



## Convention on Biological Diversity

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### AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING

Seventh meeting

Paris, 2-8 April 2009

Item 3 of the provisional agenda\*

### REPORT OF THE MEETING OF THE GROUP OF LEGAL AND TECHNICAL EXPERTS ON CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES

#### INTRODUCTION

##### *A. Background*

1. In paragraph 11 of its decision IX/12, the Conference of the Parties to the Convention on Biological Diversity decided:

“[...] to establish three distinct groups of technical and legal experts on: (i) compliance; (ii) concepts, terms, working definitions and sectoral approaches; and (iii) traditional knowledge associated with genetic resources. The terms of reference of the groups, including the criteria for the selection of experts are laid out in annex II to the present decision;”

2. Section B of annex II to decision IX/12 reads:

“1. A group of technical and legal experts on concepts, terms, working definitions and sectoral approaches is established to further examine the issue of concepts, terms, working definitions and sectoral approaches in order to assist the Working Group on Access and Benefitsharing. The expert group shall provide legal and technical advice, including, where appropriate, options and/or scenarios. The expert group will address the following questions:

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

(b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;

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\* UNEP/CBD/ABS/7/1.

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

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

2. The expert group shall be regionally balanced and composed of thirty experts nominated by Parties and a total of fifteen observers from:

(a) Different sectors including, *inter alia*, industry, research institutions/academia, botanical gardens and other *ex situ* collection holders;

(b) International organizations and agreements, non-governmental organizations; and

(c) Including three representatives from indigenous and local communities nominated by them.”

3. Accordingly, the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches met in Windhoek, Namibia, from 2 to 5 December 2008, in accordance with the above-mentioned decision and terms of reference provided by the Conference of the Parties. The meeting was hosted by the Government of Namibia and co-hosted and financially supported by the Government of Canada. Financial support was also provided by the Governments of Austria, Germany and Spain

#### **B. Attendance**

4. In accordance with annex II of decision IX/12, 30 participants were selected among government-nominated experts from each geographic region, taking into account their expertise, the need to ensure faire and equitable geographic distribution, and gender balance. In addition, fifteen observers were selected from among representatives of indigenous and local communities, industry, research institutions/academia, botanical gardens, other *ex situ* collection holders, relevant international organisations and agreements and non-governmental organizations. The list of selected experts and observers was approved by the Bureau of the Conference of the Parties.

5. The meeting was attended by experts nominated by Brazil, Canada, Costa Rica, Cuba, the Czech Republic, the European Community, Ethiopia, France, Georgia, Germany, Indonesia, Japan, Mauritius, Namibia, the Netherlands, Nigeria, Peru, Philippines, Switzerland, the United Kingdom, and Uruguay. Experts from the following countries, who had been selected and invited to the meeting, were unable to participate: Egypt, India, Islamic Republic of Iran, Niger, Pakistan, Saint Lucia, Tajikistan, Thailand and United Republic of Tanzania.

6. Experts from the following organizations participated in the meeting as observers: the South Africa National Botanical Gardens, the Secretariat of the FAO Commission on Genetic Resources for Food and Agriculture, the Secretariat of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, Biodiversity International, Instituto Indigena Brasileiro para Propriedade Intelectual (INBRAPI) and the Indigenous Information Network, Abbott Laboratories, Plantum NL, Eli Lilly and Company, Limagrain, the International Union of Biological Sciences, the Smithsonian Institution, and the Protestant Church Development Service (EED). An observer from the Government of the United States of America also attended. Three selected observers did not attend, namely the experts from Phytotrade, Friends of the Earth (Togo), and the indigenous observer from Dena Kaych Institute.

7. In addition, the Co-Chairs of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, Mr. Timothy Hodges of Canada and Mr. Fernando Casas of Colombia, a representative

of the President of the ninth meeting of the Conference of the Parties to the Convention (Germany), and a representative of the host country of the tenth meeting of the Conference of the Parties (Japan), attended as *ex officio* observers. A representative of the United Nations Environment Programme (UNEP) also attended.

## ITEM 1. OPENING OF THE MEETING

8. The meeting was opened at 9 a.m. on Tuesday, 2 December 2008.

9. The Honourable Minister of Environment and Tourism of Namibia, Ms. Netumbo Nandi-Ndaitwah, welcomed all participants in the meeting and emphasized their huge responsibility kicking off the series of legal and technical expert meetings that would help enabling the adoption of the international regime on access and benefit-sharing at the tenth meeting of the Conference of the Parties, to be held in Nagoya, Japan, in 2010. She emphasized that Namibia would like to see a strong and legally binding regime driving sustainable use and conservation of biodiversity through an effective and wide-ranging system of benefit-sharing. She reminded the participants that, to date, the road towards the realization of the third objective of the Convention had not been an easy one. However, she expressed her encouragement with regard to the positive spirit that prevailed at the sixth meeting of the Open-ended Working Group on Access and Benefit-sharing, held in Geneva in January 2008, as well as during the recent deliberations at the ninth meeting of the Conference of the Parties to the Convention. Stating that the current meeting was not a negotiating session, she stressed the need to look at the issues in a frank and open manner where established views could be challenged and addressed head on. Finally, she thanked the Government of Canada for co-hosting the meeting, as well as all those Governments who had provided financial and other support, and wished the participants wisdom and success in their deliberations.

10. Mr. Olivier Jalbert, Principal Officer, Secretariat of the Convention on Biological Diversity, speaking on behalf of Mr. Ahmed Djoghla, the Executive Secretary of the Convention, expressed his gratitude to the Government of Namibia for hosting the meeting. He noted that the Namibian Government and people had expressed their support for the principles conservation and sustainable use of biodiversity in many ways and emphasized the active role and leadership provided by Namibia within the framework of the Convention, in particular in the African region with respect to access and benefit-sharing. He also expressed his deep appreciation to the Governments of Canada—co-host of the meeting—Austria, Germany and Spain for their generous financial support, which had made the meeting possible. He recalled the mandate of the Group as contained in annex II to decision IX/12 of the Conference of the Parties and emphasized that the participants had been selected on the basis of their expertise and were requested to provide legal and technical expert advice on issues related to the basic architecture and concepts underlying the international regime on access and benefit-sharing. Finally, he welcomed the Co-Chairs of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, as *ex officio* observers, as well as representatives of the current President of the Conference of the Parties and the host of the tenth meeting of the Conference of the Parties, and wished the participants a fruitful meeting.

## ITEM 2. ORGANIZATIONAL MATTERS

### 2.1. *Officers*

11. At the opening session, on 2 December 2008, participants elected Mr. Pierre du Plessis (Namibia) and Mr. Desmond Mahon (Canada) as Co-Chairs of the meeting.

## **2.2. Adoption of the agenda**

12. The Group adopted the following agenda on the basis of the provisional agenda (UNEP/CBD/GTLE/1/1):

1. Opening of the meeting.
2. Organizational matters;
3. Concepts, terms, working definitions and sectoral approaches relating to the international regime on access and benefit-sharing.
4. Adoption of the report.
5. Closure of the meeting.

## **2.3. Organization of work**

13. At its opening session, the Group decided to work initially in plenary, with the possibility of breaking up in smaller working groups, as needed, during the following days.

### **ITEM 3. CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES RELATING TO THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING.**

14. In addressing the items laid down in its terms of reference, the Group had before it a compilation of submissions received from Parties, indigenous and local communities, international organizations and stakeholders regarding concepts, terms, working definitions and sectoral approaches (UNEP/CBD/ABS/GTLE/1/2 and UNEP/CBD/ABS/GTLE/1/2/Add.1) and a note by the Executive Secretary prepared for the fourth meeting of the Working Group on Access and Benefit-sharing entitled “Further consideration of outstanding issues related to access and benefit-sharing: use of terms, definitions and/or glossary, as appropriate” (UNEP/CBD/WG-ABS/4/7). It also had before it, as information documents, a report submitted by the International Chamber of Commerce on good business practices and case-studies on biodiversity (UNEP/CBD/ABS/GTLE/1/INF/1) and a submission from an international workshop on the topic of “Access and Benefit-sharing in Non-Commercial Biodiversity Research”, held in Bonn from 17 to 19 November 2008 (UNEP/CBD/ABS/GTLE/1/INF/2).

15. Over the four days of the meeting, the experts examined in great detail the concepts, terms, working definitions and sectoral approaches based on the four questions posed by the Conference of the Parties in order to assist the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing, mindful that their mandate consisted in providing legal and technical advice to the Working Group.

16. Late in the final session, during the adoption of the report, the expert from Cuba noted that due to the departure of a number of participants the remaining experts no longer reflected an adequate balance among regions and asked that her intervention be noted in the report of the meeting.

17. The outcome of deliberations is contained in the annex to the present report.

### **ITEM 4. ADOPTION OF THE REPORT**

18. The present report was adopted at the final session of the meeting, at 10:30 p.m. on 5 December 2008.

**ITEM 5. CLOSURE OF THE MEETING**

19. At the final session of the meeting, on 5 December 2008, participants expressed their appreciation to the Government of Namibia for hosting the meeting, to the Government of Canada for co-hosting, and to the Governments of Austria, Germany and Spain for providing the necessary financial support.

20. Following the customary exchange of courtesies, the meeting was closed at 11 p.m. on Friday, 5 December 2008.

*Annex***OUTCOME OF THE MEETING OF THE GROUP OF LEGAL AND TECHNICAL EXPERTS  
ON CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES**

1. The Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches met to provide legal and technical advice, including, where appropriate, options and/or scenarios, regarding the questions identified for its consideration in decision IX/12, annex II, section B, paragraph 1. The following reflects the outcome of discussions.

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

2. The experts first discussed the different ways of understanding biological resources and genetic resources. Reference was made to the definitions contained in Article 2 of the Convention on “biological resources”, “genetic resources” and “genetic material”.

3. According to Article 2:

- “*Biological resources*” includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
- “*Genetic material*” means any material of plant, animal, microbial or other origin containing functional units of heredity.
- “*Genetic resources*” means genetic material of actual or potential value.

The experts observed that according to these definitions genetic resources are a subset of biological resources. As such, biological resources could contain a genetic resource.

4. In the discussion some participants were of the view that research is showing that deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), the functional units of heredity, are found in virtually all cells and cell types and in many other parts of organisms. They felt that, for example, wood and wool contain DNA and could therefore be considered genetic resources as well as being biological resources and commodities, depending on their use.

5. Regarding the Convention’s definition of the term “genetic resources”, it was concluded that further clarification would be helpful to further understand the practical implications for access and benefit sharing within the international regime.

6. The renegotiation of the definitions in the Convention was not considered as practical.

*Biological resources*

7. The experts recalled that the preamble to the Convention reaffirms that states have sovereign rights over their own biological resources.

8. The experts observed that some Parties have national legislation on access and benefit-sharing that also applies to biological resources.

9. Some felt that access to biological resources for other uses could lead to their use as genetic resources and that it is within a State’s sovereign rights to subject them to mutually agreed terms. They also felt that the international regime could be used to support compliance with mutually agreed terms

extended over biological resources in this context. They suggested that this issue should be addressed by the legal and technical expert group on compliance.

10. The experts recognised that biological resources used as commodities are subject to a separate set of international norms and rules and there was general agreement that commodities should be outside the scope of the international regime for purposes of prior informed consent, recognising that the scope of the regime was outside of the mandate of the expert group. It was also recognised that access to genetic resources from material traded as commodities may need to be addressed in the negotiation of the international regime.

#### *Genetic resources*

11. Greater clarity could be premised on the use of genetic resources since it is their use that connoted actual or potential value of the genetic material from which benefits could be ultimately derived, and “the utilisation of genetic resources” is specifically referenced in the third objective of the Convention.

12. Genetic resources are defined as “genetic material of actual or potential value”. Actual or potential use of genetic material indicates an attribution of value. The categories of activities listed below use genetic material and thereby could provide further clarification to the understanding of the definition of "genetic resource" as used in the Convention on Biological Diversity.

13. Following lengthy discussions regarding possible uses of genetic resources and on whether the activities listed below all constitute typical uses of genetic resources, participants agreed that the list below is not exhaustive.

#### **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, microorganisms
- 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

#### **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

**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

**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

**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.

**6) Characterization 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

**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)



14. With respect to the item listed in the fifth bullet under category 2, industry observers and an expert indicated that it should read “active compounds for all industrial production”. Some experts suggested that it should read “active and inactive compounds”.

15. The observers from the industry sector felt that the items listed in the second, third and fourth bullets under category 7 do not constitute use of genetic resources on the basis that these activities use derivatives that do not contain functional units of heredity and therefore do not meet the definition of a genetic resource.

16. It was suggested that the development of inventories or catalogues of what constitutes a utilization within the meaning of paragraph 7 of Article 15 of the Convention for specific chains of users may be useful in the domestic implementation of the international regime. However, there was no detailed discussion on this idea.

17. It was also suggested that the differentiation into categories of utilization: non-commercial research, research and development (R&D) and commercialization might be useful in domestic implementation of the international regime. This idea was appreciated by the group without going into a detailed discussion.

#### *Derivatives and products*

18. The experts were reminded that the Convention text did not provide any definitions for the terms “derivatives” and “products”. A number of experts recalled that the Bonn Guidelines mention derivatives and products in the context of prior informed consent (para. 36 (1)) and mutually agreed terms (paragraph 44(i)).

19. In order to address the different ways of understanding derivatives and the implications of these understandings, the expert group sought to compile a list of the different understandings drawn from proposals included in document UNEP/CBD/WG-ABS/4/7, submissions made to the group and reflected in documents UNEP/CBD/ABS/GTLE/1/2 and UNEP/CBD/ABS/GTLE/1/2/Add.1, as well as contributions from individual experts. The compilation, found below, shows clearly that there is no common understanding of the concept. Instead, the term “derivative” is used to denote a continuum of very general to very specific concepts.

#### **Compilation of ways of understanding derivatives**

(a) A naturally occurring chemical compound (metabolite) produced as a result of the expression of an organism’s genetic make-up.

(b) A chemical compound produced by human activity using genetic material.

(c) Gene segments produced or isolated by human manipulation of genetic material.

(d) Synthetic gene segments produced by human manipulation (one segment being a derivative of all the various genetic materials used in its construction).

(e) Information or knowledge derived from genetic materials in general, or a specific gene sequence in particular.

(f) Synthetic analogue chemicals or gene segments inspired by a particular naturally occurring metabolite or gene segment.

(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).

(h) The meaning given to the term derivatives should be mutually agreed between the provider and the user of genetic resources.

(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.

(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;

(k) Derivatives that are genetic resources and derivatives that are not.

20. The experts observed that most of the different understandings of derivatives enumerated above can be grouped as follows:

- Derivatives understood as the results of an organism’s metabolism
- Derivatives understood as any result of human activity utilizing a genetic resource
- Derivatives understood as information on genetic resources

21. In the discussion, it was observed that naturally occurring derivatives can be accessed without also accessing the genetic resource at the same time, which raised the question of whether they would not fall under the international regime, but could be regarded as biological resources and therefore be subject to national sovereign rights and mutually agreed terms.

22. In considering the different ways of understanding derivatives, the expert group observed that there is a continuum from derivative, to derivative under research and development, to product, noting that all products are derivatives but not all derivatives are products.

23. Several experts proposed indicators against which a derivative could be judged to have become a product such as: (i) commercialization and availability on the open market/for sale to the public; (ii) seeking marketing or other approvals such as product registration; (iii) submission of applications for intellectual property protection; and (iv) the identification of a specific use for a derivative.

24. Some participants indicated that derivatives including information about genetic resources may be considered to be in the public domain. Some experts also suggested that this issue would need to be considered by the Working Group on Access and Benefit-sharing.

25. The Group noted that monetary benefits would not be dependent on the derivative becoming a product. Furthermore, there are many existing examples of opportunities for non-monetary benefits.

26. It was noted that products that are not genetic resources themselves are not subject to prior informed consent but should be addressed under mutually agreed terms in order to ensure the sharing of benefits.

27. Some experts expressed the view that this would not imply that products which are genetic resources will be subject to prior informed consent.

28. After having considered the different ways of understanding derivatives, and agreed that the concept was a continuum as described above, the Group examined the implications of these understandings for the development of the main components of the international regime by focussing on access to genetic resources and fair and equitable benefit-sharing.

29. The Group noted the contribution of indigenous and local communities, but felt that the components related to compliance and traditional knowledge did not need to be addressed at the current meeting as these issues would be specifically taken up by the other relevant expert groups. It was also felt that the issue of capacity may not need to be specifically addressed in this context.

30. The Group was then invited to consider how access and benefit-sharing requirements related to access to genetic resources and fair and equitable benefit-sharing apply to these different types of derivatives.

31. Experts provided information regarding how their national legislation addresses the issue of derivatives in relation to prior informed consent and mutually agreed terms. The examples provided illustrated that a variety of approaches had been adopted by Parties.

32. In a number of cases, it appears that the access requirements address the authorised activities or uses of genetic resources which may relate to derivatives. It was evident that the requirements related to single or multiple applications for prior informed consent varied depending on the access and benefit-sharing legislation or upon specific access and benefit-sharing arrangements between a user and a provider.

33. Examples at the national level include situations where prior informed consent is granted initially with no need to return, others require obtaining further prior informed consent if a derivative is developed. In some cases, benefits can be addressed at the initial stage of prior informed consent and all conditions of use can be included in the initial mutually agreed terms, or alternatively through subsequent negotiations of mutually agreed terms.

34. It was highlighted that a number of Parties address derivatives in mutually agreed terms, in accordance with the Bonn Guidelines.

35. Several experts noted that if there is an obligation to return for prior informed consent at a later stage when a use is identified, then this could involve great costs and risks to users which may have already invested considerably in the process of research and development, for instance.

36. A number of individual experts raised points for consideration in determining requirements for access to genetic resources and fair and equitable benefit-sharing that included the following:

- Choices adopted will depend on situation and level of confidence between user and provider
- A risk assessment and management exercise could be carried out on a case-by-case basis to determine which requirements for prior informed consent or monitoring would be most suitable to ensure that the costs do not outweigh the benefits
- Where there are excessively burdensome national requirements, costs may exceed the benefits derived
- Discrimination on the basis of nationality is an issue

37. The last part of question (a) in the terms of reference of the Expert Group, regarding the implications of the different ways of understanding these terms in relation to sectoral and sub-sectoral activities, and in relation to commercial and non-commercial research, was addressed under questions (b), (c) and (d) below.

38. In order to address questions (b) and (c), the experts were asked to divide themselves into self-designated “sectors and sub-sectors”. The resulting groups could have been different if more or different experts had been present:

1. Non-commercial research, including *ex situ* collections
2. Food and agriculture
3. Pharmaceuticals and biotech
4. *Ex situ* conservation (microbial collections).

39. Each sectoral subgroup examined:

- Genetic resources used by their sectors
- How these genetic resources are used by the sector based on the list of typical uses identified earlier during the meeting
- What are the mechanisms for benefit-sharing used in each sector
- Whether any standards for benefit-sharing had been developed for the sector
- Specific characteristics of the sectors

40. The reports by the sector subgroups were discussed, but not agreed by the Group as a whole. The following sections are reproduced in the form received from the sector subgroups.

**(b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;**

41. The subgroups provided information on the utilization of genetic resources in relation to sectoral activities in the context of Article 15, paragraph 7, of the Convention using as a basis the list of typical uses identified above.

42. The subgroups were also invited to provide standards and codes of conduct. The information provided is included in the appendix.

43. In response to question (b) in the terms of reference of the expert group, each sector identified the genetic resources used by their sector and how they are used, as follows:

**1. Non-commercial research**

(i) *Genetic resources used:*

- Live and dead organisms and parts thereof

(ii) *Different forms of utilization:*

- Conservation (category 5): maintenance of stocks for research through deposition in diverse collections, breeding centre
- Characterization and evaluation (category 6) using all methods listed
- Production of naturally occurring compounds (category 7)
- DNA synthesis as part of research process

## 2. Food and agriculture

- (i) *Sources of genetic resources:*
  - Crops, farm animals, forestry, fisheries, micro-organisms and insects related to food and agriculture, and their wild relatives
  
- (ii) *Different forms of utilization:*
  - Category 1 applies, see first bullet
  - Category 2 does apply to a limited extent, such as for starch production in potato and production of essential oils from medicinal plants (raw materials that feed into other industries)
  - Category 3 is a major application
  - Category 4 applies, including for the purpose of food production but also for the examples mentioned under biosynthesis (category 2)
  - Category 5 applies; major *ex situ* collections exist in the plant and micro-organism domains; increasingly important in the domains of farm animals and fish; weak representation of neglected and underutilized species and crop wild relatives
  - Category 6 applies, all bullets important
  - Category 7 is not very relevant

## 3. Pharmaceuticals and biotech

- (i) *Genetic resources used:*
  - Plants
  - Animals
  - Microbes
  
- (ii) *Different forms of utilization*
  - Categories 1-4, 6-7

## 4. *Ex situ* conservation (Microbial Resource Center)

- (i) *Genetic resources used:*
  - Micro-organisms
  
- (ii) *Different forms of utilization:*
  - Collection
  - Identification
  - Preservation
  - Distribution

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

*Mechanisms for benefit-sharing*

44. Each sector identified the mechanisms for benefit-sharing used in their sector, as follows:

**1. Non-commercial research**

- (i) Standard mutually agreed terms and benefit-sharing arrangement terms (both monetary and non-monetary):
- Bilateral agreements for non-commercial research, with specifications concerning exchange, loan, and third-party uses of material obtained under prior informed consent
  - Standards terms of use at the institution (for purposes of negotiation; e.g., storage in seedbanks, DNA extraction and storage, cultivation for display and education)
  - Benefits to be shared
  - Standard clauses in agreements governing relationships with provider countries and exchange of material among institutions
    - The role of research institutions and researchers from the provider country in the proposed project
    - Specification of the intended research, e.g.:
      - Project objectives
      - Methods to be applied
      - Results to be expected
    - Declaration of non-commercial intentions, e.g.:
      - No economic utilization of genetic resources or research results
      - No search for industrial property protection
      - No product development
    - Declaration of adherence to national and international laws and regulations
      - Proving rights of ownership
      - Adherence to CITES regulations
    - Specification of (non-monetary) benefits to be generated and shared, e.g.:
      - Forms of scientific collaboration (between provider and user side)
      - Conditions for co-authorship
      - Capacity building measures

- Training activities, both *in situ* and *ex situ*, and
- Technology and equipment to be shared
- Reporting requirements and approach to monitoring compliance
- Disposition of genetic resources and other research materials in suitable repositories for access by the research community
- Conditions of transfer of genetic resources to third parties, e.g.:
  - Assurances that type specimens and cultures will remain accessible to the research community
  - Assurances that transfers from either subject to the consent of the provider or only under the same conditions as in the present agreement
- Provisions concerning change of intent (from non-commercial to commercial research), e.g.:
  - Obligation to seek new prior informed consent and/or to re-negotiate material transfer agreement

## 2. Food and agriculture

### (i) *ABS patterns and mechanisms:*

#### *Crops*

- Facilitated access common denominator:
  - International Treaty and SMTA (self-standing international legally binding agreement; specific ABS regime for plant genetic resources for food and agriculture; facilitated access; detailed benefit-sharing provisions; dispute settlement provisions; funding strategy in its first phase of implementation); principles an example for other domains, no blue print for adoption in other domains
  - UPOV (breeder's exemption, farmers' privilege; access regulated; various opinions on benefit-sharing)
  - Traditional practices: farmer-to-farmer exchange
- Public-private partnerships and international partnerships are common (training and cooperation)
- FAO Code of Conduct for Collecting example of standard

#### *Animals*

- No international ABS mechanisms (few exceptions in Africa and former Soviet bloc)
- Almost all exchanges are private law transactions
- Low government interference (but strong on veterinary precautions)
- Customary law amongst pastoralists
- Most transfer North-South and South-South but examples of South-North transfer known

*Fisheries and forestry*

- Awaiting study reports on use and exchange patterns from FAO Commission on genetic resources for food and agriculture

*Micro-organisms for food and agriculture*

- Relatively open access
- Many different and highly sophisticated exchange systems and material transfer agreements
- Use mainly in the form received
- Major *ex situ* collections

*Insects*

- *Biological control agents*
  - Domain dominated by public sector, little private initiatives
  - Free and expeditious access for all stakeholders
- *Beneficial insects*
  - Pollinators, e.g., bees
  - Collections developed
  - Free exchange organized

**3. Pharmaceuticals and biotech**

(i) *Mechanisms:* Use of material transfer agreements and collaboration agreements

(ii) *Benefits:*

- Monetary:
  - Up-front payments for samples
  - Milestone payments
  - Royalty payments
- Non-monetary:
  - Technology transfer (equipment, education of health professionals on diseases, treatment and pharmaceuticals)
  - Scientific collaboration
  - Training (student exchange and scholarships)
  - Information exchange (e.g. geographical prospecting data (GIS); sharing of research results)

**4. *Ex situ* conservation**

(i) Non-monetary benefits:

- Sharing of microbes
- Conservation of microbes for sustainable use
- Consultation of treatment of microbes, such as cultivation and preservation



*Sector-specific characteristics*

45. The subgroups also identified specific characteristics of their sectors:

**1. Non-commercial research**

- (a) Willingness to disclose the scope and methods of research projects
- (b) Eagerness to engage provider country research institutions and researchers in projects
- (c) Willingness to provide access to research results to the provider country and international research community
- (d) Interest in providing training and technical assistance to provider countries with the goal of building their national research capacities
- (e) Commitment to transparency and open sharing of benefits, without proprietary ownership of any potential commercial benefits stemming from the research, and
- (f) Explicit agreement to a default benefit-sharing arrangement for unanticipated commercial benefits, or willingness to inform provider countries if any unanticipated potential commercial benefits are uncovered and to renegotiate the ABS agreement to include a new benefit-sharing arrangement for commercial intellectual property rights

**2. Food and agriculture**

- (a) Sector provides the basis for global food production
- (b) Sector contributes to income generation of farmers and pastoralists and to farmers' and pastoralists' livelihoods
- (c) Genetic resources are used for food production, as well as for the production of new genetic resources through recombination and breeding
- (d) All products are human-made (breeders and farmers)
- (e) Use is a condition for sustainable conservation (on-farm management; neglected and underutilized crops and breeds, crop wild relatives)
- (f) From their centres of origin genetic resources for food and agriculture have travelled across the world, and countries have become strongly interdependent for their food production
- (g) Major genetic diversity exists within species rather than between species; this is the basis for well adapted food production
- (h) Sector continuously re-uses its own genetic resources for the generation of new products; it needs access to a wide range of different genetic resources for the development of new products
- (i) Input materials are generally available free of restrictions for further research and breeding
- (j) For plants and micro-organisms large *ex situ* collections exist
- (k) FAO Commission coordinates GR activities at the international level, and also addresses ABS issues

**3. Pharmaceuticals and biotech**

- (a) High risk

- (b) Long research and development cycles
- (c) High investment
- (d) Low probability of success
- (e) Critical need for legal certainty over a long period of cooperation
- (f) Need for reliability of material delivery over course of research
- (g) Significant rate of failure among small/medium innovative companies
- (h) Many material transfer agreements with successful benefit-sharing without development of a product; however, inability to communicate successes due to confidentiality requirements and industry competition

#### 4. *Ex situ* conservation

- (a) Microbes are freely available for non-commercial research
- (b) Users have to negotiate mutually agreed terms if they want to use accessions commercially

#### *Differences between sectoral approaches*

46. The experts were asked to discuss the differences between sectoral ABS approaches on the basis of the characterizations the sector groups had provided. They were encouraged to ignore superficial similarities and look for meaningful evidence of differentiated sectoral approaches.

47. In the ensuing discussion it was pointed out that some additional sectors and sub sectors of importance to ABS had not been represented or characterized, including the cosmetics and nutraceuticals sectors, the crop protection sector and sectors which are covered by other international frameworks, such as the International Plant Protection Convention (IPPC) and the World Organisation for Animal Health (previously known as the Office international des épizooties (OIE)), which contribute to the public health and are characterized by a high level of international interdependence.

48. One difference identified was that some sectors had taken a more active approach to ABS and had developed very detailed mechanisms and approaches. This was done to build trust among providers and users and could serve as a foundation for further development of the ABS regime.

49. It was highlighted that the agricultural sector is unique due to a number of factors, including the following:

- (a) Under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture, prior informed consent is not required to access breeding material;
- (b) Plant breeding needs access to a wide pool of genetic resources and then creates a product that is also a genetic resource;
- (c) Countries have become strongly interdependent for their food production;
- (d) The sector continuously reuses its own genetic resources for the generation of new products and needs access to a wide range of different genetic resources for the development of new products.

50. These factors explain why wide facilitated access is so useful and prevalent in the agricultural sector. The International Treaty and its Multilateral System were developed to respond to the particular needs of this sector. The basic approach is one of open access, with mandatory benefit sharing coming

into effect when access for further research and breeding is restricted by a recipient. Some companies in the agricultural biotech industry do however abstain from access under these conditions.

51. Another significant difference between sectors was the way in which they sourced genetic resources, with some sourcing mainly from *ex situ* collections and others mainly through intermediaries. The pharmaceutical industry, for instance, acquires by far the majority of genetic resources from intermediaries such as culture collections. Only a few pharmaceutical companies directly access genetic resources from *in situ* conditions.

52. A cross-cutting issue for many sectors was that they needed access to resources for basic research before developing value chains. Most requests for *in situ* access therefore are for research purposes. The experts recognised that this underlines the need for the Working Group to give particular consideration to non-commercial research and associated benefit-sharing.

53. In addition, it was observed that ABS arrangements range from highly standardised forms of transactions to customized arrangements to meet the specific circumstances and interests of both provider and user. Use is also made of phased agreements, where, for instance, a research agreement is concluded for a first phase, and later on a second agreement might be concluded that will cover product development and commercialisation. The experts therefore considered that a “one size fits all” approach would not be suitable under the international regime.

54. The following differences between sectors were identified by the expert group:

- (a) Each sector has specific references to prior informed consent, access and benefit-sharing;
- (b) Groups of users respond to different interests;
- (c) Differences in techniques or activities depending on the sector.

55. It was also noted that within some commercial sectors there are very significant differences regarding the size, technological capacity, research and development strategies and target markets of companies, which underscored the need for the international regime to retain flexibility.

**(d) What is the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?**

56. Characteristics of the access and benefit-sharing practices of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) were discussed in the context of coherence with a potential international regime. It was highlighted that many lessons could be drawn from the ITPGRFA, but that it was a special case addressing a specific sub-sector.

57. During the discussions experts highlighted the following points:

- (a) Efforts to bring about coherence should not negate the need for flexibility in the international regime, to accommodate different practices of different user groups, which can be done by building approaches based on the same principles;
- (b) Coherence is easier in sectors with uniform management systems and transparency;
- (c) Some sectors handle very large numbers of samples or require that access be granted very quickly, which makes a standard approach in the international regime more difficult;
- (d) Key concepts for the international regime are “room for multilateral approaches, simple, effective, applicable, legal certainty”;

(e) The international regime needs to address the concerns of people at local level by building awareness and ensuring transparency;

(f) The international regime should aim to bring together users and providers;

(g) The international regime could provide for minimal access and benefit-sharing requirements that apply across sectors if no specific system is in place. These default access and benefit-sharing provisions or minimum access and benefit-sharing requirements would cover all access and benefit-sharing activities in the absence of more specific systems for particular sectors;

(h) An enabling clause could allow for sectors to develop their own system with the agreement of contracting parties in order to respond to their particular needs;

(i) How much flexibility can be accommodated within the international regime will determine how strong its enforcement can be;

(j) Although different sectors may need to develop approaches to meet their specific needs they should aim towards the same objective.

58. Some experts suggested the development of model clauses for potential inclusion in material transfer agreements. It was stressed that the use of such clauses should be optional in character to leave the flexibility for both provider and user in establishing mutually agreed terms.

59. Presentations from the sectoral subgroups highlighted many examples of national and international voluntary codes of conduct and best practices that bring coherence. These have been developed in different sectors using genetic resources, including by the research community, botanical gardens, microbial collections, the biotech industry or pharmaceutical companies.

60. Some experts considered that the international regime could be a framework agreement that sets a minimum international understanding and agreement of what is needed across the board that provides flexibility for sectors to develop their own access and benefit-sharing approaches, especially multilateral ones. The international regime may provide a default position of minimum requirements and the Working Group on Access and Benefit-sharing should consider how this can be achieved.

*Appendix***EXAMPLES OF ACCESS AND BENEFIT-SHARING STANDARDS AND CODES OF CONDUCT****Non-commercial sector**

- Codes of conduct within disciplines, e.g., Principles on Access to Genetic Resources and Benefit –Sharing (<http://www.bgci.org/resources/abs/>); International Society of Ethnobiology (<http://ise.arts.ubc.ca/>); EMBRAPA standards for approaching indigenous and local communities (<http://www.embrapa.br/english>); Brazilian Guidelines to Indigenous Peoples, Local Communities and Family Farmers for Cultural, Natural and Spiritual Patrimony Protection ([http://www.inbrapi.org.br/abre\\_noticia.php?noticia=339](http://www.inbrapi.org.br/abre_noticia.php?noticia=339)).
- Professional standards for integrity and openness of scientific research e.g., NIH Office of Research Integrity (<http://ori.dhhs.gov/policies/>)
- Standard procedures for handling material, especially type specimens, and for scientific conduct e.g., the *International Code of Zoological Nomenclature* (<http://www.iczn.org/iczn/index.jsp>); the *International Code of Botanic Nomenclature* (<http://ibot.sav.sk/icbn/main.htm>); FAO standards for plant collecting (<http://www.fao.org/biodiversity/conventionsandcodes/plantgermplasm/en/>).
- Data standards for managing collections and tracking transactions and compliance e.g. IPEN exchange system, (<http://www.bgci.org/resources/ipen/>), Taxonomic Database Working Group (<http://www.tdwg.org/standards/>); FAO plant accession data standard (<http://www.fao.org/biodiversity/conventionsandcodes/en/>).
- Guidelines for good ABS practices e.g., the Swiss Academy Good Practices for Academic Research on Genetic Resources (<http://abs.scnat.ch/>), the German Research Foundation (DFG) ABS Guidelines ([www.dfg.de/forschungsfoerderung/formulare/download/1\\_021e.rtf](http://www.dfg.de/forschungsfoerderung/formulare/download/1_021e.rtf))
- Standard institutional ABS policies and agreements have been developed by many institutions (for instance, Royal Botanic Gardens, Kew ([www.kew.org/conservation](http://www.kew.org/conservation)), South African National Biodiversity Institute (SANBI) (<http://www.sanbi.org>), National Herbarium of Ethiopia (<http://www.ihc-et.org/>); NIH (<http://ori.dhhs.gov/policies/>), Rio Botanic Gardens (<http://www.jbrj.gov.br/>); MOSAICC (<http://bccm.belspo.be/bccm/mosaicc>); World Federation of Culture Collections (<http://wcdm.nig.ac.jp/wfcc/>) and many others

**Pharmaceutical and biotech**

- Association of University Technology Managers (AUTM) Uniform Biological Material Transfer Agreement (MTA)
- Michigan State University Material Transfer Agreement (MTA) (and other universities)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) ABS Guidelines
- EuropaBio Guidelines
- Biotechnology Industry Organization (BIO) Guidelines for Members Engaging in Bioprospecting
- National Institutes of Health (NIH) Letter of Collection
- US National Park Service General Conditions for Scientific Research and Collecting Permit
- Japan Bioindustry Association (JBA) and Ministry of Economy, Trade and Industry (METI) Guidelines on use of genetic resources
- Company-specific policies