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# ‘Genetic Resources’ in the CBD

## The Wording, the Past, the Present and the Future

Peter Johan Schei and Morten Walløe Tvedt

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## The Wording, the Past, the Present and the Future[1]

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[1] The Fridtjof Nansen Institute (FNI) of Norway is also contributing as part of a research project on Access and Benefit Sharing, which started in 2009 and is carried out in cooperation with the multi-donor ABS Capacity Development Initiative for Africa. www.fni.no/projects/abs_capacity_development_africa.html The authors thank Kristin Rosendal and Ole Kristian Fauchald (both of FNI) for useful comments on the manuscript; final responsibility rests, however, with the authors.

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**Abstract**

This paper, 'Genetic Resources' in the CBD: the Wording, the Past, the Present and the Future, aims at contributing to the development of an International Regime on Access and Benefit Sharing (ABS) by clarifying the concept of 'genetic resources' as it has emerged and keeps evolving - particularly in light of the new knowledge and understanding developed in genomics and proteomics since 1992, the establishment of ex situ collections of genetic material and data bases of genetic information, the emerging global markets for these resources, and recent developments in modern biotechnology, biochemistry and synthetic biology. It takes a look at several examples of different ways in which the term 'genetic resources' is used in other international arenas than the CBD. All these developments have laid the foundations for new ways of understanding and realising the values of 'functional units of heredity'. This may have implications for the formulation of scope and other articles under the ABS regime. Finally, this paper has discussed the report of the meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, and its relevance to the subject in question.

Knowledge about and techniques using genetic material are evolving rapidly. If the concept of genetic resources is understood only narrowly, in senses related to the original or current state of knowledge, the ABS system may not be able to capture the future potential value of genetic material, not least when it is used in or as a basis for synthetic biology or other new bio-economic technologies. An International ABS Regime could maintain a broad and dynamic understanding of the concept of genetic resources. There is however a dilemma and a contradiction between on the one hand leaving a definition dynamic and flexible, at the same time as it is understood in a manner which creates legal certainty and thus is enforceable.

**Key Words**

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# Contents

# 1 Background for this Paper

This study has been commissioned further to the request to the Ad Hoc Working Group and pursuant to the *Terms of Reference* provided by the Executive Secretary, on this background:

> During the last meeting of the Working Group, Parties requested the Executive Secretary to initiate, in the context of 'traditional knowledge and associated genetic resources', a short review paper on the history of the concept of 'genetic resources' as it emerged and keeps evolving in the context of:
>
> (a) Ex situ collections, such as gene banks and data bases;
>
> (b) 'Bio-economy', i.e. the emerging competitive global market based on genetic resources;
>
> (c) The rapid developments of modern biotechnology and biochemistry, including genomics, proteomics and synthetic biology.

As the definition of 'genetic resources' builds on the definition of 'genetic material' and in the end rests on the understanding of 'functional units of heredity', these links are reflected in this study.

The definition of 'genetic resources' was drafted in an era of scientific and technological reality different from what the ABS is facing today. This paper discusses the following questions:

- What does the definition of 'genetic resources' in the CBD mean?
- How was the concept to be understood as it emerged?
- How may new technologies, scientific knowledge and bioeconomic developments change the understanding of genetic resources in relation to ABS?
- How has the concept genetic resources been used in different discursions since 1992?
- What effect should these changes have on today's interpretation?
- What should be the implications for ABS and the triggering of benefit sharing in relation to the utilisation of such resources?

# 2 A Closer Look at the Definition of 'Genetic Resources' in the Wording of the CBD

It is crucial to the functionality of Access and Benefit Sharing (ABS)[4] as embedded in Article 15 and Article 3 to specify and develop a common understanding of the existing definition of 'genetic resources' in an easily interpretable, implementable and enforceable way. This requires a look at the definition itself. An international regime (IR) on ABS would benefit from a more detailed understanding of what is meant by 'genetic resources'. The effectiveness of ABS partly depends on Parties having a common understanding of its coverage and definitions throughout all stages of each individual ABS transaction.

Prior to the Convention on Biological Diversity (CBD),[5] 'genetic resources' was not a commonly used legal concept, nor did it represent clearly defined objects of ownership. Its definition rests mainly in the wording of the CBD and related interpretive materials. Importantly, to the extent that there is no common agreement concerning its details, the Conference of the Parties (COP) has considerable discretion to specify and clarify the meaning of the concept. The term 'genetic resources' has spread since its inclusion in the CBD, and appears in numerous international treaties, discussions and documents,[6] and in many national laws. It has been used with various differently expressed or implied meanings. Lack of consistency creates legal uncertainty in ABS transactions, and this will have to be resolved for an international regime to be functional. Thus, there is a need to develop the existing understanding of genetic resources in a consistent and enforceable way.[7] This paper will not focus on interfaces with other regimes or treaties,[8] nor is the intention to discuss how ABS contracts may be drafted.

One overall virtue is that an international regime needs to be made in a manner that can offer *legal certainty* for both providers and users of 'genetic resources'. Legal certainty implies that the persons operating under the law can predict their obligations and rights according to the regime. Procedures need to be operational and cost-effective. The regime must be enforceable across borders. The regime must maximise the incentives for users to comply, it should minimise the negative incentives and seek to close any loopholes.

The CBD Article 2 defines 'genetic resources' as follows:

> 'Genetic resources' means genetic material of actual or potential value.
>
> 'Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity.

From the definition one can observe that the genetic material may have any biological origin, whereas of 'plant, animal, microbial or other origin'. As has been expressed elsewhere, 'genetic resources are a subset of biological resources'.[9] The wording of the definitions gives rise to discuss two elements in further detail: functionality and value.

## 2.1 Functional Units of Heredity – Genetic Material

The qualifying element in the definition is the specification that 'genetic material' is any material containing 'functional units of heredity', which is not further specified in the wording of the CBD. Thus the language must be interpreted according to the principles of international law and in relevant situations for use of the material. The term 'functional' has several meanings in the English language, two of which are relevant here: '1 ... relating to, or having a function. ... 3 working or operating. ...'[10] To have a function is thus a broad concept. This broadness is also reflected in the words 'working or operating', where the emphasis is any way of having a function or operating. 'Functional' includes a dynamic element as the state of knowledge and technology necessarily develops through history. Thus a dynamic element is included in the wording of the definition.

Functionality is used in connection to the term 'units of heredity'. As the term 'units of heredity' relates to biology, knowledge and technology, the biological and biotechnological functions are essential for its understanding. In section 5 below, examples of the current status of what can be 'functional' in a biological sense are developed further.

In international law, the 'the preparatory work of the treaty and the circumstances of its conclusion' can be used as a supplementary means of interpretation.[11] Therefore, we expand on the historical meaning of the term in section 4 below, to shed light on and contribute to the understanding of the concept, without this being decisive for the detailed interpretation.

From this, genetic material can be understood as material from any biological source where units of heredity are operating or having a function.

## 2.2 Genetic Material with Actual or Potential Value

The term 'genetic resources' is defined as genetic material with 'actual or potential value'. The definition of 'genetic resources' seeks to capture the value – actual and potential – of the genetic material. The wording refers to an ideal situation where it is possible to recognise and separate genetic resources from biological resources based on assumptions of the realisation of the value in the inherent hereditary material. This has proven complicated in practice, and is one of the challenges an international regime must deal with if ABS is to be functional.

The ordinary understanding of the term is not restricted solely to economic value. Value is commonly understood as being 'social, economic, cultural and spiritual in nature.'[12] Non-economic values of 'genetic material' have been identified as relevant to ABS on numerous occasions. There is, for example, a strong emphasis on non-monetary benefits in Appendix II to the Bonn Guidelines, which lists ways of sharing benefits. Although not binding for the interpretation of the definition of 'genetic resources', that text may contribute to its understanding. Such an emphasis on the non-monetary benefits that could be shared indicates an acceptance of ABS as being not only an economic mechanism. In consequence, any type of value might be relevant when one is to determine whether something is to be regarded as 'genetic resources' or not. This leaves to term 'value' without limiting effects on the scope of the definition.

The definition uses both *actual* and *potential* to describe the value aspects of 'genetic resources'. This could be read as a reference to the technological state of the art: the actual value would then concern the value of genetic material in combination with the techniques known and developed as of the timepoint of access; where as potential value could then be understood as the possible new techniques in the future which might realise the potential value of the functional units of heredity.

*Actual* value might be more or less evident or clear. Also actual value is not static as the material might have one value in some types of uses and a different value in other kinds of uses. The reference to 'potential' value is broader and adds a dynamic aspect to the definition of 'genetic resources' in several ways. The value of the material at access timepoint is potential in the sense that one cannot know the specific value before it has been realised. Also the value might prove to be for something else than originally thought. Thus, also where there are no evident current values, the genetic material could qualify as being genetic resources. The use of the term 'potential value' captures future ways of realising the value of the functional units of heredity. Potential value entails also a reference to knowledge and technological developments, as the material will probably be recognised as having new values as knowledge and technology change.

All this may sound tempting, but this criterion is not readily enforceable legally. To capture the potential value at the *point of time of access* has proven far from simple. The value (both actual and potential) of the material accessed for its functional units of heredity is generally not manifest when the material is accessed. At that point, the user will usually not know what can expect from an innovative research process based on the accessed material. As there is a lack of manifest actual value of the genetic material at the access timepoint, the potential value becomes an important element of the definition. However, to determine any potential value (economic and other) – even whether the genetic material has potential value for its units of heredity – is no easy matter at this juncture. It is also impossible to conclude with certainty that the material will not have any value. Here the need for a knowledge-independent definition becomes evident: units of heredity previously regarded as junk may later be viewed as important.

The definition of 'genetic resources' is based on the definition of genetic material. The interrelation between these two elements of the definition can be explained as genetic resources being material of any biological origin with functional units of heredity which has either an actual or potential value because of them. Since potential value and the level of knowledge regarding the functionality in biology change, the wording of the legally binding definition suggests being dynamic in the sense that it captures the evolving knowledge and technological state of the art. One can say that all biological material will be covered by this definition when *its use captures* either the actual or the potential value of the hereditary elements.

## 3 Relationship between the Genetic Resources and Traditional Knowledge

From a strict reading of article 2 and the wording of the definition of 'genetic resources' there is no explicit reference to 'traditional knowledge'. Traditional knowledge has huge importance in its current and evolving use situations. In the ABS landscape, TK is important both in the access situation and in the utilisation phase when the value of genetic material is captured.[13] At the point of time of access, TK can play an extremely important role in the search for interesting material. From a bioprospecting perspective, in this phase of ABS activities the TK plays primarily a role as an indicator in the search for new and interesting material. Later in the innovative process, TK can be used variously, in connection with genetic resources and as the object of innovative activities. TK is also used in far broader settings, but those described here are the most relevant ABS situations for TK.

In World Intellectual Property Right Organization (WIPO) discussion forum Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC), traditional knowledge is one of the three main topics.[14] Despite the slow pace of progress, there is now a comprehensive text up for discussion. On the table for the next session of the Committee in May 2010 is a document on 'Revised provisions for the protection of traditional knowledge'.[15] The document was opened for comment until the end of February 2010 and then revised on the basis of these comments and represented to the WIPO-IGC. It is divided into three main parts – policy objective, general guiding principles and substantive principles. This includes 16 different policy objectives to consider, 10 general guideline principles, and 14 substantial principles all connected to traditional knowledge from an intellectual property perspective, and covering such matters as overall objectives for promoting respect for TK as well as outlining more specific provisions for its protection. The IGC approaches TK in a broad way and by looking at it from an intellectual property right perspective and not strictly linked to genetic resources. That approach gives rise to other challenges than when discussing how TK could be included in an international ABS regime.

An international regime on ABS could include TK in various ways. There are three (at least) important features to consider in seeking a more uniform and consistent view as to exactly what TK constitutes for ABS purposes: First, it might be that a functional ABS needs to define 'TK for ABS purposes' (TK-ABS) in a more enforceable manner than TK in general is understood to make it feasible for legal systems to ensure benefit sharing based on its use. Second, an international regime would need to consider whether and how the access side of ABS should react to TK-ABS. Today there is a diversity of how the national laws address TK-ABS. Third, an IR would need to establish clear rules for benefit-sharing requirements to apply to a user who has realised the value of someone else's TK-ABS. Such a clear benefit-sharing obligation would probably go further than the strictly legally binding obligations set out in the CBD. If there is political agreement to include TK in an international regime, it will be necessary to define which types of 'utilisation of traditional knowledge' will trigger a benefit-sharing obligation. The regime would need to establish rules to facilitate determining whether TK has in fact been used. Such legal certainty would allow both users and providers to predict their rights and obligations with some degree of certainty. Also to make such an obligation enforceable, the system needs to be legally enforceable and create incentives for users to actually enter into mutually agreed terms (MTA) and receive prior informed consent (PIC) from the relevant persons, groups and authorities in the providers.

Various approaches have been taken to establish systems for TK protection. Here we may note the approach taken by Natural Justice in South Africa, drawing upon *Open Source* or Free Software movement.[16] One issue in this debate is how to make a system which does not obstruct non-commercial uses, but which captures commercial or other benefits developed from the use of TK. There exist some fundamental differences between innovation *in software* and those driving innovation based on TK and TK-ABS, for example there is already a recognised intellectual property right to software by copyright, and the innovative structure is different (software is developed by many individuals, whereas developing a product based on TK will most probably involve one entity drawing on the knowledge of the many).

When the negotiators of an international ABS regime under the CBD are to determine its scope, the extent to which TK should be included in or excluded from the regulations must be clarified. If such an international regime is to be operational and functional in a legal sense, it will be necessary to include – or exclude – TK in a way that can be handled in a legal context. Thus, an international regime will need to develop the linkage between the definition of genetic resources as its subject matter and the TK aspects to be covered. Clarity is essential as to the object of the right, who shall be the holder of the right, whether it shall be made exclusive and other related issues.

## 4 History: What Was Meant to Be Captured by 'Genetic Resources' Historically?

When the CBD was negotiated from 1989 to 1992, there was a general feeling of optimism related to the possible benefits arising out of the use of genetic resources in modern biotechnology, particularly through recombinant DNA techniques. Early field trials of genetically altered bacteria took place in the 1980s, and the first successful field trials of genetically engineered (GE) cotton were carried out in the 1990s. Discussions on the objectives of the Convention had a clear focus on these new technologies and their expected benefits, and this contributed to the choice of the concept of 'genetic resources'. That led to the inclusion of the term 'genetic resources' in the third objective of the CBD regarding the fair and equitable benefits sharing as well as in Article 15.

Although clearly understood as a subsection of 'biological resources', there was a fairly open understanding of how to interpret the concept of 'genetic resources'. There was, however, a general agreement to exclude from this objective any utilisation of biological material as commodities or 'in bulk', where the genetic material or information was not utilised per se. The type of actual or planned utilisation of any accessed biological material was therefore an essential basis for realising benefit sharing.

As the definitions of 'genetic resources' and 'genetic material' in the end rest on the understanding of the concept of 'functional units of heredity', which is not defined in the Convention, it is important to realise what was meant by this concept when the CBD definitions were agreed. The general understanding was that it was fairly synonymous with the 'gene' concept, which can still be understood as the functional units of heredity of DNA-material. The word 'functional' was basically used to distinguish genes/genetic material from the larger part of DNA in most eucaryot organisms which did not code for any protein, and at that time were called 'junk DNA', because nobody really understood what functions, if any, this DNA-material had in the total genome of a cell.

The understanding was also that benefits from use of any genetic material in a cell, including mitochondrial and chloroplast DNA, should be included. Moreover, both the use of the genetic material as such and the coding information embedded in the nucleotide sequence should be seen in a similar way, although not many DNA sequences had yet been decoded at that time.

Regarding more indirect uses of the genetic material/genetic resources, through e.g. extraction of specific enzymes or other commercially relevant medical or industrial products from biological material, without knowing or using the genetic resource or information directly, there was no clear consensus on understanding, neither to include nor exclude them. This point was not really clarified, although the general understanding of the benefit-sharing objective was to include benefits from a broad set of modern biotechnological uses. The CBD is based on a thought that conservation must be seen in the context of sustainable use and benefit-sharing. One objective was to capture a fair part of benefits generated from the use of biodiversity back to the countries providing those resources. One objective could therefore be described as to capture the value of modern uses. Types of uses of genetic material will develop over time, which indicates a dynamic element to the definition. This links in with the current discussion of derivatives, and the discussion on where to draw the line regarding ABS obligations. Such details were however not fully discussed so there is still flexibility in the interpretation, but it is difficult to draw firm legally binding arguments beyond this.

## 5 Changes in Knowledge and Technology and the Concept Genetic Resources

Much has happened in the knowledge and technological fields since the entry into force of the CBD. It is therefore interesting to develop an understanding of how genetic material now is being used today.

### 5.1 Genomics

In the scientific community there has been a drive towards mapping the complete genome of organisms, or *full genome sequencing* as it is also known. The area of genomics is currently providing knowledge and understanding of all the genes in a cell or tissue, and how DNA, mRNA or even proteins function in the cell under different conditions. Genomics can provide a better understanding of the totality of how a gene may have different functions under varying conditions. The starting point is the DNA, RNA or even a protein, but the emphasis is on the knowledge and informational dimensions of the resource. Genomics has the potential to expand our understanding of how different conditions interact with the DNA, mRNA and proteins. The focus of these activities is to better understand the functions of genetic material and developing this into information which in turn can be used in research and development.

### 5.2 Proteomics

Proteomics can be explained as large-scale study of proteins, in particular their structures and functions. Where genomics looks at the DNA and

RNA, proteomics focuses on the protein which stems from DNA and RNA. The goal is a comprehensive, quantitative description of protein expression and its changes under the influence of biological perturbations such as disease or drug treatment.[17] This is an example of how new knowledge can open new units as functional in organisms, supporting a dynamic understanding of the concept of 'genetic resources'.

## 5.3 Bioinformatics

Bioinformatics refers to the application of computer science and information technology to the field of biology, molecular biology in particular. It has proven a crucial tool for genomics and the sequencing of the DNA of various organisms, and to proteomics as well. By applying information technology, mankind can further expand and develop the understanding of biological processes. In practice, bioinformatics is a way of realising the value in the genetic material disconnected from the biological sources where it was originally found.

## 5.4 Synthetic Biology

Synthetic biology is a rapidly growing field of research and molecular engineering. The concept was first used in 1974, but it was not until this century that the term gained widespread use. Its meaning and purpose has been broadly summarised as follows:

> (Synthetic Biology) attempts to recreate in unnatural chemical systems the emergent properties of living systems....(the) engineering community has given further meaning to the title....to extract from living systems interchangeable parts that might be tested, validated as construction units, and reassembled to create devices that might (or might not) have analogues in living systems.[18]

If or when knowledge and technology makes it possible to recreate biology in such ways securely and precisely, the use of the microphysical genetic material might be relegated to a more remote position. However, as synthetic biology copies biology in a synthetic way, it has probably been some use of genetic material in the process. Also in synthetic biology, the link back to the genetic material becomes more remote. This is a way to realise the value in the informational aspects of functional units of heredity.

## 5.5 New Development in Genetic Knowledge since 1992

Today we know far more about genes, gene expression and gene functioning than was the case in 1992. Several species, including *Homo sapiens,* have had their genomes fully mapped, and there is a better understanding of what turns genes on and off, and what regulates gene expression in the various cells, although our knowledge here is still fragmentary.

The 'one gene–one protein' thesis has been shown not to be valid in many cases. Through so-called 'differential' or 'alternative splicing' and other forms of m-RNA-editing after transcription to RNA from DNA, thousands of different proteins may come from one gene. The genetic composition of an organism can therefore not be used alone to predict a given protein composition of the cell under different biological and ecological circumstances. The functionality of the gene may be highly variable, depending on several regulatory factors originating from outside the gene itself, even through signalling from outside the cell. The amount of gene expression in different cells is also regulated by external factors. All this indicates that 'functional units of heredity' must be interpreted beyond the gene itself, and that there is a need for more flexibility in the interpretation. Some scientists even hold that it is the full genome that should be seen as the ultimate 'functional unit of heredity', given the present state of our knowledge. 'The atomistic view of the genome is untenable'.[19]

There is also a growing feeling among several scientists that the Central Dogma with unidirectional information flow, DNA→mRNA→protein, may not be totally valid. There is a lot more feedback regulation circuits, reparatory and natural engineering mechanisms, and signal transduction networks than earlier anticipated.

The 'junk-DNA' may not be so junky after all. We now know that several of the small, regulatory, non-coding RNAs, which are so important for gene expression, are coded for in these parts of the genome, and there is a feeling that more is to come. Perhaps the non-coding sections of DNA also contain several functional units of heredity, although not protein-coding sequences? Surely it stands to reason that evolution does not bring forward a lot of 'junk' after all. The new knowledge acquired through genomics and proteomics will certainly change our understanding of what parts of the genome being functional units of heredity. Already now we realise that there is an interaction between the genes and their regulatory environment that may have implications for how we interpret this concept.

Today it is a fairly straightforward matter to read and copy long sequences of DNA or to exchange nucleotides in naturally occurring genetic material. This indicates that the interpretation of the definition of 'genetic resources' and their uses need to be dynamic as regards new technologies, in order to meet the overall objectives of the benefit-sharing objective and obligation in the CBD. How much information from existing genomes or proteomes do we use, and how much do we contribute through human engineering? And how much can be changed before the obligation to share benefits from the use is being lost in the production chain? There is a risk that the new technology can make it easier to circumvent the obligations of the CBD. It may also prove very difficult to trace a given accessed genetic resource once it has been altered and engineered through several technological stages. Using a protein amino acids sequence of a given protein to backtrack the mRNA (and DNA) sequence is also possible today. This might indicate that also some or all forms of indirect use of genetic material, should be part of the scope of an international regime on ABS. Thus we see the importance of keeping abreast of the many rapid changes in knowledge and technological capacity.

## 5.6 'Bio-economy': the Emerging Competitive Global Markets

'Bio-economy' is a broad and vague term, often taken to mean economy based on biology. Such an understanding would cover most of the value of biological resources in addition to the values of the genetic material. Huge expectations are presented in connection to bio-economy. According to one business-oriented organisation, for instance: 'Biotechnology will drive expansion of the global economy, increasing wealth while reducing Humankind's environmental footprint.'[20] Also the OECD has been working on the potential of bio-economy by launching a study on the matter:

> The biosciences add value to a host of products and services, producing what some have labelled the 'bioeconomy'. The bioeconomy project assessed the pervasiveness of biotechnological applications, prospects for future development, potential impacts on the economy and society and potential policy solutions to promote and diffuse these innovations in a way that is consistent with broader policy goals.[21]

This quotation is from the presentation of a book launched by the OECD describing and analysing the bio-economy. These prosperous views on the potential for creating economic values based on bio-economy contrast with the statements of the CBD that genetic material is of limited interest or value to industry. It is a challenge for the Ad Hoc Working Group to react to these new developments from an ABS perspective.

## 5.7 Two Dimensions of Genetic Resources

From these discussions it can be observed that sources of biological material could serve as 'genetic resources' in different ways – that the value of the functional units of heredity might be captured in (at least) two dimensions: the genetic structure per se can be utilised; or the information encapsulated in the nucleotide sequence of the genetic material can be read and digitalised and easily acquired. The digital form may be used in more or less close connection to the micro-biological material. This has implications for how the concept 'genetic resources' can function in ABS for the future. The informational dimensions of genetic resources are becoming increasingly valuable as our knowledge about them expands and becomes widely accessible in databases of the functions of hereditary material. Technology for capturing the economic value of the genetic material is becoming more advanced and sophisticated, and increasingly based on the electronic or digital use of DNA. The flexibility of the definition of 'genetic resources' in the CBD allows for these two dimensions. There is, however, a need for further clarification of how an international regime could function in such situations, not least as regards how to trace such information back to the original physical material.

# 6 Examples on How the Concept ‘Genetic Resources’ Has Been Used

In the time after the entry into force of the CBD, as this section will show, ‘genetic resources’ has been used as a term, in a variety of situations often with divergent meanings. To develop a better understanding of how ‘genetic resources’ has evolved as a legal and political concept, it is relevant to look at some examples of the various ways it has been used.

## 6.1 FAO and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

In the International Undertaking on Plant Genetic Resources (IU) Article 2.1 the following understating was agreed (however not legally binding) in 1983.[22]

> (a) ‘plant genetic resources’ means the reproductive or vegetative propagating material of the following categories of plants:
>
> i. cultivated varieties (cultivars) in current use and newly developed varieties;
>
> ii. obsolete cultivars;
>
> iii. primitive cultivars (land races);
>
> iv. wild and weed species, near relatives of cultivated varieties;
>
> v. special genetic stocks (including elite and current breeders’ line and mutants;

The core of this understanding in 1983 was ‘reproductive or vegetative propagating material’. This is basically a references to seeds used as breeding material to achieve new plant varieties by conventional breeding methods. The IU did not refer to ‘functional units of heredity’ of ‘potential of actual value’. It can be said to apply a specific and narrow understanding of plant genetic resources targeting the object which was in relevance for food security and the other concerns regulated in the IU at that time.

For the purpose of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the term ‘plant genetic resources’ is defined in Article 2:

> ‘Plant genetic resources for food and agriculture’ means any genetic material of plant origin of actual or potential value for food and agriculture.
>
> ‘Genetic material’ means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.

With the term ‘reproductive and vegetative propagating material’ the definition of genetic material diverges from the general definition in the CBD, and takes a step closer to the understanding applied in the IU. The ITGRFA definition builds partly on the definition in the CBD, but narrows its scope. Such a narrower and more targeted object of regulations is also reflected in the scope of the Multilateral System (MLS). This gives the impression of a more specific understanding of what a genetic resource is for the purpose of the ITPGRFA: mostly accessions of plant breeding material. This gives good meaning as the intention of the Multilateral System (MLS) which it established is to ensure access to *accessions* of plant breeding material. Moreover, access through the MLS is meant to be solely for 'food and agriculture' purposes, indicating that new techniques and non-food uses fall outside the understanding of 'plant genetic resources'.

## 6.2 Commission on Genetic Resources for Food and Agriculture

The Commission on Genetic Resources for Food and Agriculture (CGRFA) discussed ABS and thus also issues related to 'genetic resources' at its 12th Session in October 2009. The overall broad and imprecise impression from the report is that the term 'genetic resources' is used describing in conventional biotechnology and breeding. In relation to gene banks:

> The Commission agreed on the need for revising the Genebank Standards in order to ensure that plant genetic resources are conserved under conditions that meet recognized and appropriate standards, based on current and available technological and scientific knowledge.[23]

The use of the term 'plant genetic resources' here gives the impression of talking about the accession of seeds and other material in gene banks rather than including the informational dimensions of 'genetic resources'. This is also easily explainable, since a gene bank is a facilitator of conservation of the diversity of accessions.

Another example is the statement connected to '... on-farm management of plant genetic resources for food and agriculture, and in situ conservation of crop wild relatives and wild plants for food, particularly in developing countries ...'[24] When 'plant genetic resources' are managed on farm this will also typically be done in a conventional way, which basically means seeds and other plant material used for propagation or sowing. Again the CGRFA uses a concept linked to conventional uses.

Where 'animal genetic resources' are dealt with, the impression is of reference to *genetic diversity* rather than breeding material only.[25] Here the term is used mostly at a general level related to sustainability and to maintaining diversity within breeds as well as among breeds and species.

Moreover, in the section in the CGRFA Report about invertebrates and micro-organisms there is no mention whatsoever of the term 'genetic resources'.[26] That would indicate that the work of the CGRFA on invertebrates and micro-organisms is not seen as an issue of genetic resources, but has other objectives.

The use of the concept in relation to aquatic genetic resources is kept in general terms, making it difficult to extract any specific meaning.[27]

In the section about biotechnology for food and agriculture, the emphasis turns towards new technologies in the sector. We may note one core element:

> The Commission requested FAO to prepare a scoping paper describing the range of biotechnologies being applied to the conservation and utilization of genetic resources for food and agriculture, the current status of application of these technologies and matters relevant for their future development, including relevant policy developments in other international forums, for consideration at its next regular session.[28]

Here the concept of 'genetic resources' is used in connection with utilisation. However, this is a topic for further elaboration, so it is not easy to identify exactly how the concept is used in this section of the Report. The indication is that at this point CGRFA opens for a discussion of utilisation of genetic resources, which might imply a reference to the application of techniques.

We see that the term 'genetic resources' is used in different contexts, apparently with different content, in this one document from the CGRFA. This look at the CGRFA has limited itself to the latest Report from the 12th Commission meeting: it might be that 'genetic resources' has been used differently or more consistently in other documents and discussions from this body.

## 6.3 The Intergovernmental Commission on Genetic Resources, Traditional Knowledge and Folklore (IGC)

The most recent document of the Intergovernmental Commission on Genetic Resources, Traditional Knowledge and Folklore (IGC) contains the following reference to 'genetic resources':

> (a) defensive protection of genetic resources; (b) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (c) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.[29]

Here the conception of 'genetic resources' diverges from that in the CGRFA and the ITGRFA. The first alternative, as to defensive protection, implies a reference to intellectual property rights, patents in particular. The patent system itself, however, does not use the concept of 'genetic resources'. Thus, when the IGC talks about defensive protection systems, the notion of the term indicates something that stands in relation to a patentable invention. Here the informational dimension of genetic resources as understood in the CBD becomes evident: when applying for a patent, it must involve an *intangible* element in the invention because of the system of patent law. The difference to the use of the concept of genetic resources in the CGRFA Report lies in the fact that the IGC focuses on 'genetic resources' as sources for innovation, whereas the CGRFA uses the term as being more closely connected to breeding material or as an overall concept describing genetic diversity. Similarly, in connection with the disclosure requirement, 'genetic resources' is used as a basis for innovation including an implicit reference to the informational dimension. The third reference to the concept of 'genetic resources' in the IGC paper goes back to CBD Article 15 and the procedures for PIC and MAT. This is the first of these examples where the other organisation uses the concept 'genetic resources' as it is used in the CBD.

To sum up: the IGC understanding of the concept of genetic resources either refers back to the understanding in the CBD, or is focused mainly on the informational dimension of genetic resources as used in context with patents.

## 6.4 Patent Arenas: WIPO and WTO

Patent law is dealt with internationally in several fora and agreements, notably the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as part of World Trade Organization (WTO),[30] Patent Cooperation Treaty (PCT/WIPO),[31] and in the Standing Committee on Law of the Patents (SCP) – both under the auspices of the World Intellectual Property Organization (WIPO). In the TRIPS Agreement and in the PCT, the term 'genetic resources' is not used. In these fora, the concept 'genetic resources' is used in connection with proposals for disclosure requirements (see the discussion in previous section). There is little guidance to be found here, as to the use of the concept 'genetic resources'.

## 6.5 Convention on Law of the Sea

The United Nations Convention on the Law of the Sea (UNCLOS) was adopted in 1982 and entered into force in 1994. It contains provisions concerning the rights and obligations of states in the marine environment. UNCLOS regulates the exploitation of natural resources, but does not explicitly address the exploitation of 'genetic resources'. Thus, UNCLOS cannot contribute extensively in this respect.

Since 2004, discussions of relevance to the concept of genetic resources have been carried out in the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction, established by the UN General Assembly (UNGA): see resolutions 59/24, 63/111 and 64/71. In resolution 63/111, the term is used three times, two of which are the following:

> 123. Recognizes the abundance and diversity of **marine genetic resources** and their value in terms of the benefits, goods and services they can provide;
>
> 124. Also recognizes the importance of research on **marine genetic resources** for the purpose of enhancing the scientific understanding, potential use and application, and enhanced management of marine ecosystems;

In paragraph 123, the notion of its use is that of genetic *diversity* but is also linked to the value of the material. In paragraph 124 there is greater linkage to the informational dimension of genetic resources: the 'scientific ... understanding, potential use and application', indicating a reference to marine genetic resources as a basis for scientific research. This contributes to the enrichment of the informational dimension and refers mostly to non-commercial uses.

## 6.6 Antarctic Treaty System

The Antarctic Treaty System (ATS) is a set of agreements regulating various aspects of the area south of 60° S latitude. The discussions of bioprospecting in the Antarctic in the ATS are the ones most relevant for the concept of 'genetic resources'.[32] Here the focus is in terms of the activity, rather than on the resources as such, and are mainly concerned with sample collection.

## 6.7 *Ex situ* Collections

How has the term 'genetic resources' been understood in relation to *ex situ* collections? In asking this question we take a pragmatic and factual approach rather than analysing legal texts. *Ex situ* collections have various objectives and they work in diverse ways. This is partly since different types of genetic material require storage under different conditions. For example, plant genetic material can be stored in a cold place like a freezer or in old underground mines (as is done at Svalbard in the Arctic). Animal genetic material requires different conditions: eggs, sperm and embryos must be stored in liquid nitrogen at extremely low temperatures. Other collections may keep the biological material in extracts as raw material for scanning and research.

Collections differ in their objectives as well. For instance, collections of plant genetic material often are kept available under open access regimes for breeding of new plant varieties, like those included under the MLS of the ITPGRFA. Other collections could be established as facilitators for research and development based on new techniques. How the *ex situ* collection uses the concept of genetic resources will be depend upon the objective of the collection and for which purposes it is used.

In the context of genomics, proteomics, bioinformatics and bio-economy, *ex situ* collections are not mainly samples of biological material, but rather the digitalised form of DNA, RNA or proteins. Here the microphysical dimension of genetic resources is less evident, and the intangible informational dimension is crucial.

## 6.8 Lessons Learned

The main lesson from this look at some recent examples of 'genetic resources' as conceived in various international forums and agreements is that the concept is not used with any one single, consistent meaning. We note a range of differences, from a focus on accessions for breeding, through DNA, to the informational dimension, pure digitalised information, and to the generalised concept of biological diversity at the gene level. From this brief survey no legally binding conclusions can be drawn regarding the specific understanding of 'genetic resources' as it is used in the CBD. However, we find strong indications of multiple dimensions, which could argue for a broad understanding of the concept in an international regime on ABS. If the informational and digital dimensions are removed from the concept, valuable ways of realising the potential value of the functional units of heredity could fall outside the scope of an international ABS regime.

## 7 A Closer Look at the Work of the Expert Group on Definitions

The Ad Hoc Working Group has already addressed the further clarification of the main concepts for an international regime. In 2008 the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (Expert Group on Definitions) met and produced the report UNEP/CBD/WG-ABS/7/2. This report is discussed here. Two of the main areas involve ways to utilise genetic resources and derivatives, but first let us add some important perspectives to the application of the concept 'genetic resources' in ABS.

### 7.1 Perspectives on the Definition: Application of the Definition at Access and at Utilisation[33]

There are differences in how the definition of 'genetic resources' will work at the time of access and at the point of *utilisation*. At the **time of access** to genetic resources, the value of genetic material is mostly *potential*. The crucial issue to determine is whether the accessed material will be used to realise the potential or actual value of the units of heredity. As yet, this is not externally verifiable. To determine this, one will need to know the *intentions* of those accessing the material. When someone takes any type of biological material across a border, it is not easy to prove or know the intention involved – moreover, the intention might change later. This introduces considerable legal uncertainty at the timepoint of access, and is probably one reason why ABS has yielded only limited benefit sharing until now. Any transaction of biological material – in fact, any cross-border commodity transfer – has the potential to take some advantage of the value of the functional units of heredity. This potential, however, is realised only at a later, often much later, time. An ABS system based *solely* on access legislation cannot be functional. If an international regime does not solve this challenge, a huge loophole is created or maintained in the system.

At the *time of utilisation* of genetic resources, the actual or potential value of the genetic material becomes evident and more easily realised. Once the benefits have been created, it is easier to know and prove before a court that genetic material, directly or indirectly, has formed part of the *value capturing process* in retrospect. This is also recognised by the Expert Group on Definitions: 'Actual or potential use of genetic material indicates an attribution of value'.[34] At the point of time of *use* of genetic material, the scope of the ABS requirements is easier to determine.

Enforcing ABS at the time of utilisation, however, raises another problem: that of sovereignty. ABS in the CBD is based on the assumption that the genetic material is taken from the territory of one country, to be used in another country. At the time of utilisation and thus realisation of the value, then, the benefits are in fact beyond the regulatory scope of the providing country. Only recently has interest emerged in developing the concept of *utilisation of genetic resources* as the actual trigger of the benefit-sharing obligation.[35] Utilisation – in opposition to the intent of future use – can be externally verified, and therefore be enforceable as a legal term. Still, various technical legal problems may make it difficult to use traditional legal mechanisms to enforce the obligations on the user of genetic resources, particularly if the user and the collected biological material are beyond the jurisdiction of the providing country.[36]

## 7.2 Developing a List of Utilisations

The Expert Group on Definitions has presented a list of ways to utilise 'genetic resources'.[37] The main trigger point for benefits sharing is, according to Article 15.7, the 'utilization' of genetic resources. The CBD thus provides for a criterion specially adapted for defining the point of time when the benefit-sharing obligation kicks in. The development of the understanding of what is meant by utilisation of genetic resources is a good opportunity for the Ad Hoc Working Group to capture the two dimensions of genetic resources in an international regime on ABS. The term 'utilisation of genetic resources' is not specified in the wording of the CBD. The list provided by the Expert Group includes types of uses that are relevant for ABS – the question is whether these activities entail using 'genetic resources' as defined in the CBD. As pointed out in section 5.7 above, the concept of 'genetic resources' captures different dimensions of the molecular structure and the informational elements connected to it.

Discussion of these activities could be done *de lege ferenda* or politically, by asking whether each activity should be included in ABS. Since CBD is already legally binding on its members, a different approach could be taken to discussing this list: *de lege lata*, looking for the binding interpretation of law. In line with the methodology of international law, this is done by interpreting the ordinary meaning of the words in the treaty. That makes it relevant for us to examine each item on the list and indicate how it relates to the definitions and concepts of the CBD. Each section refers first the text from the Expert Group, followed by a brief discussion.

### 7.2.1 1) Genetic modification

> Development of new variations within non-human species (micro-organism, plant, animal, and other organisms) through genetic modification techniques such as:
>
> - Transfer of a genetic trait, such as a gene for pesticide resistance taken out of one species and put into another
> - Genetic modification of a micro-organism for a specific purpose such as the production of enzymes or biofuels
> - Production of recombinant cell lines or attenuated vaccine strains
> - Production of transgenic organisms, animals, plants, micro-organisms
> - Use of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA); and direct injection of nucleic acid into cells or organelles
> - Use of fusion of cells beyond the taxonomic family

Common to these examples is that they target techniques of *genetic modification* by taking genes from one organism and relocating these into another one. As regards the definition, these techniques clearly capture the value of the functional units of heredity. The units of heredity here are functional in the sense that they are intended to work in another organism. Such uses obviously fall within the binding interpretation of what is meant by 'utilisation of genetic resources' and will therefore trigger benefit sharing.

#### 7.2.2 2) Biosynthesis

Use of genetic material as a 'factory' to produce organic compounds, such as:

- Antibodies
- Vitamins
- Hormones
- Enzymes
- Active compounds for pharmaceutical production
- Other naturally occurring compounds

Here it is relevant to ask whether this use of 'genetic material as a factory to produce organic compounds' involves realising the value of the functional units of heredity. The valuable product in these activities lies in the end result, but in creating them the genetic material is utilised in a fairly direct manner, so that they might well fall under the scope of the definition and thus the benefit-sharing obligation. Although these techniques were not fully developed at the time of the CBD, still they realise the value of the genetic material.

#### 7.2.3 3) Breeding and selection

Creating new varieties, breeds, or strains of non-human species with particular characteristics through sexual or asexual reproduction such as:

- Plant breeding (e.g. crossing, artificial mutations, haploid production, hybrids)
- Breeding of animals (e.g. crossing, artificial insemination, cloning)
- Selection of microorganisms or algae with specific traits
- Domestication of plants and animals from wild species

These categories include long-term types of utilisation of genetic material that predate the CBD. They reflect what is probably the most common everyday understanding of 'utilisation of genetic material', and they fall under what is utilisation of genetic resources.

### 7.2.4 4) Propagation and cultivation of the genetic resource in the form received

Production of non-human organisms through sexual and asexual reproduction for purposes such as:

- Cultivation of microorganisms or plants
- Propagation of animals
- Production of plant, animal and microbial products

From a purely linguistic point of view, one could argue that in these processes, the genetic material is in use in a direct way. This would indicate that also these activities would fall under the scope of utilisation of genetic material.

### 7.2.5 5) Conservation

Preservation of non-human organisms for conservation of genetic diversity, genetic resources or reintroduction purposes through activities such as:

- Captive breeding programmes
- Deposition in seedbanks, genebanks, culture collections, botanical gardens, zoos, and aquaria, etc.

These groups of uses of genetic material have a somewhat different objective in terms of their conservation purpose. Depositing genetic material in a collection is beyond doubt one way to preserve its potential value. Thereby these activities fall within the understanding of the definition of genetic resources in the CBD. In the context of utilisation and benefit sharing, it is less clear whether these are uses which directly create benefits that can be shared (beyond the obvious benefit of conservation). Such collections have the potential to serve as centres that promote research and development based on the genetic material in their collections. Thus over time, these activities can indeed be said to have potential value and create long-term benefits.

### 7.2.6 6) Characterisation and evaluation

- Sequencing genes or genomes (e.g. identification of genes coding for useful traits; molecular systematics for understanding evolutionary relations; genotyping of micro-organisms, plants and animals for identification and subsequent purposes; DNA barcoding of plants, animals and fungi for identification; environmental genomics)
- Phenotyping of the characteristics of plants, animals and micro-organisms for ecological and other studies and purposes
- Experimental evaluation of heritable characteristics
- Creation of collections of reference specimens in repositories such as museums and herbaria
- Isolation of a compound from genetic material for the purpose of characterization and evaluation

These groupings of uses of genetic material have a distinct flavour of academic uses, and there have been strong calls for general exemptions for academically-based access to genetic resources.[38] There are good reasons for not imposing heavy burdens on users with scarce financial resources and pressing time-schedules. The need for academic institutions to have easy access could be resolved by combining easy access with well-drafted, functional and enforceable rules in user countries. Such rules could also capture whether the way of use is changed later. However, several question and difficulties remain in establishing such an enforceable system across borders. Given the close linkages between academic institutions and commercially based developments, an international regime may risk creating a loophole if access for academic purposes is exempted from ABS.

#### 7.2.7 7) Production of compounds naturally occurring in genetic material

- Screening and extraction of metabolites from genetic material
- Chemical synthesis of metabolites occurring in genetic material
- Synthesis of short DNA segments based on genetic material (e.g. oligonucleotides, probes and primers)
- Production of copies of DNA segments through PCR (polymerase chain reaction amplification)

These categories of uses are similar to some of the new techniques discussed above in section 5; they target mainly the informational aspects of genetic resources.

#### 7.2.8 A Link to Benefit Sharing

When specific types of uses are defined like this, it opens for a fundamental next question. What level of benefits sharing would meet the obligation of ‘fair and equitable’ for each of these groupings of utilisations of genetic resources? This is a less evident question to ask as the CBD Art 15.7 only requires that the benefits shall be distributed in a *fair and equitable* manner without specifying or clarifying nuances in this respect. Here there is a potential for the Ad Hoc working group to go into the details for establishing elements of clear and enforceable obligations.

### 7.3 Derivatives and the Definition of ‘Genetic Resources’

A politically charged and analytically difficult issue concerns whether and to what extent ‘derivatives’ should be covered by ABS. The Expert Group on Definitions has provided a listing of relevant types of objects that might be subsumed under the term ‘derivatives’. This list was developed in document UNEP/CBD/WG-ABS/7/2, paragraph 19.

A formalistic approach to determining whether each of these objectives falls under the ABS obligation could be to go through the list, element by element, and assess each against the concept of ‘genetic resources’ discussed above. The aim would be to decide whether each of these uses of biological material qualifies as ‘genetic resources’ or even ‘utilisation of genetic resources’, which would trigger the benefit-sharing obligation according to CBD Article 15.

a) **A naturally occurring chemical compound (metabolite) produced as a result of the expression of an organism’s genetic make-up**: This is an example of the genetic material producing a particular chemical compound.

b) **A chemical compound produced by human activity using genetic material**. This alternative use of the term 'derivative' overlaps with what was discussed in section 7.2.2 about biosyntheses, where the use of genetic material in the production of biochemicals is indicated as one type of use. Therefore, this could rather be subsumed under 'utilisation of genetic resources' than understood as to being a 'derivative'.

c) **Gene segments produced or isolated by human manipulation of genetic material**. This alternative is a highly technical one. It too is closely linked to the utilisation of genetic material and can be argued to fall under the definition, as it involves a way of using the functional units of the organism.

d) **Synthetic gene segments produced by human manipulation (one segment being a derivative of all the various genetic materials used in its construction)**. Here the starting point also seems to be the micro-physical genetic material which has a biological source or origin.

e) **Information or knowledge derived from genetic materials in general, or a specific gene sequence in particular**. This way of talking about derivatives needs to be considered in the light of recent knowledge about and altered technological uses of genetic material. This notion used as 'derivatives' seems to assume that 'genetic resources' involve only the micro-biological material and not the informational elements.

f) **Synthetic analogue chemicals or gene segments inspired by a particular naturally occurring metabolite or gene segment**. This refers back to the discussion about synthetic biology discussed above.

g) **A 'derivative' is the result of the utilization of a genetic resource through human activity: a) genetic resources used for research (research not aiming at commercialization), b) products under development (research and development aiming at commercialization) c) products (commercialization)**. This way of understanding 'derivatives' is probably the broadest one, including a reference to a wide scope of ways to utilise genetic material.

h) **The meaning given to the term derivatives should be mutually agreed between the provider and the user of genetic resources**. This alternative basically would it up to the parties to MAT or PIC to define in each single contract or administrative decision to define 'derivatives' for its purpose. This alternative leaves the concept unresolved and opens for practice to develop it further.

i) **Any and all parts found within a biological resource even if the material obtained no longer contains any genetic material of functional units of heredity**. This alternative is not easily understood, but indicates a reference to the elements in biological material which can be said not to contain functional units of heredity.

j) **Something derived from biological and genetic resources such as varieties, strains or breeds, blood, proteins, oils, resins, gums, genes, seeds, spores, pollen, urine, bark, wood, leaf matter and**

**the like as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes**. This grouping is broad and covers rather diverse objects which relates to 'genetic material' in divers ways.

k) **Derivatives that are genetic resources, and derivatives that are not**. It is not completely easy to understand what this alternative means, and it appears somewhat circular. It is also not very clear how this could be converted into a legally enforceable criterion of law.

This look at the list of derivatives provided by the Expert Group does not intend to resolve the difficult issue of derivatives, but contribute to a more technical discussion of this topic for the Ad Hoc Working Group.

## 8 Final Observations Regarding the Concept 'Genetic Resources'

This paper has discussed the concept of 'genetic resources' and how it is embedded in the definitions and obligations of the CBD, both as to its historical meaning and in relation to current knowledge and utilisation. We have noted several examples of different ways in which the term 'genetic resources' is used in other international arenas than the CBD. We have also seen how new knowledge and technologies may create new and inventive uses of genetic resources with a future potential for ABS. Finally, this paper has discussed the report from the Expert Group on Definitions and its relevance to the subject in question.

Knowledge about and techniques using genetic material are evolving rapidly. If the concept of genetic resources is understood only narrowly, in senses related to the original or current state of knowledge, the ABS system may not be able to capture the future potential value of genetic material, not least when it is used in or as a basis for synthetic biology or other new bio-economic technologies. An International ABS Regime could maintain a broad and dynamic understanding of the concept of genetic resources. There is however a dilemma and a contradiction between on the one hand leaving a definition dynamic and flexible, at the same time as it is understood in a manner which creates legal certainty and thus is enforceable.

## Notes

[4] In this paper ABS is used to refer to 'Access and Benefit Sharing' under the CBD in total; when reference is made to an international regime on ABS which is currently being negotiated, the term 'an international regime' is used.

[5] Tvedt and Young 2007, p. 56, n. 3, save from a rather specific use in the plant sector, where the term 'plant genetic resources' was often used as synonymous with accessions of seeds for plant breeding.

[6] *See*, e.g., the Intergovernmental Commission on Genetic Resources, Traditional Knowledge and Folklore (IGC), the discussions in the WIPO Standing Committee on Law of the Patents (SCP), in FAO and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and in the TRIPS Council of the WTO.

[7] See UNEP/CBD/WG-ABS/7/2, paragraph 5.

[8] The FNI has published a study about the interfaces between an international regime on ABS and other regimes: Regine Andersen, Morten Walløe Tvedt, Ole Kristian Fauchald, Tone Winge, Kristin Rosendal and Peter Johan Schei. International Agreements and Processes Affecting an International Regime on Access and Benefit Sharing under the Convention on Biological Diversity - Implications for its Scope and Possibilities of a Sectoral Approach. FNI Report 3/2010.

[9] UNEP/CBD/WG-ABS/7/2, Annex paragraph 3.

[10] Compact Oxford English Dictionary on web, www.askoxford.com/concise_oed/functional?view=uk .

[11] Vienna Convention on the Law of Treaties, Article 32.

[12] UNEP/CBD/WG-ABS/8/INF/3, p. 28.

[13] The topic traditional knowledge has been addressed in e.g. UNEP/CBD/WG-ABS/7/INF/7, UNEP/CBD/WG-ABS/8/INF/1 (including language which could be implemented in an IR), and UNEP/CBD/WG-ABS/8/INF/4.

[14] See also UNEP/CBD/WG-ABS/7/INF/3/Part.2, paragraphs 38–43.

[15] WIPO document WIPO/GRTKF/IC/16/5 Prov.

[16] For an initiative concerning a TK Commons, see the information from the TK Commons Workshop: http://naturaljustice.org.za/index.php?option=com_content&task=view&id=55&Itemid=94 .

[17] The US Library of Medicine, www.ncbi.nlm.nih.gov/pubmed/9740045 .

[18] Benner, S.A. and Sismour, M. (2005) Synthetic Biology. Nature Reviews Genetics 6, pp. 533–543.

[19] Shapiro, J.A. (2007), http://shapiro.bsd.uchicago.edu .

[20] See www.bio-economy.net/bioeconomy/about_bioeconomy/index_about_bioeconomy.html

[21] www.oecd.org/department/0,3355,en_2649_36831301_1_1_1_1_1,00.html

[22] From Resolution 8/83 of the Twenty-second Session of the FAO Conference, Rome, 5–23 November 1983.

[23] CGRFA-12/09/Report, paragraph 28.

[24] CGRFA-12/09/Report, paragraph 32.

[25] CGRFA-12/09/Report, paragraph 35–43.

[26] CGRFA-12/09/Report, paragraph 58–65.

[27] CGRFA-12/09/Report, paragraph 66–69.

[28] CGRFA-12/09/Report, paragraph 72.

[29] WIPO/GRTKF/IC/16/6 Prov, paragraph 5.

[30] TRIPS became international law together with the entry into force of the WTO in 1995.

[31] PCT (Washington DC, 1970), amended in 1979 and modified in 1984 and 2001 (PCT Union); by 2008 it had 139 country members.

[32] For a complete look at the papers on bioprospecting in Antarctica, see Tvedt 2010, forthcoming, in *Polar Record.*

[33] This section goes further than the original TOR, and has been prepared solely at the initiative of the FNI, in order to place this paper in the broader context of ABS.

[34] UNEP/CBD/WG-ABS/7/2, annex paragraph 12.

[35] Tvedt and Young 2007 op.cit. Chapter 3, n.3, provides a survey of existing literature on user-country measures. This is also underscored by the fact that the Expert Group devotes more space in its report to utilisation issues than to the genetic resources UNEP/CBD/WG-ABS/7/2, Annex paragraphs 13–17.

[36] For an analysis, see Young and Tvedt 2009, *Balancing Building Blocks of a Functional ABS System,* UNEP/CBD/WG-ABS/8/INF/2.

[37] UNEP/CBD/WG-ABS/7/2 (annex paragraph 13).

[38] See for example the report: *Preserving international access to genetic resources for non-commercial biodiversity research,* which was presented as document UNEP/CBD/WG-ABS/8/INF/6.

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