plant Breeders' Rights

The UK Plant Varieties Act 1997 (PVA) grants plant breeders' rights (PBRs) to those who breed varieties, or discover (i.e. growing in the wild or occurring as a genetic variant) and develop them.

In line with the 1991 UPOV Convention, a variety qualifies for PBR protection if it is distinct, uniform, stable (DUS) and new. A variety is deemed to be new if it has not been sold in the UK within a year of the date of application and if it has not been sold outside the UK within 4 years (6 years for vines and trees) prior to the date of application.

UPOV has established a detailed set of general principles for the conduct of the examination of plant varieties for DUS and more specific guidelines for some 210 genera and species. These guidelines are widely used by UPOV Member States within their own PBR systems and also form the basis for the technical protocols established by the Community Plant Variety Rights Office (CPVO).

PBRs granted in the UK apply only in the UK. In order to seek protection in another country, a separate application for a grant should be put forward to the relevant national authority. Within the European Union, however, there is a system of European plant breeders' rights which is administered by the (CPVO). A Community PBR granted by the CPVO is applicable throughout the 25 EU Member States.

Benefit-Sharing

Neither the CBD nor the Bonn Guidelines determine what benefits should be shared between the provider and the user of genetic resources. Both instruments make clear that this should be the subject of mutually agreed terms, which, by there very nature, are established on a case by case basis. However, the Bonn Guidelines include a list of examples of what form benefit sharing might take. The terms of benefit sharing would normally be determined at the time of access to the genetic resources and included in the material transfer agreement (MTA).

The Bonn Guidelines distinguish between "monetary" and "non-monetary" benefits but in reality IPRs are economic tools that may facilitate, but do not guarantee, a monetary return. Where commercialisation takes place, monetary benefit sharing is likely to be involved in most cases. Although monetary benefit sharing can also take a number of forms, including up-front payments and milestone payments, in practice, the sharing of royalties is probably the most common approach.

Investigation of mechanisms which will aid in the achievement of benefit sharing is currently underway in the WIPO Intergovernmental Committee on genetic resources, traditional knowledge and folklore (IGC).

In accordance with the CBD and as suggested in the voluntary Bonn Guidelines developing Article 15 of the CBD, royalties obtained through IPRs ought to be fairly and equitably shared with the relevant stakeholder(s) of the provider country. This may include national authorities. What amounts to fair and equitable will, of course, depend upon the individual circumstances surrounding the creation of the IPR and will depend, amongst other things, upon what was agreed at the time of access to the raw genetic material (in, for instance, an MTA) and on the amount of contribution that the relevant stakeholder(s) in the provider country has made to the development of the subject of IPR protection.

4.6 Intermediaries

The CBD Secretariat recognised in a paper presented at COP 5 in 2000 that most genetic resource exchanges are not limited to a simple user/provider relationship.[26] In the great majority of cases and across sectors, companies gain access to samples through intermediaries such as universities, research institutions, genebanks, botanic gardens and independent or freelance collectors which may acquire material on behalf of others.

Two thirds of respondents declared using intermediaries when acquiring biological material. The use of intermediaries was widespread in all sectors consulted.

Intermediaries are increasingly relied upon not only to acquire promising materials but also to obtain government approval for collections. Several organisations stated that they do not check whether the intermediary obtains the material in accordance with the relevant laws of the source country. As one representative from industry said "it is the suppliers' liability to comply with legislation (from the source country). Exchange agreements specify that as far as possible suppliers believe they can legally supply." A typical plant breeder comment was: "it is not our duty to check if someone else is complying with relevant laws". Others had a different view, typically: "it is the responsibility of the collaborating organisation to ensure that the relevant permissions have been acquired. They are asked whether this has been done prior to the joint collection". It appears that in most cases when organisations claimed they had no difficulty in obtaining materials, they relied upon counterpart organisations in the source country which, in theory, would have dealt with any national ABS requirements.

4.6.1 Intermediaries: use of MTAs

Agreements between intermediaries and companies generally deal only with the rights and benefits of the immediate parties, rarely addressing the rights of providing country institutions.[27] However, MTAs could require them to do so. Regrettably, from the responses and limited number of policy statements received during the course of the survey, it appears that when intermediaries are involved, the material is transferred under conditions that do not confirm that PIC has been obtained. Neither are there requirements to share benefits with the original provider or to ensure that transfer to third parties is only allowed under terms consistent with the original terms of acquisition.

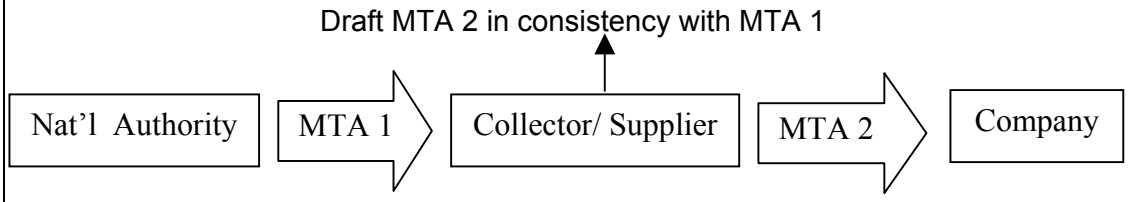
When this happens, the simple two or three party scheme around which the concept of ABS was created, will no longer work if downstream recipients are detached from the previous processes. In other words, parties using a variety of independent intermediaries will no longer be linked through a chain of

[26] UNEP/CBD/COP/5/8.
[27] ten Kate and Laird, p. 322.

MTAs with similar terms and where the final MTA respects the conditions of use established in the first MTA (see Box 8).

Box 8 - Example of a chain of Material Transfer Agreements (MTAs)

Typical content of MTA:
- Legal acquisition (or prior informed consent – PIC)
- Permitted uses (including supply)
- Benefit-sharing



Source: ten Kate, K., Laird, S., Royal Botanic Gardens, Kew, The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing,, Earthscan Publications Ltd, London, European Communities, 1999, p.23.

Intermediaries, especially if they are an individual working largely alone (e.g. university personnel or a for-profit independent agent), appear more likely to be poorly equipped in terms of resources and expertise to obtain PIC and to negotiate benefit-sharing. Part of the solution might be for recipient organisations to share the administrative burden faced by intermediaries in negotiating access and benefit-sharing arrangements. Furthermore, the recipient should seek reasonable assurance that all appropriate procedures have been adhered by any intermediaries.

In addition to collection intermediaries, research and development on genetic resources for both scientific and commercial purposes frequently involves numerous parties making different contributions to the end product. The role of non-end users is increasingly complex and this has implications for the core ABS issues. A project may include more than one academic, governmental and industrial partner in multiple countries. Tracing the parties involved in acquisition becomes difficult, particularly in relation to checking compliance with PIC requirements, whilst the practical responsibility for benefit-sharing becomes particularly complex.

The number of collaborators has increased in recent years as activities have become more specialised. The collection, preparation and distribution of samples, as well as testing, analysis, product development and marketing may each involve one or several organisations.

The complexities of trade in genetic resources with multiple intermediaries need to be taken into account when designing new policies, laws and regimes. An international certificate of origin/source/legal provenance for commercial purposes should be considered. Examples of contractual clauses

and MTAs could be made available to stakeholders involved in ABS transactions to help achieve a common and equitable approach.

4.7 *Ex-situ* collections

Chart 2, above, shows that to a large extent organisations tend to use their own in-house collections or other organisations' collections as the source of material. In particular, a minority but still important number of organisations acknowledge acquiring material from *ex-situ* sources in the UK.

The vast majority of materials held in *ex-situ* collections were acquired before the entry into force of the CBD, and are thus not subject to its provisions. However, some collections also have policies to share benefits from the use of pre-CBD material.

Whilst managers of collections are increasingly using MTAs to regulate access to materials within their collections, the great majority of those materials can still be accessed without any commitments to share any resultant benefits on the part of recipients.

If the acquisition of new material from *in-situ* conditions abroad becomes particularly difficult, organisations will be tempted to focus their attention towards more easily available national sources, including *ex-situ* collections. We have seen in Chapter 2 - Importance of Genetic Resources, how several organisations have noticed an increase in interest in the use of existing national collections, and in the study and characterisation of genetic resources using improved modern technology.

Several organisations replied that one or more major UK *ex-situ* collections is their source of material and assumed that those collections meet all the requirements of the CBD. The growing importance of *ex-situ* collections as a source of material will place an extra burden on them, particularly if the mutually agreed terms include ensuring that the original ('upstream') terms of use are respected and that no subsequent commercialisation takes place without the prior knowledge and consent of the original provider.

Box 9 – An Example of Best Practice:
Principles on Access to Genetic Resources and Benefit-sharing for Botanical Institutions

Between 1997 and 2001 the Royal Botanic Gardens, Kew coordinated a project to bring together a group of botanical institutions to agree to common sectoral guidelines on ABS. The result was a set of Principles on ABS, Common Policy Guidelines and Explanatory Text which those initial 28 institutions adopted and committed to use when acquiring, using and supplying biological material.

The Principles on ABS agreed are the following:

- Honour the letter and spirit of the CBD, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and laws relating to access and benefit-sharing, including those relating to traditional knowledge.

Acquisition of genetic resources

- In order to obtain prior informed consent, provide a full explanation of how the genetic resources will be acquired and used.
- When acquiring genetic resources from *in-situ* conditions, obtain prior informed consent from the government of the country of origin and any other relevant Stakeholders, according to applicable law and best practice.
- When acquiring genetic resources from *ex-situ* collections (such as botanic gardens), obtain prior informed consent from the body governing the *ex-situ* collection and any additional consents required by that body.
- When acquiring genetic resources from *ex-situ* sources, whether from *ex-situ* collections, commercial sources or individuals, evaluate available documentation and, where necessary, take appropriate steps to ensure that the genetic resources were acquired in accordance with applicable law and best practice.

Use and supply of genetic resources

- Use and supply genetic resources and their derivatives on terms and conditions consistent with those under which they were acquired.
- Prepare a transparent policy on the commercialisation (including plant sales) of genetic resources acquired before and since the CBD entered into force and their derivatives, whether by the Participating Institution or a recipient third party.

Use of written agreements

- Acquire genetic resources and supply genetic resources and derivatives using written agreements, where required by applicable law and best practice, setting out the terms and conditions under which the genetic resources may be acquired, used and supplied and resulting benefits shared.

Benefit-sharing

- 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, and, in the case of commercialisation, also monetary benefits.
- Share benefits arising from the use of genetic resources acquired prior to the entry into force of the CBD, as far as possible, in the same manner as for those acquired thereafter.

Curation

In order to comply with these Principles, maintain records and mechanisms to:

- record the terms and conditions under which genetic resources are acquired;
- track the use in the Participating Institution and benefits arising from that use; and
- record supply to third parties, including the terms and conditions of supply.

Prepare a policy

- Prepare, adopt and communicate an institutional policy setting out how the Participating Institution will implement these Principles.

Source: www.rbgkew.org.uk/conservation

4.8 Conclusions: Observance of the CBD and compliance with national legislation

Having learned where the genetic material used by respondent organisations was acquired, it would have been desirable to ascertain to what extent the material was obtained in observance of the CBD provisions, as implemented through national legislation in the providing country. However, this is obviously a very difficult task which requires not only extensive interviews but also the release of some very sensitive and possibly uncertain information by respondents. The survey has barely attempted to ascertain this important, yet difficult to resolve, issue, but it has looked at more general factors related to the acquisition and use of material in conformity with the CBD. These include, contact with competent national authorities, negotiations of mutually agreed terms (MAT), development of ABS policies and use of intermediaries. Once the main difficulties are identified, some recommendations to tackle the crucial problem of non-observance and non-compliance are provided in Chapter 6.

The data from the survey on this issue are inconclusive. 99 respondents out of 127 stated that steps were taken to find out whether the providing country had any laws and regulations relevant to ABS. However, responses varied widely. Whilst some declared to go through “great pains” to find out about ABS laws, others relied on the local contact or supplier for this; some confused applicable legislation on ABS with CITES or sectoral legislation;, a few respondents admitted to not having taken any such steps. Of 69 respondents almost 70% said that they check whether the intermediary used to obtain the material respects the relevant laws of the source country.

A few respondents have noted difficulties identifying national competent authorities in spite of the national focal points list in the CBD website. In addition, national legislation has been difficult to understand and procedures bureaucratic, and in some instances practically impossible. Some respondents have expressed their frustration with national procedures when collecting material abroad.

Whether intentionally or not, the use of intermediaries can result in bypassing or ignoring complex and difficult local and national ABS procedures. This may not be deliberate; a few interviewees have reported that in some cases unknowingly to them at first, their in-country partners were unaware of the relevant correct procedures.

In any case, we should assume that either intentionally or unintentionally, an indeterminate number of UK organisations may have failed to comply with ABS laws and regulations when collecting material abroad. In these cases, it is very likely that lack of awareness of the CBD and ABS and their implementation through law in the providing country is the main reason for lack of compliance. Applicable procedures may not be easy to identify or to understand, but at a minimum, national competent authorities for ABS have to be contacted and informed before any collection takes place.

Lack of compliance with national procedures could not only result in legal action by the providing country but could also severely undermine other collecting or bioprospecting activities of not just the same organisation, but of the whole sector and other British organisations. A number of proposals for international mechanisms for “naming and shaming” are already in the pipeline.

More work to explain the current CBD regime should be undertaken by Defra and in particular, the use of the Bonn Guidelines and the development of ABS policies and material transfer agreements (MTAs) should be strongly encouraged and facilitated.

Chapter 5 – Supply

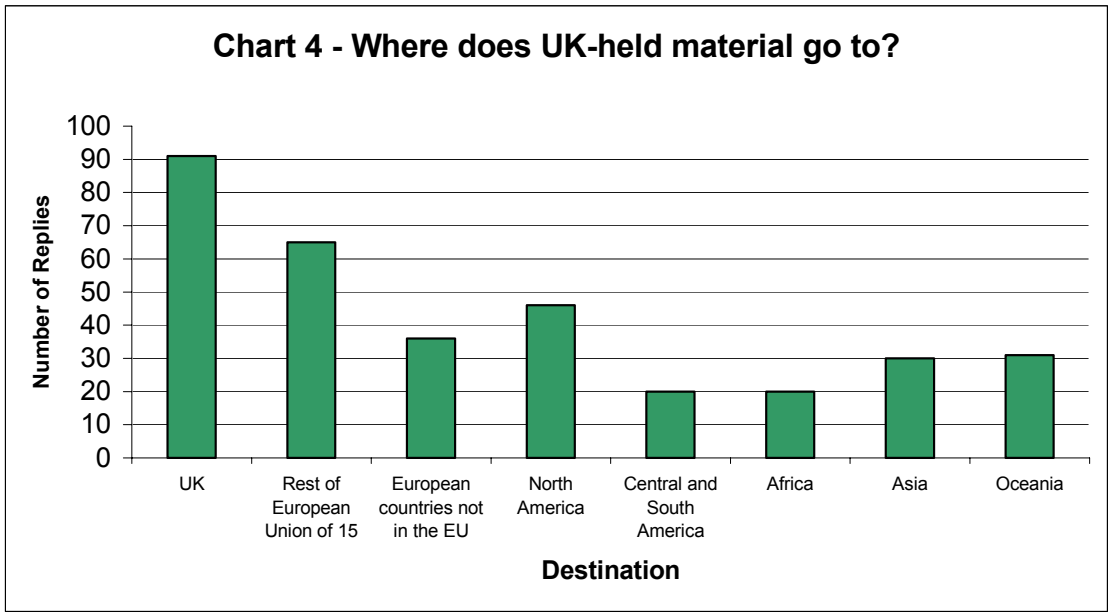
5.1 Introduction and general findings

Biological material can be supplied from *ex-situ* or *in-situ* sources. *In-situ* refers to where genetic resources exist within their natural habitats, and in the case of domesticated or cultivated species, to the surroundings where they have developed their distinctive properties. We understand then that an *ex-situ* collection means managed and documented biological material, maintained in conditions other than *in-situ* and that the management of such a collection constitutes the main activity of the organisation.

Many organisations have their own in-house collections. In this review, however, in order to avoid overlapping the survey results from the private and the public sector, the term *ex-situ* collection is restricted to public and semi-public collections.

The great majority of all respondents (close to 80%), in one way or another supply genetic resources. Approximately one third of respondents supply genetic resources outside their own organisation, of which two thirds have outlined criteria on the supply of material (e.g. through a policy, standard terms and conditions, etc.). Only a third of respondents provide material indirectly through intermediaries.

Chart 3 shows the world regions that respondents identified as the main recipients of their material in the last 10 years. One response may identify more than one destination. Just over a quarter of organisations that replied to the set of questions covered in this chapter provide material to other UK organisations. Almost a third of organisations supply material to Europe (EU and non-EU countries). Close to a quarter of organisations supply material to North America and Oceania (e.g. Australia). 20% of organisations send biological material to Asia, Africa and Central and South America: this is the same percentage of organisations, although not necessarily the same ones, that obtain material from those regions (see previous chapter). Exchange of material between organisations can also be considered as a form of non-monetary benefit-sharing and might also be part of broader cooperative partnerships.



5.2 *Ex-situ* collections

Compliance with the CBD of *ex-situ* collections (which can potentially supply material) in the UK varies from sector to sector. Botanical institutions in the UK are generally among the most CBD-aware organisations. The larger organisations have been participating in various aspects of the implementation and some of them have been present at important international meetings such as the COPs.

An important number of microbial collections are held in the UK. However, worldwide less than 1% of all microbes are held *ex-situ* and therefore *in-situ* sourcing is much more important. The United Kingdom National Culture Collection (UKNCC) co-ordinates the activities, marketing and research of the UK national service collections of microbial organisms. Several of its members have policies not only on the safety aspects of supplying material (particularly important for such organisms) but also on ABS. However, we have seen in the previous chapter how some of these collections have serious concerns about the practical difficulties in implementing their own policies.

Zoos have large collections used for public display and conservation through international programmes. In addition, the animal breeding sector has large collections of cryopreserved (i.e. frozen, usually in nitrogen dioxide (NO_2)) genetic resources. The UK has a wide diversity of native and imported farm animal breeds of sheep, cattle, pig and goat listed in Defra's national database, which include close to 50 breeds at risk (i.e. locally adapted, distinctive and rare breeds). The private animal breeding sector also has large collections of mainstream commercial breeds. At the moment, there are no express ABS provisions contained in either UK regulations or in the various international rules governing the import and export of animal breeding

material. However, the possibility of establishing an international policy/regulatory framework is currently being considered in the FAO.

Publicly funded *ex-situ* collections in the UK are generally well aware of the CBD's objectives and ongoing work: many participate actively in its implementation and provide expertise at international and national level. Awareness is also high of ABS issues and this group 'scored' highest in the survey in relation to number of ABS policies and their substance. Nevertheless, large *ex-situ* collections need to be extra vigilant of ABS issues. First, an important number of respondents admitted to acquiring material from these collections, including a common mention in policies that material was acquired from "reputable sources" and therefore, seemingly placing the onus of ABS compliance on them. Second, it also seems that, for a number of reasons, including the increased difficulties in collecting abroad, interest in national *ex-situ* collections has increased in the last few years.

Consequently, those reputable *ex-situ* collections should do all they can to be in compliance with the CBD requirements on accessing material and sharing benefits (and not only when provider countries have legislation in place). A number of additional measures, if not already in place, could be considered, such as the refusal of any unsolicited gifts or material delivered by intermediaries (including material from market stalls) without clear evidence of national authorities' consent and respect of the terms of the original acquisition; and, the inclusion or clarification of ABS terms in loans of material. In addition, best practices such as making ABS policies publicly available , should be strongly encouraged.

Organisations can also ensure that when material is passed on to a third party, the original terms of acquisition are respected, including the permitted uses of the material (in particular, at a minimum, commercial uses) and the sharing of the benefits derived from the use of the material. However, the practicalities of undertaking such a policing task are considerable. Not all the onus should fall on these collections. Ultimately, any organisation involved in collecting biological material for academic or commercial research (i.e. bioprospecting), must respect national laws and the mutually agreed terms under which the material was obtained. This means that if a commercial company approaches an *ex-situ* collection with the intention of acquiring material, the *ex-situ* collection must draft an MTA respecting the original terms of acquisition. The commercial company receiving the material must observe those terms. These should include specifications of intended use (e.g. commercial or non-commercial, permission or not to further supply the material, etc) and benefit-sharing requirements (this may include, for example, up-front monetary payments per sample, equipment and training or joint research and publications).

5.3 *In-situ* sources

5.3.1 Great Britain and Northern Ireland

Great Britain and Northern Ireland have a rich assemblage of terrestrial and marine habitats created by its diversity of micro-climates, geology, topography, and land use. It hosts significant proportions of the European and geographical ranges of habitats such as estuaries, heaths, moors and raised bogs, and also has some habitats such as Caledonian pine forest which are found nowhere else in the world.

Over the last 50 years, terrestrial wildlife habitats have been significantly reduced in extent, and their condition has declined due to pressures such as agricultural intensification, afforestation, urban development, population density and atmospheric pollution. In addition, coastal habitats, particularly in the south and east of the country, are being subject to erosion and increasingly to the effects of climate change. Networks of national and local wildlife sites provide a major mechanism for protecting and managing important habitats. These sites are further supported by a range of wider countryside and landscape initiatives and designations.

More than half of the UK is used for intensive agriculture or is developed. The remainder is largely semi-natural. Woodlands occupy about a quarter of UK semi-natural land, with broadleaved and coniferous types about equal in extent. Heaths and bogs cover a third of the low intensity land; semi-natural swards (including rougher examples of improved swards) form over a quarter. Depending on management, agricultural land can also be a very important habitat in the UK. Montane and coastal habitats, while important, are small in extent. Nature reserves, many of which have special grazing regimes, are crucial for biodiversity conservation in the UK.

The four countries of the UK differ markedly from each other. Intensive uses affect over three-quarters of England, about two-thirds of Northern Ireland and about half of Wales. In Scotland, less than a quarter is intensively farmed or developed.

However, the richest taxonomic diversity in the UK is found in the adjacent seas which extend to more than three times its land area.[28] The issue of access and benefit-sharing in the maritime environment had been, until the present year, largely overlooked. A report commissioned by Defra Science on marine biopropecting was published in January.[29] The report assesses the current legal framework within the UK for the development of marine

[28] 867,000 sq. km including territorial seas (waters up to 12 nautical miles from the baseline - the low water mark and various defined lines across bays and inlets and around some of the Scottish Islands) and those areas defined by the UK Continental Shelf Designated Area which has been set out in orders made under section 1(7) of the Continental Shelf Act 1964.

[29] "A Study into the Legal Framework for Marine Biotechnology Development in the United Kingdom" by Daniel Owen. The Institute of Marine Engineering, Science and Technology, January 2004. Available at http://www.defra.gov.uk/science/project_data/DocumentLibrary/ME1403/ME1403_1275_FRP.pdf

biotechnology to conclude suggesting Government to consider a licensing system to manage marine bioprospecting in the UK.

In common with other developed countries, the UK has not introduced specific legislation in response to the CBD to regulate access to genetic resources. Rather, the rules governing access to genetic resources are found in other areas of UK law, particularly those relating to property, trespass, statutory protection of species and site protection and intellectual property. Other areas of law, such as health and safety legislation and regulations concerning the handling of dangerous organisms are also relevant. The survey undertaken did not address the issue of whether providers and potential providers of genetic resources fully understand the law applicable to ABS in the UK.

Given the nature of common law, which is subject to constant change, and taking into account changing statutory provisions relevant to ABS issues, it is recommended that coverage of ABS issues in UK law should be reviewed in the future. Pending such a review the following provides a brief overview of existing UK law.

In the absence of specific law on ABS, the general rule is that in order to enter onto land for the purposes of collecting wildlife specimens, the permission of the owner should generally be sought. Entering onto land without such permission will normally be a trespass[30] against the owner.

Anybody wishing to access genetic resources in the UK must obtain the permission of the owner. The owner's permission is needed for access to domesticated and cultivated plants, animals and other genetic resources (including those in *ex-situ* collections). In the UK, ownership of 'wild' or '*in-situ*' genetic resources is largely determined by who owns the land upon which they are found. In England, Wales and Northern Ireland, generally speaking, a person owns any genetic resources found *in-situ* on his or her land, including plants, micro-organisms, domestic animals and livestock. Wild animals (other than game or fish) are an exception, as they are not owned by anybody, so to take them without permission is not theft, and any associated genetic resource is obtained legitimately. Game and Poaching laws limit this exception so that a land-owner has rights over rabbits, hares and game birds. Also, the Theft Act makes it an offence, in England and Wales, to take, without permission, fish from private property or where there is a private right of fishery. The law is different in Scotland but the effect appears to be similar, at least with respect to salmon and sea trout.

Permission from the owner of the genetic resources is generally sufficient to access wild genetic resources, since an owner is free to dispose of his/her property voluntarily, whether by gift or sale. However, if the genetic resources

[30] Trespass to land is any unjustifiable intrusion by one person upon land in someone else's possession. The slightest crossing on to the land is sufficient to be a trespass; removing soil or part of a building is a trespass; placing anything on someone else's land is a trespass (e.g. leaving rubbish). It is not necessary to know that the land belongs to somebody else — i.e. it is no defence that the trespass was due to ignoring or mistaking the law or a fact.

are themselves protected species or found on a protected site, additional permission will be required from the statutory authority responsible, in accordance with relevant domestic and EU law. Also, if the applicant for access wishes to collect the specimens by him or herself, permission is needed from the landowner to enter the land. Information on who owns land in the UK is found in the respective Land Registries. Areas of special scientific and environmental interest are protected and normally include the richest sites in biodiversity in the country. However, even if land is protected (e.g. in a National Park), it does not necessarily mean that it is publicly owned.

There is no government guidance on benefit-sharing terms (although the use of the Bonn Guidelines is strongly encouraged) for genetic resources found in the UK. The rationale behind the CBD requirement to involve national authorities in bilateral agreements between private parties is to ensure that those benefits revert to biodiversity conservation. In the UK, where there is a wealth of expertise in conservation and reserve management, the nature reserve authorities are well placed to negotiate any possible benefit-sharing returns (which are generally likely to be modest) and to control any collecting abuses (i.e. over-exploitation).

In 2002, following a Decision from the Conference of the Parties to the CBD, a web-based UK Focal Point on ABS was established as the point of reference for organisations wanting to collect material in the UK (www.defra.gov.uk/science/geneticresources). However, the emphasis here is on access rather than the sharing of benefits.

Unfortunately, only a third of 120 respondents were aware of this website; and many remarked how difficult it was to find the site. Making the webpage a more accessible tool so that it actually plays a role as first port of call on ABS issues to anyone involved in acquiring biological material in the UK should be a priority for Defra.

Many organisations have experienced an increased interest by outsiders in collecting material from their land. Government assistance to clarify the concept and practice of ABS, or more specifically, to provide guidance for drafting policies or MTAs or promoting best practice, needs to be considered.

5.3.2 Overseas Territories

The 13 UK Overseas Territories (OTs) and the two Sovereign Base Areas (SBAs) are: Anguilla; Bermuda; British Antarctic Territory; British Indian Ocean Territory; British Virgin Islands; Cayman Islands; Falkland Islands; Gibraltar; Montserrat; Pitcairn, Henderson, Ducie and Oeno Islands; St Helena and St Helena Dependencies (Ascension and Tristan da Cunha); South Georgia and South Sandwich Islands; The Turks & Caicos Islands; and the Sovereign Base Areas of Akrotiri and Dhekelia.

The situation of the OTs is pressing, given the general lack of awareness and clarity of the applicable law, and the potential for much more significant

returns. A number of biodiversity-rich OTs have expressed urgent concerns about bioprospecting issues.

The list of biodiversity 'hotspots'[31] proposed by Conservation International, includes several OTs. The Caribbean region, which includes Anguilla, British Virgin Islands, Cayman Islands, Monserrat and Turks and Caicos, as well as Bermuda at its margin, is considered to be in the top 5 of the 25 world hotspots.

The territories are semi-autonomous, most with locally elected governments to whom most domestic matters, including the enactment of local legislation, has been devolved under their respective constitutions. The exact relationship between the Overseas Territories and the UK differs from territory to territory. In such circumstances, the OT would then implement the treaty in its territory.UK acts on behalf of OTs regarding foreign policy and, in the case of international treaties, they extend to OTs only if the OTs so decide. Cooperation and coordination on the development of policies on CBD issues between the respective OTs and the appropriate authorities in London is undertaken by the Foreign and Commonwealth Office (FCO).

Ratification to the CBD was extended to British Virgin Islands, Cayman Islands, Gibraltar and St Helena and dependencies (i.e. Ascension and Tristan da Cunha) at the time of UK ratification (6 June 1994) and come into force on 1 September 2004. Bermuda, the Falklands and Turks & Caicos Islands have all expressed an interest/are working towards having UK ratification extended too.

Some of the OTs appear to be in a vulnerable situation regarding ABS issues. Whilst some initial contacts for ad hoc advice between the UK Government and some of the OTs' Governments are already taking place, more co-ordinated assistance including awareness-raising, capacity-building, strengthening institutional links and perhaps even common policies, guidelines or contractual clauses are all worth considering.

[31] A term coined by British scientist Norman Myers in two papers in 1988 and 1990 to designate areas richest in biodiversity and severely threatened, and used for global priority setting into the international conservation arena.

Chapter 6 – Observations, Conclusions and Recommendations

6.1 Observations and Conclusions

6.1.1 Importance of genetic resources

- A wide range of stakeholders based in the UK were approached: research institutions, culture collections, botanical gardens, zoos, aquaria, universities, pharmaceutical industry, botanical and natural medicine (including Chinese), livestock production (animal breeding), agribusiness (plant breeding and agrochemicals), cosmetics, industrial biotechnology, wildlife traders and ornamental horticulture. A relatively high level of response (21%) was achieved but two sectors - natural medicine and industrial biotechnology - did not send any replies and therefore are not included in the review. The response rate of the cosmetics industry was low but the replies were considered. It is not possible here to ascertain the reason for the low response rate for these sectors and further survey work would need to explore this.

- The importance of genetic resources for the groups of stakeholders consulted is very high (2/3 of respondents considered them crucial for their work). Only 3% of respondents considered them irrelevant to their activity.

- It appears that the largest users of genetic resources in terms of quantity and potential revenue are the pharmaceutical, cosmetics, livestock production, agribusiness and horticulture industries. Investment in research and development in terms of funds and time in these sectors is also very significant.

- The use of genetic resources in both the private and public sectors seems to be increasing, possibly owing to the advancement of genomic science and new technologies. However, this does not necessarily imply that this growth will be satisfied through genetic resources obtained from by biodiverse developing countries (indeed there seems to be some evidence to the contrary).

6.1.2 Awareness of international framework: CBD, ABS provisions, Bonn Guidelines and their relation to other international instruments

- More than 80% of respondents were aware of the CBD and 55% were familiar with its provisions on access and benefit sharing. However, only a third of respondents believed the CBD has relevance to their work.

- Awareness of the CBD seems to be significantly higher in botanical gardens, zoos, research institutions, universities, culture collections (all broadly in the public or semi public sectors), and the pharmaceuticals and plant breeding industry/agribusiness (in the private, commercial sectors. Organisations involved in cosmetics, horticulture and wildlife trade appear to have less information on the CBD.

- Awareness of the Bonn Guidelines appears to be low, except in the large *ex-situ* collections.

- The CBD is proving a very complex and difficult instrument to put into practice. In particular, the understanding of CBD ABS provisions is low (its scope, implications and implementation are often not properly understood).

- Understanding of the ABS provisions of the CBD seemed much higher in the research institutions, universities and botanical gardens responding.

- Potential and actual overlaps between the CBD and other international instruments such as CITES and UPOV seem to have created confusion. The overt complementarily between the ABS provisions of the CBD and the ITPGRFA (which only came into force on 29 June 2004) has still to be articulated in practice.

- The rationale of the CBD seems to be generally supported and perceived as a “good thing”. However, the survey suggests that it is generally believed that the implementation of the CBD, in particular its provisions on ABS, will have a negative impact on the work of organisations (both public and private).

- Industry in particular appears to perceive the CBD negatively. Whilst industry is flexible and adaptable to market and other external factors, the lack of clarity of CBD provisions and implementing national laws; increasing bureaucracy; and difficulty with practical implementation, are all cited as contributing to this negative image.

- There is some frustration at the outcome of ABS provisions. Some interviewees have simply remarked: with the CBD it is easier to log the forests than to do biodiversity research (not only for commercialisation but also for conservation). This highlights the need to strengthen the link between biodiversity conservation and ABS (first and third objectives of the CBD) in any new relevant instrument or regime at national or international level.

6.1.3 Acquisition

- It is generally perceived that since the entry into force of the CBD it has become more difficult to collect material from overseas.

- Common difficulties encountered include: identifying relevant national authorities and law in providing countries (although some organisations have praised the improvements of the CBD website on National ABS Focal Points); lack of clarity of relevant measures; cumbersome bureaucracy and delays;

unrealistic expectations of partners; and government interference in private business.

- The great majority of material accessed in the last 10 years by the respondent organisations came from the UK or EU (although much of such material came from *ex-situ* collections we do not know if the UK or EU Member State was the country of origin). Just under 20% of material came directly from Asia, Africa or Central and South America.

- Similarly, those respondent organisations that supply material sent the great majority of specimens to other UK and EU organisations. About 20% of material was supplied to Asia, Africa or Central and South America.

- Universities appeared to be the only organisations whose main source of biological material is field collections (i.e. *in-situ* sources).

- Whilst only a few companies have developed specific policies in response to the CBD, a number of organisations have introduced policies to clarify their approach to requirements of prior informed consent and benefit-sharing. Within the larger players there seems to be an increasing use of material transfer agreements.

- Compared to most commercial organisations, research organisations and the public/semi-public sector (working in the biodiversity field) have, generally, greater dependence on biological material and have less flexibility to change core activities. This exposes them to CBD requirements to a greater extent than the private sector (working on “life sciences”) which are generally more adaptable to changing circumstances. A specific concern, because of ABS requirements, relates to the possible prejudice to the flow of new sourced material from biodiverse developing countries on which these organisations particularly rely. This needs to be addressed with practical solutions.

- The private sector has reacted to the advent of ABS with a range of alternative measures: decrease in collecting activities, consolidation of collecting programmes into fewer countries and in some cases concentration on domestic collections. In a few cases companies now use intermediaries and outsourcing, further reliance on synthetic material and structural changes (for example, sourcing from a branch based in another country, merging with other companies to increase R&D capacity and in house *ex-situ* collections or, as a final remedy, outsourcing R&D business).

- A number of sectors (mainly, horticulture and wildlife trade) have traditionally traded biological material as a commodity. However, improvements in technology can now make the regular need for, and therefore supply of raw material, redundant. Consequently, only a few specimens are needed for further breeding or propagation, resulting in use of *ex-situ* genetic material. If not carefully handled this has the potential, actual or perceived, of circumventing benefit sharing obligations under the CBD. On the other hand, measures to enable the sustainable trade of regulated species and

achievement of conservation goals might need to be re-balanced in the wider policy framework.

- Several respondents noted that the Bonn Guidelines being voluntary might create an unlevel playing field. Their use should be further encouraged across and within sectors.

- Two thirds of respondents use intermediaries to provide them with biological samples. In addition, many respondents also rely on them for obtaining PIC and MAT (acquiring relevant permits and negotiating ABS arrangements).

- Data from the survey on the extent of compliance with ABS legislation abroad is inconclusive. It can only be assumed that either intentionally or unintentionally an indeterminate number of UK organisations, fail to comply with ABS laws and regulations when collecting material abroad. In these cases it is likely that lack of awareness of the CBD and ABS and implementation by law in the providing country, is the main reason for lack of compliance. Applicable procedures may not be easy to identify or to understand but, at a minimum, national competent authorities for ABS should always be contacted and informed before any collection takes place.

- Lack of compliance with national procedures would not only entail the possibility of legal action by the providing country. It can also severely undermine other collecting or bioprospecting activities of not only the same organisation but of other British organisations.

6.1.4 Supply

- Many respondents (35%) use their own collections or other organisations' collections as source of material.

- UK main *ex-situ* collections are an important source of genetic resources for UK based organisations. Reliance on these collections is likely to increase. Consequently, such collections have to ensure that they honour the spirit and letter of the CBD and implement its provisions on ABS by acquiring material in accordance with PIC and MAT, and also supply material which respects the conditions under which it was acquired. The policies and practices of such collections should fully take into account the requirements of ABS and should also address the issue of loans, gifts and donations of material.

- Many organisations with material in *in-situ* conditions have experienced an increased interest by outsiders in collecting material from their land. In other words, *in-situ* collections in the UK appear to be of increasing interest to scientists and bioprospectors.

- The effective coverage of ABS issues in the national legal systems in Great Britain and Northern Ireland is generally covered by well established laws of trespass, ownership and rights, and this appears to be adequate for current requirements. However, due to the changing nature of common law and those

statutory laws, the body of applicable ABS law in the UK should be reviewed in the future. In addition, further guidance to providers and potential provider organisations holding biological resources *in-situ* (including organisations that manage land and landowners) is necessary.

- Some of the United Kingdom's Overseas Territories (OTs) are amongst the most biodiversity rich areas in the world. There is often a lack of regulation and policy, which might be prejudicial to their interests. Whilst a few have ratified the CBD, others have already approached the UK government for advice and guidance on ABS issues, in particular as regards bioprospecting (i.e. collection of biological material for commercial purposes).

- The concerns of stakeholders on acquisition and supply issues confirm the need to involve stakeholders from the start in the development of access and benefit-sharing regimes. This should ensure that any emerging measures or instruments take into account their divergent interests as well as their expertise.

6.2 Recommendations

British organisations should not only be aware of international law relevant to their work but should comply with any applicable legislation or regulation when acquiring material abroad or when it originated abroad. Failure to comply with these requirements can entail legal action by the courts of the country providing the material, "bad press" and injure reputation. This can have a detrimental effect not only on the organisation in question but also on other British organisations.

Trust is a very important element in the current state of developments involving ABS. Defra should continue its active involvement in ABS and ensure that organisations are aware of the relevant issues and are prepared to fulfil all specific requirements on ABS.

Two sets of recommendations aim at improving compliance with ABS provisions in international and national law: **raising awareness** and understanding of the issues and; **engaging organisations** in policy-making and encourage respect of all relevant law and use of best practice.

6.2.1 Awareness raising

Defra should consider further awareness raising, particularly the dissemination of information and broadening of the understanding of the CBD and its provisions on ABS. Certain elements will need to be sector specific.

Recommendation 1: **Update and improve the website-based National Focal Point on ABS and access to it:** clarifying main ABS issues and synergies between international instruments, ITPGRFA, CITES, 1991 Act of UPOV and WTO TRIPS in particular; and making relevant information readily accessible through linkages with information already available, for example:

the CBD Clearing House Mechanism (CHM) and the European Community Biodiversity CHM.

Recommendation 2: **Consider the need and focus of case study/ies on ABS arrangements** (e.g. giving detailed examples of a full PIC and MAT processes and MTA agreed). This would be posted on the website and be used to raise awareness and provide practical guidance to stakeholders.

Recommendation 3: **Promote further use of the Bonn Guidelines and identify experience with their use,** bearing in mind Objective 13.1 of the Message from Malahide[32] to fully apply them in the EU by 2006. The UK should support this joint EU effort, which will encourage a critical mass of ABS practice and hopefully achieve a similar response from countries and organisations throughout the world. This should result in an important contribution to a level playing field.

Recommendation 4: **Defra should also identify any best practice relevant to ABS**. What is actually lacking in relation to implementation of ABS and also in relation to the negotiations of an international regime is good practical examples of what works and what does not. Organisations have a wealth of experience negotiating ABS arrangements which is not publicly available. Hence, experience and best practice needs to be shared by organisations with government and other organisations. In particular, large organisations should cascade their best practice to medium and small organisations. Although all organisations would suffer if the UK is perceived as negligent on ABS requirements, sharing best practice might create a competitive disadvantage for those organisations that invest resources and time in ABS compliance. Consequently, **the practical means and advantages of encouraging organisations to share their best practice with government and other organisations needs to be considered.**

Recommendation 5: Given the nature of common law, which is subject to constant change, and taking into account changing statutory provisions relevant to ABS issues (e.g. trespass, property, nature protection, etc.) the **coverage of ABS issues in UK law should be reviewed in the future**.

Recommendation 6: The situation of ***in-situ* UK providers and potential providers** needs to be addressed, in particular the current lack of guidance on benefit-sharing. Main organisations **should be encouraged to consider developing ABS arrangements**. Defra should be ready to provide advice on ABS policies and MTAs.

Recommendation 7: Defra is already addressing Overseas Territories' concerns on ABS on an *ad hoc* basis. At a later stage and in the light of experience gained from Recommendations 2, 3 and 4, Defra should **consider in collaboration with the Foreign and Commonwealth Office (FCO) developing a policy/basic guidelines in order to have a consistent approach for OTs**, at a minimum the biodiversity-rich ones, on ABS.

[32] http://www.dk-chm.dk/convention/cbd_regional/F1084886121/1086862003

Recommendation 8: Defra **might also consider in consultation with the FCO, the merits of fact sheets on ABS available for distribution to missions abroad** so that British organisations acquiring material are aware of implications and responsibilities.

6.2.2 Engaging organisations

Communication with organisations/stakeholders needs to be strengthened. This would be a "win-win" situation. On the one hand, organisations (including those in the private sector) could learn about ABS as well as have a more direct input into policy-making. On the other hand, organisations' technical expertise (in their specialist areas/sectors, including research and/or product development) and implementation experience, would be very useful to Defra to develop practical and realistic ideas and clear, cost-effective measures. A number of measures should be considered:

Recommendation 9: **Setting up a pool of specialist industry and institution contacts**. This would be a small, selective group with a wide range of expertise relevant to ABS which could give first hand input to government. Those key contacts could also help cascade information and consultations to the wider stakeholder audience.

Recommendation 10: **Setting up a wider stakeholder network** (via internet or actual meetings) which would facilitate communication between government and organisations affected by ABS issues, and between the organisations themselves. This network could bring together UK users and providers, private sector and public sector, as well as *ex-situ* and *in-situ* providers. Through this medium government (Defra, DTI, DfID and FCO) could gain a more detailed insight into the different stakeholder groups and industry sectors, the size and nature of the different markets and uses for genetic resources, as well as research processes and product development.

Consultations through these networks could readily provide valuable contributions to policy development and to Defra's input in international negotiations.

The approach to ABS of intermediaries needs improvement given their increasing role in ABS arrangements and their often medium and small size and limited awareness of ABS, often resulting in lack of capacity and difficulties implementing the CBD. Consequently, Defra's awareness raising about ABS and particularly MTAs and benefit-sharing, should be a priority in this target group which includes universities, research institutes, culture collections, botanic gardens and freelance agents.

Recommendation 11: Defra should focus its engagement and cooperation with relevant international fora (e.g. WIPO, UPOV and WTO TRIPS) as a means of informing its policy development and its involvement with the CBD and ITPGRFA.

Recommendation 12: In order for **stakeholders** to minimise the negative repercussions of failing to comply with the various provisions on ABS, they **should take action**:

- train staff on ABS issues so that when collecting material abroad, acquiring material from intermediaries or supplying material they are aware of the risks and legal issues; staff should be made aware that it is always essential to seek and obtain or verify national authorities' consent as appropriate.

- publish policies on ABS and, if appropriate, standard MTAs and examples of best practice.

- cooperate amongst similar institutions (e.g. at sectoral level) by, for example, sharing experiences in implementation and possible coordination on drafting common policies and MTAs. Nomination of sectoral focal persons should be helpful to improve communication with government in the UK and with the appropriate authorities in other countries.

Annexes

Annex 1 – Stakeholder Groups, Further Background, Facts and Figures

Private Sector

1. Agribusiness

Value: The UK crop output[33] (including cereals, industrial crops, forage plants, vegetables and horticulture (non-ornamental), potatoes, fruit and other crop products) was valued at £6.1 billion in 2003.[34]

R&D: See Box 3.

General background: Until the early 1960s, plant breeding in Britain was largely confined to publicly funded research. In 1964 legislation under the Plant Varieties and Seeds Act allowed plant breeders to collect royalty payments on individual plant varieties. This triggered a rapid expansion of plant breeding as a commercial enterprise. Today, the majority of commercial plant breeding takes place within the private sector, with over 60 companies based in the UK. According to the British Society of Plant Breeders, this sector employs around 5,000 people, and supports a further 5,000 jobs in seed production and distribution.

The constant aim of plant breeding is to improve the quality, range of choice and performance of agricultural crops - developing plants better adapted to end-use requirements and environmental conditions. For example, it is estimated that genetic improvement in varieties through plant breeding has contributed around half of the three-fold increase in UK wheat yields recorded from 1947 to 1992. Crops characteristics are continuously improving. As well as developing new varieties, plant breeders maintain the genetic purity of existing lines and pre-commercial seed supplies year by year. This is essential to maintain the quality and performance of each variety.

2. Horticulture

Value: The EU's production of flowers (not cut flowers) and plants was worth about €16 billion per year in 2001. The sector is growing in size and value. The Netherlands produced about 30 % of the EU's ornamentals (in product

[33] Given the complexity of the agricultural production chain, variety of produce and structure of the industry, comparative global market data is not given.

[34] The gross value added at current prices in 2003 of the whole farming sector (which includes livestock output, see next stakeholder group below) in the UK was £7.9 billion. This meant a total contribution of agriculture to the national GDP of 0.8% in 2003. The total workforce employed in agriculture was 533,000 people in the UK in the same year.

value terms), Germany 16%, Italy 15 %, France 14 % and the United Kingdom 7 %.[35]

Figures for plant sales in 2003, including bedding, pot plants and hardy nursery stock (trees, shrubs, roses, herbaceous perennials) were around £1.8 billion (cut flowers were an additional £1.3 billion).

R&D: The time and cost involved in breeding new ornamental varieties varies considerably, depending on the species concerned, the extent of breeding and the propagation techniques used. The time needed may range from one or two years to more than ten, and the cost from virtually nothing to $5 million.[36] Several commercial breeders suggested that a new hybrid would take from a minimum of five ranging up to ten years, often from five to eight years. A five year breeding programme might cost on average $2-4 million. Only one out of every 100 ornamental variety hybrids developed is a success.

General background: The ornamental market in the UK can be broadly divided into two sectors: retail and landscape (amenity). The retail sector comprises independent garden centres, DIY shops, retail nurseries and mail order. The amenity sector is made up of sales to landscapers and local authorities. Both sectors have expanded substantially during the last decade despite continuing and growing concerns about price sensitivity, market over-supply and import competition. These issues are especially pertinent since currently fierce competition prevails across the ornamental sector generally.

Environmental and legislative pressures are increasing and the industry is having to adapt quickly. The main issues are: invasive species; pesticide inputs; water and peat consumption; recycling waste; and integrated crop management.

The UK ornamental market continues to expand steadily, despite fierce import competition, rising costs, labour shortages and the effects of increasing regulation. Gardening continues to enjoy a high media profile as a leisure activity.

3. Livestock Production

Value: Livestock production generates more gross revenue than any other single output in UK agriculture. The value of livestock output (i.e livestock production and products) in 2003 was £9.2 billion of which £5.9 billion was livestock production.[37]

General background: Animal genetic resources in the UK are classified into two groups: mainstream breeds and breeds at risk. Both groups include native and exotic (non-native) breeds.

[35] Data from http://europa.eu.int/comm/agriculture/publi/fact/horti/2003_en.pdf
[36] ten Kate and Laird, p. 165.
[37] No comparable global market data was found.

Mainstream breeds are very much influenced by imported material, especially in the case of cattle. The dairy industry is dominated by the non-native Holstein, and has small inputs from four other exotic breeds. Most red-and-white dairy breeds have experienced genetic introgression (i.e. crossing) from the Holstein. Three exotic breeds (Limousin, Charolais and Belgian Blue) are the most numerous in the beef industry, and most native beef breeds have experienced introgression from these exotic breeds. Two exotic breeds (British Texel and Charollais) play a major role in the sheep industry. The pig industry is focused on the production of hybrids based upon lines or breeds of global importance. Poultry are maintained as strains rather than breeds. The equine industry deals with a wide variety of breeds with the Thoroughbred dominant. All of these exotic breeds originated in the rest of Europe or North America.

Breeds at risk are those not generally used in mainstream production but with a particular local adaptation, with distinctive genetic characteristics or rare and in need of conservation action.

The dairy, pig and poultry industries have increasingly moved to global breed improvement policies. Dairy and poultry breeding have been strongly influenced by the import of North American genes. The poultry sector also imports genetic material from Asia. In the pig and poultry sectors a large proportion of production is now owned by international companies who sell directly to supermarkets that exert a direct influence on the desirable characteristics of products.

Conservation of native breeds at risk, including rare breeds, depends primarily on the dedication of small breeders (i.e. small-scale producers or part time breed enthusiasts).

In addition to those trends, the UK Country Report on Farm Animal Genetic Resources to FAO in 2002[38] noted that there is widespread concern felt in the livestock industry as to the future viability of existing livestock production systems and how they will fit into the post CAP Reform modern rural economy. It is widely acknowledged that change is needed to ensure future prosperity in the livestock sector and that this will be prompted by the decoupling of EU subsidies from livestock production. Breeding objectives will change as the delivery of public goods such as enhanced biodiversity, environmental sustainability and animal welfare become economically more important partly through cross compliance rules associated with the single farm payment. These factors coupled with expanding international trade in UK animal genetic resources are seen as vital in revitalising the sector in line with sustainable development objectives.

A National Steering Committee on Farm Animal Genetic Resources has now been set up to advise Government and the animal breeding sector on the conservation and sustainable use of farm animal genetic resources through the development of a National Action Plan. The UK Government has an

[38] Available from www.defra.gov.uk/farm/geneticresources

obligation under the CBD to ensure that genetic diversity is maintained in its native breeds.

Livestock production is regulated by wide ranging EU legislation covering husbandry, transport, animal health and welfare, environmental legislation (e.g. nitrogen limits) and rural development and biodiversity. Increasing public awareness of many of these issues is also having an impact particularly with regard to food safety, the environment and animal welfare.

4. Pharmaceutical Industry

Value: This sector is one of the biggest and most profitable in the world, with annual global sales of around $400 billion.[39] It is the largest user of genetic resources and also the most research-intensive industry.

In the UK the gross value added of the industry was £7.9 billion in 2000 and it employed 83,000 people in 2002. This places the UK as the fourth largest pharmaceutical producer after the US, Japan and France. It is the UK's third most important net export. Only France and Switzerland export pharmaceuticals to a greater value. Although most UK pharmaceutical trade is with EU partners, the greatest trade surpluses are with North American and Asia/Oceania nations.

R&D: Research funding plays a crucial role in drug discovery. The amount spent on R&D has doubled world-wide since 1991 to over $50 billion in 2004. In spite of such investments the number of new drugs emerging each year has fallen by half.[40]

It is estimated that it takes 12 to 15 years to create a new drug. Moreover, the success rate of the big pharmaceutical companies in the recent years has not been good – only 3% of compounds make the journey from pre-clinical studies to pre-registration and only 1% actually emerge as a drug[41] (other estimates are even lower: 0.1% of compounds make it into human trials and only one in five of those results in a drug, i.e 0.02% or 1 in 5000, at a cost of about $900 million per successful drug).[42]

General background: The pharmaceutical landscape is changing and companies are facing tough challenges, mostly in Europe, with lack of new drug approvals, harsh funding conditions, lack of investor confidence and consequent programme adjustments and cost cuttings.[43] In 2003, biotechnology companies, which are closely linked with the pharmaceutical industry, witnessed a fall in revenue for the first time . The UK still leads the

[39] The Economist, March 11, 2004.
[40] The Economist, January 29, 2004.
[41] Ernst & Young, 8th Annual European Life Sciences Report, 2001.
[42] The Economist, March 11, 2004. Smaller firms can bring drugs to the market for around $100m-200m.
[43] Ernst & Young's 11th annual European Biotech Report. Press release 13 May 2004.

European biotech market by revenues though these fell to €2.4 billion in 2003.[44]

Since the mid 1980s even fewer drugs have been making their way from discovery to the clinic, not because they do not work but because their makers fear they may not earn more than $1 billion in annual sales - the level above which drugs are considered "blockbusters".[45] In 1995, there were 17 new blockbuster drugs on the market, by 2002 there were 48 new entrants, 8 of them mega brands making $3 billion or more per year.[46] In 2004 there are 67 launches. However, production is decreasing (big pharma is predicted to launch just 50 blockbusters per year until 2006).[47] Many patents of existing products, currently generating some $80 billion of annual sales, will expire in 2005 and face the competition of generic-substitutes.

As a result of all these factors, including ABS requirements, companies will be pursuing strategies to offset stagnation of production and rising costs. Big companies, for example, despite their huge R&D spending, are expected to make some 50% of their sales from acquisitions – through licensing, partnering, co-development, co-marketing and co-promotion.[48] It is also possible that in the next years a few more mergers between big players will take place and will drive short term growth.

5. Cosmetics Industry

Value: This sector which consists of skin care worth $24 billion; make-up, $18 billion; hair-care products $38 billion; and $15 billion of perfumes (i.e. a total of almost $100 billion a year), and it is growing at up to 7% a year.[49] Five of the world's 75 top finished product manufacturing cosmetic companies in 1996 were based in the UK.[50]

R&D: Beauty firms spend just 2-3% of the value of sales on research and development compared with almost 15% by the pharmaceuticals industry. On the other hand, they spend 20-25% on advertising and promotion.[51]

General background:[52] Companies active in the natural personal care and cosmetics segment world-wide can be broadly grouped into: wholesalers of raw botanical material; speciality chemical ingredient producers and formulators; and manufacturers and marketers of finished products.

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[44] Id.
[45] The Economist July 11, 2002.
[46] Ernst & Young, Defining Issues in the Pharmaceutical Industry Report, 2002.
[47] The Economist, December 4, 2003.
[48] Ernst & Young, 8th Annual European Life Sciences Report, 2001.
[49] The Economist, May 22, 2003.
[50] ten Kate, K., Laird, S., Royal Botanic Gardens, Kew, 'The Natural Personal Care and Cosmetics Industry', *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing,*, Earthscan Publications Ltd, London, 1999, p. 266, European Communities, 1999.
[51] Id. p. 265.
[52] Id.

The first of these, wholesalers of raw plant materials, including exporters, traders, brokers, and agents, mostly sell to a range of industries, which besides personal care and cosmetics, include botanical medicines, pharmaceuticals, nutrition and food, dyes and household products.

The second group, speciality chemical ingredient manufacturers, formulate and supply ingredients and blended products to cosmetic manufacturers. Increased demand from these manufacturers for natural ingredients in stable and useable form has created a supplier market of chemical companies that provide popular natural ingredients and invent new ones by processing and recombining biological products. Thousands of compounds are supplied to the personal care and cosmetics industry as primary ingredients or additives.

The third group, manufacturers and marketers of finished products, vary in size and approach. They may be small companies, marketing primarily to health food stores, or large multinational companies selling mass and prestige products with sales valued in the $ billions. Companies may conduct little research on product ingredients, primarily formulating their products, or they may operate advanced in house R&D, including screening compounds for chemical activity.

6. Wildlife Traders

Value: The trade in wildlife – both legal and illegal – (plants and animals, dead and alive, includes parts and products such as furs, meat and timber) is big business around the world and is growing. While estimates vary, according to the wildlife trade watchdog group, TRAFFIC, the numbers show that trade in wildlife and wildlife products (excluding timber and fish harvesting) has grown from around $3/ $4 billion annually in the late 1980s to at least $10 billion in 2001. In addition, their estimates place illegal trade at $5 to $8 billion annually.

Whilst the UK is an important centre for this trade, it is dwarfed by that of the US and is significantly smaller than the markets in Japan, Taiwan and other European countries.[53]

Other background: In addition to the legal wildlife trade, which is likely to be conducted at sustainable levels that do not adversely affect the conservation status of the species in the wild, illegal trade deprives everyone of the appropriate benefits – in particular the exporting country/country of origin receives nothing. It is also damaging to wildlife and to the proper regulation of trade. Illegal trade is a particular concern to the EU, where systematic controls take place only at the EU external borders. Wild animals or plants smuggled

[53] According to CITES data, during the period 1996-2002, the EU of 15 legally imported 5.9 million live birds, 2.1 million live invertebrates and 20.8 million live orchids. This represents globally 86% of the reported total of live bird imports, about 20% of the total import of live invertebrates and close to 20% of the totality of live orchids imports. The UK in 1996 legally imported 16,000 birds, 3,000 plants and 25,000 reptiles and amphibians.

into one EU Member State can be transported to other Member States usually without further controls. After enlargement to 25 Members, border and movement control is now a much greater challenge. The global scale of illegal wildlife trade is unknown, but it could well be over a million specimens worth in excess of a billion euros every year.[54]

Public and Semi-public Organisations

7. Research Institutions and Universities

The Office of Science and Technology (OST) within DTI is responsible for the allocation of the Science Budget (currently just under £2.4 billion per annum) to research bodies via the Research Councils. Other government departments also have significant budgets for R&D. Launched in 2002, Research Councils UK (RCUK) is the new venture involving the UK's seven Research Councils, working together scientifically, strategically and operationally, alongside OST. Bioscience is the responsibility of two of the Research Councils.

The Biotechnology and Biosciences Research Council (BBSRC) is the principal public funding agency in the UK for basic and strategic research in the non-medical life sciences. Its remit includes agriculture, food, healthcare, pharmaceuticals and bioprocessing. BBSRC supports research and training in universities and institutes. In particular, it sponsors eight strategic research institutes, has set up six structural biology centres, and supports 13 other research bodies. It promotes knowledge transfer and technology interactions with industry to enhance the economic competitiveness of the UK and to improve the quality of life. Examples of landmark research funded by the BBSRC include the genetic modification of mice and farm animals for biomedical applications and its key role in the project to sequence the genome of *Arabidopsis*, the first plant genome to be fully sequenced.

The Natural Environment Research Council (NERC) funds and carries out research and training in the environmental sciences. Its work covers the full range of atmospheric, earth, terrestrial and aquatic sciences, from the depth of the oceans to the upper atmosphere. Its science focuses on detecting change; diagnosing why change is taking place; defining the boundaries of uncertainty; and seeking solutions. NERC funds a total of 4 centres and supports another 15 collaborative centres, but only half of these are related to biological sciences.

Research is also one of the key activities undertaken by many of the 171 universities and colleges in the UK. Research offers valuable support to teaching, generating new knowledge and deepening understanding, and contributes to the knowledge economy, by stimulating national and regional

[54] TRAFFIC Report. “Expanding borders: New challenges for wildlife controls in the European Union”, April 2004.

competitiveness and innovation and quality of life. Universities are now seen to be at the productive heart of the economy, rather than as passive consumers of resources.

In spending reviews, Government recognises this role by the funds it makes available. The settlement for research in the Spending Review 2000 provided additional funds close to £1bn between 2001 and 2004. By the end of 2004, government funding for university-industry interaction/innovation will have tripled. In the last few years, the average return to research-active universities in the UK from licensing and commercialisation is now on a par with that of US universities. In addition, the 2004 Spending Review sets a ten year ambition to increase the ratio of UK R&D spend to national GDP from the current level of 1.9% to 2.5%, with science spending through DfES and DTI over £1 billion higher in 2007-2008 than in 2004-2005, an annual average growth rate of 5.8% in real terms.

8. Botanic Gardens

The United Kingdom is home to more than 80 botanical gardens and other plant collections holding a total of approximately 600,000 to 700,000 recorded living plant accessions, comprising 70,000 to 80,000 taxa (c.50,000 species). It has been estimated that 70% to 80% of this material was obtained before the entry into force of the CBD in December 1993.

The *ex-situ* plant collections held in the UK exist as a decentralised network of collections of varying size and specialisation, rather than as a single national genebank. Many plants are conserved in 'field gene banks' in botanical gardens and arboreta. PlantNetwork is the organisation that brings together and represents virtually every major plant collection in the UK and Ireland; it also coordinates best management policy.

With notable exceptions, most botanic gardens have only relatively limited links with seed banks. However, they constitute an important germplasm resource, have an important role to play in *ex-situ*, conservation of non-crop species, and offer considerable potential for research. Unlike seed banks, which tend to focus on a particular plant species or group, botanic gardens have historically collected a wider range of plants.

9. Zoos and Aquaria

A survey conducted in 2001 amongst the UK Zoo Federation collections revealed that during the previous three years, members had supported 177 projects in 62 different countries by providing financial support in excess of £6 million. Equally importantly they supplied husbandry and management skills, staff and equipment for habitat and species conservation and essential materials for local education and awareness programmes in developing countries.

10. Culture Collections

The organisations that form the UK National Culture Collection (UKNCC) hold more than 73,000 accessions which include around 2,300 algae and protozoa, over 20,000 animal cell lines, over 25,000 bacteria, over 25,000 fungi including yeasts, plus actinomycetes, cyanobacteria, nematodes and mycoplasma. The collections main interests are generally in identification and preservation but they and their parental organisations offer many more services.

Annex 2 – Terms of Reference of the Review of the Experience of Implementation by UK Stakeholders of Access and Benefit Sharing Arrangements under the Convention on Biological Diversity

The project

Rationale

1. To assist in meeting the UK's international obligations coherently and efficiently, and prior to consideration of any further policy measures, Defra is carrying out a review of the current situation in the UK on access to genetic resources and the equitable sharing of benefits arising from their use (ABS) pursuant to the Convention on Biological Diversity (CBD). This review represents the second part of a two-stage process. The first stage, a UK Policy Review on Genetic Resources for Food and Agriculture was carried out by Claire Wilding for Defra in 2002. This review will focus on the current state of implementation regarding ABS arrangements in the UK. Both reviews will enable Defra to get a better understanding of the present situation in the UK regarding genetic resources.

Objective and Scope

2. The aim of this review is to report on the efforts of different stakeholders, both providers and users, of genetic resources of all types (plants, animal and microbial but not human) in the most relevant sectors to comply with the ABS requirements of the CBD.

Background

3. The UK is involved in several international negotiations with relevance to the issue of biological diversity and genetic resources and is Party to a number of international instruments relevant to the subject. The UK participates actively in meetings of the Convention on Biological Diversity, the International Treaty on Plant Genetic Resources for Food and Agriculture, the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore and the World Trade Organization's Committee for Trade and Environment and Council for Trade Related Aspects of Intellectual Property Rights.

CBD: Access and Benefit Sharing

4. The UK, in addition to the general obligation to report on the implementation of the 1992 Convention on Biological Diversity (CBD) pursuant to its Article 26, has a number of international commitments related to access to genetic resources and benefit sharing in the context of the CBD laid out in Articles 8(j), 15, 16.3, 19.1 and 19.2. Moreover, the CBD Conference of the Parties (COP) has encouraged Governments to explore, develop and implement guidelines and practices, in collaboration with relevant stakeholders, to ensure benefit-sharing (Decision III/15, paragraph 5), and to include in their national plans or strategies and legislation measures for the equitable sharing of benefits arising out of the use of genetic resources (Decision III/9, paragraph 2 (c)). The COP has also urged recipient countries to adopt measures to support efforts made by providers of resources to ensure that access to genetic resources is subject to Articles 15, 16 and 19 of the Convention (Decision V/26 A, paragraph 4 (c)). COP 6 invited Parties and Governments to use the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization when developing and drafting legislative, administrative or policy measures on ABS, and contracts and other arrangements under mutually agreed terms for ABS and invited Parties to provide financial and technical assistance to support developing countries in implementing the Bonn Guidelines (Decision VI/24A, paragraphs 4 and 5).

5. Finally, and perhaps more importantly, COP 6 also called Parties to make available to the Executive Secretary, detailed information on the measures adopted to implement access and benefit-sharing as well as other information such as that listed in Decision V/26, paragraph 12 (which notes that there is a particular need for more information regarding, among others, user institutions, the market for genetic resources, non-monetary benefits, new and emerging mechanisms for benefit sharing, incentive measures and 'intermediaries') (Decision VI/24 D, paragraph 6).

6. Furthermore, paragraphs 44(n) and (o) of the Plan of Implementation agreed at the World Summit on Sustainable Development in Johannesburg in August 2002, have respectively, reinforced those commitments and set an additional mandate, by calling signatory countries to:

> "(n) Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization, as an input to assist the Parties when developing and drafting legislative, administrative or policy measures on access and benefit-sharing as well as contract and other arrangements under mutually agreed terms for access and benefit-sharing".
>
> "(o) Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources".

7. Developed countries have taken a variety of means to implement the CBD provisions on ABS. The UK gives effect to its obligations under the CBD by administrative measures and has not enacted specific legislation with respect to ABS arrangements. Defra is anxious to ensure that there are no deficiencies in implementing these provisions for both providers and users of genetic resources and so is reviewing current practice. In addition, there have been significant initiatives in this field, (e.g. the Principles and Common Policy Guidelines on ABS for Botanical Institutions) which should be taken account of during the current review.

8. Whilst the Bonn Guidelines are a relatively recent innovation (April 2002), the UK believes that they are a most useful basis for giving practical effect to access and benefit sharing. It would therefore be helpful to identify current experience on anticipated use of the Guidelines or similar mechanisms in the context of the Review.

Methodology

9. The present review will entail carrying out a survey of the state of affairs in the UK regarding the implementation of the ABS provisions of the CBD paying particular attention to the use of the voluntary "Bonn Guidelines".

10. First of all, the terms of reference (ToR) and questionnaire will be drafted and all necessary Defra clearances will need to be obtained (Forms Control Section, Survey Control Liaison Unit) and consultations (Forms Design Unit and Legal Services) undertaken.

11. Secondly, the main stakeholders based in the UK will need to be identified and a detailed programme of consultations will have to be prepared. And thirdly, a wide consultation with those stakeholders will be undertaken, chiefly through questionnaires and interviews - we are aiming for as comprehensive a consultation as possible. Among the stakeholders to be consulted there should be representatives from the public sector at national and regional level, universities and research institutions, botanical gardens, museums, NGOs and the private sector (including the pharmaceutical industry, the cosmetics industry, the natural medicines industry, the horticultural industry and agribusiness).

12. In addition, before and after such consultation an interdepartmental meeting involving all interested Whitehall Departments, Devolved Administrations and Public Bodies will be convened to give advice and discuss main findings and recommendations.

Outputs

13. In essence, the review will try to ascertain to what extent the ABS provisions of the CBD are known, to what degree, if at all, the Bonn Guidelines are influential, and what experiences of ABS the stakeholders

have had. It will also provide an opportunity to the relevant stakeholders to identify best practices and offer their opinion on the subject, which will inform policy development in Defra.

15. The review will provide:
    - a description of the current situation in the UK regarding the implementation of arrangements on access to genetic resources and benefit-sharing under the Convention on Biological Diversity;
    - an analysis of such information gathered in the survey identifying what the problems and needs are, if any;
    - conclusions and recommendations to government and the rest of stakeholders on how key concerns could be better addressed.

16. The aim is to complete the review by the summer of 2004.

Annex 3 – Bibliographical References and Further Reading

- Non-Defra sources and further reading materials:

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