





CONVENTION ON BIOLOGICAL DIVERSITY

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AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING Fourth meeting Granada, 30 January – 3 February 2006

MATRIX ON THE ANALYSIS OF GAPS

I. INTRODUCTION

- 1. At its third meeting, in February 2005, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing undertook an initial review of the process, nature, scope, potential objectives and elements of an international regime on access and benefit-sharing, in accordance with the terms of reference set out in annex to decision VII/19 D of the Conference of the Parties.
- 2. In recommendation 3/1, paragraph 5, the Working Group « in order to facilitate further analysis of gaps in existing national, regional and international legal and other instruments relating to access and benefit-sharing," invited "Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders to provide information to the Executive Secretary on the basis of the matrix contained in annex II to the present recommendation and the potential additional elements and options three months before the fourth meeting of the Working Group".
- 3. In paragraph 6, the Working Group, also requested "the Executive Secretary to consolidate the information provided by Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders on the basis of annex II... and make it available to the Working Group on Access and Benefit-sharing at its fourth meeting;"
- 4. A notification was sent out to Parties, Governments, indigenous and local communities, relevant organizations and stakeholders inviting them to provide information to the Executive Secretary on the basis of the matrix contained in annex II to recommendation 3/1. Submissions were received from Canada, Costa Rica, the European Community, India, Japan, Norway, Switzerland, the United States of America and the International Plant Genetic Resources Institute (IPGRI).
- 5. In order to facilitate consideration of the information provided by Parties and relevant organizations on the basis of the matrix, eight separate tables were created covering the clusters of issues under the sub-headings included in the matrix. Thus, each table covers one of the following issues: (i) access; (ii) ensuring benefit-sharing; (iii) promoting benefit-sharing; (iv) recognition and protection of rights of indigenous and local communities, (v) derivatives; (vi) promotion and enforcement mechanisms of the international regime and compliance with PIC and MAT; (vii) functioning of the international regime; and (viii) poverty eradication. These tables are available in the annex to the present document.

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- 6. The tables contain, in the first two columns, references to relevant processes and their provisions without the detailed descriptions provided by some Parties and organizations in their submissions. The next three columns contain a consolidation of the comments provided by Parties and organizations. The full text of the submissions is included in the compilation of submissions by Parties and relevant organizations (UNEP/CBD/WG-ABS/INF/4).
- 7. In addition, in order to facilitate the further consideration of gaps, the Secretariat has prepared under section II a synthesis of the main gaps identified in the submissions from Parties, Governments and relevant organizations, and how they should be addressed.

II. SYNTHESIS OF GAPS

8. Based on the submissions provided by Parties, the following table provides a synthesis of the main gaps identified, how they should be addressed and at what level (national, regional, international). It does not purport to be comprehensive.

Main Gaps	How they should be addressed, at what level?
Lack of awareness of ABS issues among	Awareness-raising at all levels of CBD website,
stakeholders and administrators in public and	regional and national websites.
private sectors at all levels is a major impediment	At national level: initiatives to promote, encourage
to implementation.	and educate through publicity, stakeholders
	meetings, requirements of practicing institutions.
National Focal Points and Competent National	National level: Need to be established at national
Authorities for ABS not established in a majority of	level and need for coordination among competent
countries and often diversity of authorities dealing	national authorities when there is more than one.
with ABS	International level: Need to be notified to SCBD
	and included in CHM
National ABS regimes not established in majority	National level: need to elaborate and implement
of countries	national ABS regimes.
	International level: Need to provide for
	capacity-building and financial resources to assist
	in the establishment of national ABS measures in
	developing countries.
Existing ABS measures often cumbersome,	National level: need for the establishment of clear
procedures non-transparent – lack of predictability	and transparent procedures
and certainty for users of genetic resources	International level: Need for capacity-building,
	technology transfer and financial resources to assist
	countries in the development of national ABS
	regimes.
Difficulty in identifying authorized representatives	Need for Governments to indicate relevant
of indigenous and local communities, relevant laws	representatives and customary laws to facilitate
and customs	access procedures for users.
Lack of uniformity among ABS measures	Regional harmonization could assist
developed in different countries	
Difficulty in ensuring benefit-sharing once genetic	Multiples levels
resources have left provider country	International mechanism to ensure compliance in
	user countries
	e.g.: certificate of origin/source/legal provenance of
	GR and associated TK
	e.g.: standard or model benefit-sharing provisions
	Measures to be taken at national level in user
	countries to ensure compliance with PIC and MAT
Lack of measures in user countries e.g.: to carry out	Multiple levels: Guidelines and codes of conduct
joint research	for users of genetic resources

Lack of incentives for users to comply with ABS measures	Disclosure of origin/source/legal provenance in patent applications Certificate of origin/source/legal provenance National level: Measures to be adopted by user countries to ensure compliance with PIC and MAT.
Identification of prior art	International level: WIPO to conclude its work on prior art
No international instrument to ensure protection of biodiversity related traditional knowledge	Measures needed at all levels
ABS measures rarely differentiate between access for research purposes or for commercialization	Multiples levels, should be addressed by the international regime
Monitoring and compliance measures are weak in a majority of ABS measures	Some are of the opinion that compliance should be addressed at the international level, through regional or international authorities, and at national level. Others are of the opinion that compliance with PIC should be addressed by provider countries and that compliance with MAT, including dispute settlement should be addressed in contractual arrangements. Possible tools for further consideration: international certificate of origin and disclosure of origin/source/legal provenance in IPR applications. CHM could provide information notified to SCBD.
No common understanding of derivatives	Some of the opinion that the issue of derivatives should be addressed at international level while others prefer to address this issue at national level.
Capacity-building	Multiple levels: Action Plan on Capacity-building to be implemented. International contributions needed for capacity-building at regional, national levels.
Areas beyond national jurisdiction, Antarctic and deep seabed	International level: discussion within CBD, Antarctic Treaty System and UNCLOS.
The Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture only covers crops and forages listed in annex I	Multiple levels: - Including more materials in annex I - regional and subregional agreements for non- annex I materials - bilateral agreements under national ABS procedures.

Annex

ANALYSIS OF GAPS

1. Access

Convention.

Elements <u>1</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 2/	Relevant provisions of existing international instruments within the framework of the CBD 3/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Access	(Canada)	(Canada)	(Canada)	(Canada)	(Canada)
Measures to promote facilitated access to genetic resources for environmentally sound uses according to Article 15.2 of the Convention on Biological Diversity; (iv)	International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), art. 10.1, 12.2. United Nations Convention on the Law of the Sea (UNCLOS) (Costa Rica) ITPGRFA and its Multilateral System (MLS) (EC) (Norway)	CBD art. 15.1, 15.2 Bonn Guidelines, section I, section II.B, section IV (Costa Rica) Bonn Guidelines (EC) (Norway) Measures by the provider: CBD (art. 15.2, 15.5, 15.6) BG (Section IV A,	Existing legislation in Canada regulates access to, and ownership of, resources in various sectors (forests, marine, environment, etc). The Northwest Territories Scientist Act includes provisions for access to, and use of, resources and TK in the North. According to this legislation, a research permit can be denied if "the research proposed to be carried out might be injurious to or unduly	Bioprospecting and commercialization of genetic resources found in the Antarctic and in the deep seabed beyond national jurisdiction. (Costa Rica) Much legislation does not promote facilitated access. Does not facilitate research. Opposition of groups to access. No knowledge about the subject.	Internationally through discussions within the CBD, the Antarctic Treaty System, UNCLOS, and other relevant fora. (Costa Rica) At national level. In user countries. Regional efforts are very poor. (EC) Access and MAT concerning genetic
	FAO International Code of Conduct for Plant Germplasm	B and C) Measures by the	interfere with the natural and social environment of	(EC) Insufficient use of existing	resources are under specific national

The Roman numerals in parenthesis following each element refer to the numbering of that element under heading (d) of the annex to decision VII/19 D. Please take into account the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to

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^{4/} It is included in Annex 1 of the International Undertaking and contains an agreed interpretation to clarify that "free access" does not necessarily mean free of charge but can embrace a range of transfers. The IT specifically deals with the processes necessary for facilitated access.

Elements 1/	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 2/	Relevant provisions of existing international instruments within the framework of the CBD 3/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	Collecting and Transfer Draft agreement between the ITPGRFA Governing Body and the International Agricultural Research Centers (IARCs). Microorganism Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) (EC) ITPGRFA, Article 12 and Annex 1 FAO Conference Resolution 4/89 (art. 5a)4/ IARCs of the CGIAR. International Databases on plant (VIEWS) and animal (Dad-IS) genetic resources (INDIA) ITPGRFA, articles 10 to 15. UPOV 1991, facilitates access to modified genetic material by	user: Principles and Common Policy Guidelines for Botanical Institutions, sections on acquisition. (EC) Information on national access legislation in the CHM Measures by user: International Plant Exchange Network (IPEN) Code of Conduct on the acquisition, maintenance and supply of plant material for botanic gardens and similar collections (Art.1) (INDIA) CBD articles 15.1 and 15.2 (see details in submission)	the territories or any part of the environment." (Costa Rica) Regional level: Central American Agreement on access and benefit-sharing (signed by countries of Central America) National level: Biodiversity Law No. 7788 Executive Decree No.31-514 MINAE of 15 December 2003, entitled: "General Standards for access to genetic and biochemical resources and elements of biodiversity." Draft: General Standards for access to ex situ genetic and biochemical resources and elements of biodiversity (EC) (Norway) Designation of NFPs and CNAs.	instruments (ABS NFPs) Lack of transparency of national ABS legislation and procedures Where provisions exist, facilitated access (i.e. regulated/controlled access, promoting benefit-sharing and without hindering actual access) has rarely been effected by practical and efficient measures. Intentionally or not national legislation has often impeded access due to delays, unnecessary bureaucracy, the lack of explicit PIC mechanisms and uninformed national authorities. Access regulations rarely provide for measures to guarantee that bioprospecting will not be detrimental to biodiversity conservation. (INDIA) Absence of uniform standards and procedures for access regimes at national/regional levels	legislations or under national ownership and contract laws. MAT are under the international civil laws and rules and shall also be considered as such. The development of appropriate guidelines at all levels for users and other stakeholders, e.g.: Bonn Guidelines, Principles and Common Policy Guidelines for Botanical Institutions. Facilitated access does not mean uncontrolled access: this could usefully be clarified. Capacity-building and financial resources for development cooperation is needed to improve processes and decisions procedures on access to genetic resources at national level. National regulation could be reviewed to take into account any detrimental effects of bioprospecting on biodiversity.

instruments, and relevant processes outside the framework of the CBD 2/ existing international instruments within the CBD 3/ national instruments, and relevant processes	international, and how should the gaps be addressed?
recognising a limited research exemption to the plant breeders' rights II.O 169 (articles 14 and 15) provide for the tribal and indigenous people the rights to their traditional lands and biological resources in their territories WTO/TRIPS – no specific measures (see comments in India submission) WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) Principle 2 of Rio Declaration (JAPAN) ITPGRFA, article 12 UNCLOS, § 62-1 ONORWAN) ITPGRFA, article 12 UNCLOS, § 62-1 ONORWAN) ITPGRFA, article 12 UNCLOS, § 62-1 ONORWAN) IIO 169 (articles 14 (see details in submission) (see details in submission) International (see details in submission) International Regime being negotiated within the CIBD (Japan) International Regime being negotiated within the CIBD (Strategy for Genetic Resources in the Nordic Regources in the Nordic Resources in the Nordic Regources in the Portoric Resources in the Nordic Regources in the Resources in the Nordic Regources in the Nordic Regources in the Nordic Resources in the Nordic Resources in the	The gaps should be addressed at national, regional and international level, considering the transboundary nature of certain genetic resources and associated TK. The gaps could be addressed by way of regional understanding among and harmonizing the access provisions to make them legally binding and implementable at international level. There are thus practically no mechanisms of any practical value. Till proper mechanisms can be agreed upon, regional cooperation is essential as well as comprehensive documentation of genetic resources and TK in the intervening period. (Norway)

framework of the CBD <u>2</u> / within the framework of the CBD <u>3</u> /		addressed?
11, 12 and 15. Agreement 2001 draft	t countries.	institutions funding
(Switzerland) ITPGRFA, art. 10.2, 12 African Model Legislation 2000, draft	Need for transparent national access legislation	research) at the international/regional/nati onal levels.
(USA) (USA) (IPGRFA UPOV 1991 WIPO Budapest Treaty Global Crop Diversity Trust IARCs (IPGRI) ITPGRFA and its Multilateral System (MLS) For further details regarding ex situ collections see IPGRI submission in INF. doc INF. doc New Ministry Guidelin on ABS put in place on April 2005 (MGL 200. National Strategy for t Conservation and Sustainable Use of Biological Diversity Culture collections – e National Institute of	Need to strengthen administrative capacities for maintenance and enforcement. Access legislation to be linked to conservation and sustainable use of biodiversity. Lack of predictability and certainty for users of genetic resources. Difficult for users to know which is competent authority for authorising access. Lack of predictable and certain legal situation for research and industry. (Switzerland) Lack of legal certainty, including the rights of participation of indigenous and local communities. No ABS national focal	countries within one region may cooperate in conservation of genetic resources. In order to facilitate exchange of genetic material between such countries there may be developed regional approach for access legislation. Capacity-building, technology transfer and financial resources are needed to assist countries in developing national legislation, and decision procedures on access to genetic resources at the national level. There is a need for a mechanism at the international level to address countries request for assistance within these cross-cutting issues. (Switzerland) National International

Elements 1/	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 2/	Relevant provisions of existing international instruments within the framework of the CBD 3/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
			Technology and Evaluation (NITE)	Crops and forages not included in Annex 1 held by	Plan of action for capacity-building
			Japan Collection of Microorganisms (JCM) National Institute of Agrobiological Sciences (NIAS)	state parties are not included in the MLS of the ITPGRFA. (For further details on gaps related to <i>ex situ</i> collections	(IPGRI) Several possibilities exist to address the gap identified by IPGRI: eventually including more
			(Switzerland)	- see IPGRI submission)	materials in the Treaty's
			Use of existing national legislation		Annex 1; regional and subregional agreements for access and benefit-
			Participation in IPEN		sharing of non-annex 1 materials; case by case
			Swiss tool for academic research		agreements brokered under bilaterally-oriented national access laws for
			ABS Management Tool		the same materials.
			(USA)		(For further details related
			US Government agencies and trusts have instituted procedures that educate users about ABS, track use of government held genetic resources, and support the principles of PIC and MAT when US Government funds are used in biodiversity research. Laws and processes include: U.S. Plant Variety Protection Act (PVPA); cooperation research and development		to ex situ collections see IPGRI submission)

Elements <u>1</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 2/	Relevant provisions of existing international instruments within the framework of the CBD 3/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
			agreement (CRADAS), permit system under the U.S. National Parks Omnibus Management Act of 1998; U.S. National Plant Germplasm System- NPGS agreement for plant exploration; NHI Research grant award terms; NCI Contracts; Smithsonian (US National Museum) collection and loan policies and procedures; BIO code of conduct; USG supported extramural research grants and programmes.		

2. Ensuring benefit-sharing

Elements <u>5</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 6/	Relevant provisions of existing international instruments within the framework of the CBD 7/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Ensuring benefit-	(Canada)	(Canada)	(Costa Rica)	(Canada)	(Canada)
sharing Measures to ensure the fair and equitable sharing of benefits from the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in accordance with Articles 15.7, 16, 19.1, 19.2. of the Convention; (ii) Measures to ensure the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and	ITPGRFA, art. 13.1 13.2, 13.3, 13(d), 10(e) UNCLOS: marine scientific research to be carried out exclusively for peaceful purposes and for the benefit of mankind as a whole. (Costa Rica) ITPGRFA (EC) (Norway) ITPGRFA, articles 12.4 and 13 (EC- Norway) art. 15.1 and 18 (Norway) - level, form and manner of benefit- sharing payments for	CBD, art. 15.7, 16.1, 16.3, 10(e), 19.2 Bonn Guidelines: section IV, section II D, Appendix II (Costa Rica) Bonn Guidelines (EC) (Norway) CBD art. 15.7 Bonn Guidelines, section IV.D.3 and Appendix II (EC) Principles and Common Policy Guidelines for Botanical Institutions:	Biodiversity Law No. 7788 Executive Decree No.31-514 MINAE of 15 December 2003, entitled: "General Standards for access to genetic and biochemical resources and elements of biodiversity." Draft: General Standards for access to ex situ genetic and biochemical resources and elements of biodiversity (EC) Nordic Ministerial	Bioprospecting and commercialisation of genetic resources found in the Antarctic and in the deep seabed beyond national jurisdiction. (Costa Rica) Few legislations on ABS in developing countries (EC) This fundamental element needs to be addressed in order for the provisions of the CBD to be achieved and for wider objectives such as the Millenium Development Goals to be realised. Difficulties in access have resulted in minimal benefitsharing.	Internationally through discussions within the CBD, the Antarctic Treaty System, UNCLOS, and other relevant fora. (Costa Rica) At national level (EC) BG set fair and practical conditions in section IV.D.3 and Appendix II. At national level the same mechanisms to grant access could be used to ensure and monitor the benefit-sharing and the distribution of those benefits.

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Elements <u>5</u> /	Relevant provisions of existing international instruments, and relevant processes outside the	Relevant provisions of existing international instruments within the	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	framework of the CBD 6/	framework of the CBD 7/			
products, in the context of mutually agreed terms; (vi) Measures for benefitsharing including, inter alia, monetary and non-monetary benefits, and effective technology transfer and cooperation so as to support the generation of social, economic and environmental benefits; (iii)	using GR taken from MLS currently debated in negotiations on the standard MTA (Material Transfer Agreement) UPOV 1991, art. 15.1, 15.2. UPOV Convention provides sui generis form of IP protection specifically adapted for the process of plant breeding and developed with the aim of encouraging breeders to develop new varieties of plants. Work of WIPO on the issue of disclosure of origin of GR. MOSAICC IARCs of the CGIAR (EC) International Database on plant (VIEWS) and animal (Dad-IS) genetic	section on benefit- sharing includes examples of non- monetary benefits IPEN Code of Conduct for Botanic Gardens, art. 2.3 (India) CBD, Art. 15.4, 15.7 Bonn Guidelines, section IV.D. on MAT, including benefit-sharing (Japan) Bonn Guidelines (Switzerland) CBD, art. 15.6, 15.6, 16.4, 19.1, 19.2 Decision VII/19E Bonn Guidelines (USA) Bonn Guidelines	Declaration on Access and Rights to GR, par. 11: recommends the Nordic Gene Bank to consider the use of the provisional MTA, used by IARCs, until the adoption of the standard MTA for the MLS. Council Regulation (EC) 2100/94 of 27 July 1994 establishing in line with UPOV a Community system of plant variety right protection (India) Andean Community Common Regime 1996, art. 2.9, 35. Draft Central American Agreement 2001, art. 19 African Model Legislation 2000 Draft ASEAN Framework Agreement 1996 India Biodiversity Act 2002, art. 21, section 6,	Often a multiplicity of national authorities dealing with the various aspects of ABS leads to confusion, lack of effectiveness, etc – cohesive arrangements and coordination among the competent authorities dealing with all elements should be encouraged to address these deficiencies Contrary to par. 48 of BG, current arrangements fail to link benefits with biodiversity conservation. (India) Lack of uniform standards or statutes for benefitsharing. Transboundary nature of certain genetic resources and associated TK pose difficulties in framing uniform measures for benefit-sharing. Lack of uniformity in provisions for PIC for access in national/regional legislations. In some countries where the laws have been enacted as	National, regional and international levels. Benefit-sharing can be ensured only if the laws are abided in the countries where the resources are being exploited. There should be specific provisions for protection of GR and TK at the international level. In view of GR and TK being exploited in countries not original holders of these, there have to be precise provisions to ensure that the country of origin gets its due recognition. (Norway) Mechanisms/modalities for benefit-sharing should be included in an international regime, for example in the form of model or standard benefit-sharing provisions. The specific details have to be left to individual contracts.

Elements <u>5</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 6/	Relevant provisions of existing international instruments within the framework of the CBD <u>7</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	resources (INDIA) ITPGRFA, art. 13 (13.1, 13.2, 13.3, 13.6), 15.3, 17.1, 18.4: benefit-sharing of GR accessed through MLS under mutually agreed terms WIPO and TRIPS UPOV: No provisions specifically for benefit-sharing however exception to breeder's right indirectly facilitates benefit-sharing. (Japan) ITPGRFA, art. 10-13 UNCLOS, §62-2.3, § 144, § 145 ILO 169, art. 13-19, esp. 14 and 15 (Switzerland) ITPGRFA, art. 12.4,		section 18(1) BDR 2004, Rule 20 Regional and national instruments like BDA 2002 have provisions to promote benefit-sharing based on MAT (Japan) MGL 2005, especially pp. 17-25 NITE concluded MOUs with Asian countries to promote fair benefit-sharing. (Switzerland) Sectorial voluntary instruments Participation in IPEN Swiss tool for academic researchers ABS Management Tool (USA) Plant Variety Protection Act (PVPA); Patent Act; Plant Patent Act; Lanham Act	listed above, benefit-sharing provisions exist, but when the genetic resources and TK are exploited in another country with no such laws, fair and equitable sharing cannot be ensured. Lack of mutual consensus among developed and developing countries regarding ABS provisions. In absence of such provisions, MAT does not get due recognition. (Japan) No gaps identified. Japan to continue to accumulate experience with MGL 2005. (Norway) This important element needs to be further developed in many fields. Seems that current national legislation/policies do not always link benefits from bioprospecting activities with measures to conserve	BG provide guidance in section IV.D.3 and appendix II. There is also a need to address trigger mechanisms for benefitsharing at the international level. (Switzerland) Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge. Standards and certificate. (IPGRI) Expansion of the Annex 1 list of the ITPGRFA; regional arrangements for multilateral exchanges and benefit-sharing for non-Annex 1 materials; bilateral exchanges on national bases for non-Annex 1 materials. ITPGRFA, art. 13.2d.ii: level, form and manner of
	13.2, 19.3(f), 21.		(trademark); Cooperation research	biodiversity. Mechanisms to be	payment currently being considered by the Contact Group for the

Elements <u>5</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 6/	Relevant provisions of existing international instruments within the framework of the CBD 7/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	ITPGRFA TRIPS and UPOV Global Crop Diversity Trust (IPGRI) ITPGRFA MLS, art. 13.2d.ii, 13.2a, b – also to be addressed by SMTA (standard material transfer agreement to be approved by first meeting of Governing Body in June 2006) See IPGRI submission in INF doc for further details		and development agreements (CRADAS); NIH Research Grant and contract award terms; Health and Human Service (HHS); Bayh-Dole Act (tech transfer); Smithsonian research, collection and loan policies and procedures; USG supported extramural research grants and programs; BIO code of conduct; US court system/contract law; US National Plant Germplasm System – NPGS agreement for plant exploration; USDA Plant Exploration Code of Conduct.	developed in order to ensure benefits are returning to the conservation of biodiversity. Lack of incentives for complying with benefit sharing provisions Lack of efficient international enforcement mechanisms in the countries where a product of GR is put on the market (Switzerland) Transparency measure: mechanism to ensure effective identification and follow-up of genetic resources, in the ABS process. No legal obligations for Parties having essentially users of genetic resources under its jurisdiction to take measures to ensure compliance with PIC and MAT. (IPGRI) List of crops in the common pool are limited to those in Annex 1 of ITPGRFA.	Development of the Standard Material Transfer Agreement.

Elements <u>5</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 6/	Relevant provisions of existing international instruments within the framework of the CBD 7/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	_	-		Level, form or manner of payment shall be made pursuant to 13.2.d.ii of ITPGRFA. (see IPGRI submission for further details)	

3. Promoting benefit-sharing

Elements <u>8</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 9/	Relevant provisions of existing international instruments within the framework of the CBD <u>10</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Promoting benefit-	(Canada)	(Canada)	(Costa Rica)	(Costa Rica)	(Costa Rica)
sharing Measures to promote and encourage collaborative scientific research, as well as research for commercial purposes and commercialization, consistent with Articles 8(j), 10, 15, paragraph 6, paragraph 7 and Articles 16, 18 and 19 of the Convention; (i) Measures to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources; (v)	Antarctic Treaty, art. III (international cooperation in scientific investigation) Madrid Protocol (collaborative research in the Antarctic) ITPGRFA, art. 13.2 (a), (b), (c), 13.3. UNCLOS (information sharing regarding knowledge resulting from marine scientific research) (provisions on the	CBD, art. 15.6, 15.7, 18, 19.1, 19.2. Bonn Guidelines, par. 11(g), 45-50, Appendix II. (Costa Rica) Bonn Guidelines (EC) Common Policy Guidelines for Botanical Institutions includes examples of written material transfer agreemens for non-commercial	Biodiversity Law No. 7788 Executive Decree No.31-514 MINAE of 15 December 2003, entitled: "General Standards for access to genetic and biochemical resources and elements of biodiversity." (EC) Ad Hoc bilateral/multilateral arrangements as promoted by, for example the UK's Darwin Initiative introduced in 1992 to encourage collaborative scientific research and the practical implementation of its results for biodiversity conservation. National research for development organisations (e.g.: CIRAD, IRD) National or regional funding for research in cooperation	Measures in developed countries to carry out joint research (EC) – (Norway) PIC and MAT processes rarely differentiate between acquisition for scientific purposes (e.g. taxonomy) and commercialisation. This provides a disincentive for partnerships between provider and user countries of genetic resources, slowing down the rate of scientific progress as well as reducing the potential sharing of non-monetary benefits in the context of non-commercial scientific research cooperation (e.g. exchange of researchers, joint research projects).	At national level (EC) National legislation needs to be framed in the light of these gaps and difficulties. (India) At national, regional and international levels, through MOUs for regional or international cooperation for scientific research and development involving the use of genetic resources and/or associated TK. There must be global mechanisms for

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^{10/} Please refer to the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the Convention.

Elements <u>8</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 9/	Relevant provisions of existing international instruments within the framework of the CBD 10/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	development and transfer of marine technology) Rules on marine scientific research in Part XIII, art. 238-239, 243 (international cooperation), 242, 244 (sharing and dissemination of scientific research), 248. (Costa Rica) ITPGRFA (EC) (Norway) ITPGRFA, art. 12.4 and 13 FAO Global Plan of Action for the conservation and sustainable use of plant genetic resources for food and agriculture FAO Global Strategy on farm animal genetic resources	purposes IPEN regulations (India) CBD, art. 15.7, 19.1 Bonn Guidelines, sections IV.D, IV A. (Japan) Bonn Guidelines (Norway) CBD, Art. 15.6, 15.7 Bonn Guidelines, section V (Switzerland) Same as above table on "Ensuring Benefit-sharing" (USA) Bonn Guidelines	Nordic Council of Ministers Declaration and Strategy and implementation measures taken by the Nordic Gene Bank which state that all material held by the NGB is under open access and is part of the MS. No demands for benefit- sharing will be made when handing out material. (India) BDA 2002 (section 21(1)) and BDR 2004 include relevant provisions for promoting scientific research, biosurvey, bioutilization, commercial research etc with prior approval of NBA (Japan) MGL 2005, especially pp. 17-25 NITE concluded MOUs with Asian countries to promote fair benefit-sharing. (Norway) Nordic Council of Ministers Declaration as well as Strategy and implementation measures taken by the Nordic Gene Bank following the Ministerial Declaration on Rights and Access to Genetic Resources	Absence of an internationally acceptable and legally binding ABS regime curtails the scope for collaborative scientific research among member countries. Absence of national legislations to deal with ABS and related biodiversity issues in many countries is a major gap. Collaborative research or commercialisation must be such that both parties must benefit from it. Mere guidelines will not ensure the promotion of interest of developing countries especially. (Japan) No gaps identified. Japan will continue to accumulate experience with MGL 2005. (Norway) Lack of common practices and principles to assess the	implementation in absence of which the parties to collaborative research may not be bound by any protocols. Until this happens, developing countries need better understanding of IPR issues and provisions such as MTAs. (Switzerland) Same as above table on "Ensuring Benefit-sharing"

Elements <u>8</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 9/	Relevant provisions of existing international instruments within the framework of the CBD <u>10</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	(India) ITPGRFA, art. 13(d), 13.2, 15.1(b), 111; 15.2 and 15.3 (Japan) ITPGRFA, art. 10- 13 (Switzerland) ITPGRFA, art. 7 and 13. (USA) TRIPS and UPOV WIPO Patent Cooperation Treaty (IPGRI) Same as above under "Ensuring benefit-sharing"		(Switzerland) Same as above table on "Ensuring Benefit-sharing" (USA) The US Government supports collaborative research ranging from basic science through joint ventures for transferring technology from the laboratory to the market: CRADAS; NIH Research grant and contract award terms; Health and Human Service (HHS); USDA NPGS agreement for exploration; Smithsonian research, collection and loan policies and procedures; USG supported extramural research grants and programs; BIO Code of conduct; Plant Varieties Protection Act (PVPA); Patent Act; Plant Patent Act; Lanham Act (trademark); Bayh-Dole Act (tech transfer); US court system/contract law (IPGRI) Same as above under "Ensuring Benefit-sharing"	value added to the product by the contribution from the genetic material used in the process. Also the trigger for benefitsharing varies in different benefit-sharing agreements. (Switzerland) Same as above table on "Ensuring Benefit-sharing" (IPGRI) Same as above under "Ensuring Benefit-sharing"	

4. Recognition and protection of rights of indigenous and local communities

Elements <u>11</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 12/	Relevant provisions of existing international instruments within the framework of the CBD 13/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Recognition and protection of rights of	(Canada)	(Canada)	(Canada)	(Costa Rica)	(Costa Rica)
protection of rights of indigenous and local communities Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located; (xv) Customary law and traditional cultural practices of indigenous and local communities; (xvi) Code of ethics/Code	ITPGRFA (protection and promotion of Farmer's rights) Art. 9 (contribution to conservation and development of PGR) Art. 12.4 (MTA) WIPO/IGC, WTO/TRIPs Council, discussions underway. (Costa Rica) WIPO/IGC ITPGRFA ILO Convention 169 UNESCO FAO (EC)	CBD, Art. 8(j), 10(c), 15.5 Bonn Guidelines, par. 11(j), sections II and IV (Costa Rica) CBD Working Group on Article 8(j) and related provisions Bonn Guidelines (EC) CBD Article 8(j) and decisions	Canadian legal regime enables communities to enter into contracts setting out terms and conditions under which confidential information will be shared. Land claims agreements contemplate this through environmental assessments. Self government agreements with legislative authority internal to the community over cultural lands and resources. In Canada, indigenous communities can adopt customary protocols and practices not inconsistent with Canadian law. Some existing codes of practices in Canadian universities require PIC when research involves indigenous and local communities. Canadian governmental research	No international instrument addresses this issue Harmonize criteria Promote cooperation National legislations have not developed these issues (x), (xvi) and (xviii). (EC) Identifying authorised representatives as well as relevant laws and customs from these communities is often a very difficult and lengthy process. Identifying prior art in use of genetic resources.	At international level to provide recommendations to countries (x) (xv) (xvi) (xviii) At national level (xv) (EC) Governments should identify relevant representatives and customary laws so that potential users are not overburdened with procedures and unnecessary delays in the granting of PIC and in the agreeing of benefit-sharing. Formal legislation is unlikely to assist these procedures.
of conduct/Models of prior informed	ITPGRFA, art. 9.2 (a)	related thereto	institutions also have in place		WIPO's work on

^{11/} The Roman numerals in parenthesis following each element refer to the numbering of that element under heading (d) of the annex to decision VII/19 D. Please take into account the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the Convention.

^{13/} Please refer to the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the Convention.

Elements <u>11</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 12/	Relevant provisions of existing international instruments within the framework of the CBD 13/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
instruments in order to ensure fair and equitable sharing of benefits with indigenous and local communities; (xviii) Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j); (x)	on Farmers' Rights ILO Convention No 169 concerning indigenous and tribal peoples in independent countries (especially art. 4, 5, 7, and 13-19) which is a partial revision of Convention No 107 on indigenous and tribal populations. Draft UN Declaration on the Rights of Indigenous Peoples. WIPO's work on recognition of prior art in the use of genetic resources (India) ITPGRFA, art. 9.2 (b), 5(c) WIPO/IGC Principle 22 of Rio Declaration International Covenant on Civil and Political Rights 1966, art.1 Universal Declaration of Human Rights, art.	Bonn Guidelines, par. 31 (India) Art. 8(j) CBD Working Group on Article 8(j) Bonn Guidelines, section IV.C, III, II.C. (Japan) Bonn Guidelines (Norway) CBD Art. 8(j) and related COP decisions. Bonn Guidelines, par.31, appendix I and II (Switzerland) CBD Working Group on Art.	codes of ethics, practices and guidelines for ensuring that PIC is provided by indigenous and local communities. Canadian law does not prevent indigenous communities from adopting guidelines and codes of conduct. (Costa Rica) Regional: Central American Agreement on access and benefit-sharing National: Biodiversity Law No. 7788 Executive Decree No.31-514 MINAE of 15 December 2003, entitled: "General Standards for access to genetic and biochemical resources and elements of biodiversity." (India) Regional measures: Central American Agreement Draft 2001, art. 31, 35 African Model Legislation Draft 2000, art.5, 18. (PIC of local communities)	No international legislations exist that accord protection of TK and recognise their customs as well as intellectual property. Though local and indigenous communities are recognised nationally, there is a general lack of awareness and there is no international instrument to address this aspect with respect to access and benefit-sharing. Protection must include positive rights and effective safeguards against illicit use and its commercialisation. Customary law and cultural practices of indigenous and local communities vary greatly, will pose a huge threat for its survival since PIC not a mandatory criteria in most nations.	recognition of prior art should be concluded. (India) There is a need for separate bodies to address local and indigenous communities to educate them about GR and TK at national level and guidance and protection instruments at international level. Also the issue of documented TK is to be addressed. Measures to ensure compliance are needed at national, regional and international levels It should be made mandatory where IP is involved to reveal the source of GR and TK when used including PIC from the concerned holder of the GR or TK.

Elements <u>11</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 12/	Relevant provisions of existing international instruments within the framework of the CBD <u>13</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	(Japan) ITPGRFA, art.9 ILO 169, art.23 (Norway) ITPGRFA, art.9 ILO Convention 169 concerning indigenous and tribal peoples in independent countries Draft UN Declaration on the Rights of Indigenous Peoples WIPO's work on recognition of prior art in the use of genetic resources (Switzerland) ITPGRFA, art. 9 WIPO/IGC: protection of TK: revised objectives and principles (WIPO/GRTK/IC/8/5) Protection of Traditional Cultural Expressions/Folklore: revised objectives and	8(j) Bonn Guidelines, par. 11(j), 16(a)(vi) (vii), 16(b) (i)(ii)(iii), 16(d)(ii),19,26 (d),30, 31, 43(a), 43(b),44(g). (USA) Bonn Guidelines Akwe: Kon voluntary guidelines	ASEAN Draft Framework Agreement (involvement of resource providers in PIC procedures) National measures BDA 2002 and BDR 2004, art. 36.5 (TK protection of local people) BDA, section 7, 21(1) and 21(2) (d) (local bodies and people included in benefit-sharing process) BDA, section 19 (approval required for obtaining biological resources and IPR protection) (Japan) MGL 2005, especially p. 24 (Switzerland) ABS Management Tool: "preservation and respect of TK and sharing of benefits when TK associated with GR is accessed and used", p. 36 (USA) Bayh-Dole Act (tech transfer) Uniform Trade Secret Act CRADAS NIH Research Grant and contract	Countries such as India have a wealth of documented knowledge, areas of concern which would need special treatment. In countries where enactments are in place there is a clear provision for PIC. However, in most of the developed nations it is not mandatory to even disclose the origin of genetic resources or traditional knowledge used in IP. Only recently, EU agreed that indication of source of origin may be mandatory for IP. (Japan) No gaps identified. Japan will continue to accumulate experience with MGL 2005. (Norway) Identifying prior art in use of genetic resources Lack of definition of	(Norway) At the national level but measures could also be taken at the international level to support recognition of the rights of indigenous peoples by national governments in the ABS process, including in PIC and benefit-sharing arrangements.

Elements <u>11</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 12/	Relevant provisions of existing international instruments within the framework of the CBD <u>13</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	principles (WIPO/GRTK/IC/8/4) (USA) ITPGRFA (IPGRI) International Code of Conduct for Plant Germplasm Collecting and Transfer CGIAR's Ethical Principles Relating to Genetic Resources in the process of being revised to reflect necessity of seeking PIC of communities before using their knowledge.		award terms Health and Human Service (HHS) Human Subjects Protection policies Smithsonian research, education, collection and loan policies and procedures USG supported extramural research grants and programmes. BIO Code of Conduct	"traditional knowledge" Lack of common practices and principles.	

5. Derivatives

Elements <u>14</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 15/	Relevant provisions of existing international instruments within the framework of the CBD <u>16</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Derivatives	(CostaRica) Do not exist	(Canada) CBD, Art. 2.	(Costa Rica)	(Costa Rica) Issue not addressed at	(Costa Rica) International
Addressing the		Based on CBD definitions,	Biodiversity Law No. 7788	the international level	Pending definition
issue of derivatives; (xii)	(India) ITPGRFA, no specific provision (Japan) ITPGRFA, art.13 (USA) ITPGRFA	derivatives fall outside the scope of the Convention and would not apply to an international regime on ABS. (Costa Rica) Bonn Guidelines (EC) A very specific and tailormade definition only for their purposes is to be found in the Principles and Common Policy Guidelines for Botanical Gardens (definition included in EC submission) (India) Bonn Guidelines, section	Executive Decree No.31-514 MINAE of 15 December 2003, entitled: "General Standards for access to genetic and biochemical resources and elements of biodiversity." Andean Community Decision 391 (India) Decision 391 of the Andean Community defines the term "derivatives" BDA, Section 21(1) NBA addresses granting of approvals including by-products, innovations, practices, application and related knowledge	(EC) There is no common understanding of what is meant by derivatives. (India) This issue has not been sufficiently addressed in any of the instruments. Its inclusion would prevent the misuse of molecule, combination of molecules, extracts of organisms of biological origin, etc if not properly defined. (Japan) No gaps identified.	and in discussion in the WG-ABS (India) A clear definition of these derivatives should be included in the various instruments at national as well as international levels (Norway) Definition/common understanding to be provided in an international ABS regime and/or at the national level with guidance from the international regime.

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Convention.

<u>16/</u> Please refer to the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the Convention.

Elements <u>14</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 15/	Relevant provisions of existing international instruments within the framework of the CBD <u>16</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
		Appendix I, B(2) (Japan) Bonn Guidelines (Norway) The CBD covers derivatives as far as they are contained in the definition of GR (e.g. "material containing functional units of heredity") Derivatives included in the scope of the BG since benefits arising from the commercial and other utilization of GR are included. Also dealt with in the context of indicative list of MATs. (USA) Bonn Guidelines	(USA) (USA) (CRADAS NIH Research Grant and contract award terms Health and Human Service (HHS) BIO Code of conduct	accumulate experience with MGL 2005. (Norway) Definitions in national legislations vary widely.	

6. Promotion and enforcement mechanisms of the international regime and compliance with PIC and MAT

Elements <u>17</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD <u>18</u> /	Relevant provisions of existing international instruments within the framework of the CBD <u>19</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Promotion and enforcement mechanisms of the	(Canada) ITPGRFA: Model MTA to ensure compliance with	(Canada) CBD, art. 8, 10, 15,	(Canada) National measures to ensure	(Costa Rica) Monitoring and	(Costa Rica) International
international regime and compliance with	provisions and principles of IT	16, 18, 19, 20 and 21. Bonn Guidelines,	compliance with the elements of sections II, III, IV, and V of	enforcement measures are	(EC)
PIC and MAT Monitoring, compliance and	(Costa Rica) WTO/TRIPs	Section V, par. 59-61.	the BG. (Costa Rica)	weak in the majority of legislations	Disputes between Parties agreeing on MAT must be resolved
enforcement; (xx)	FAO	(Costa Rica)	Biodiversity Law No. 7788	(India)	by domestic law.
Dispute settlement, and/or arbitration, if and when necessary; (xxi)	(EC) (Norway) ITPGRFA, art. 12.5 Dispute settlement/arbitration is likely to be covered in the standard MTA of the	Do not exist (EC) Bonn Guidelines, section V, (B, C, E, F)	Executive Decree No.31-514 MINAE of 15 December 2003, entitled "General Standards for access to genetic and biochemical resources and elements of biodiversity."	Enforcement is a difficult task unless there is primarily national	Bonn Guidelines: relevant provisions could be implemented nationally Compliance with the
	ITPGRFA	CGIAR: policy	(EC)	legislation in place to curb	provisions of PIC should be a matter for
	International conventions on conflicts arising from international contracts: conflict of laws and jurisdiction (European Community Convention on the Law Applicable to Contractual Obligations,	statements of ABS relevance are those that deal with aspects of third person use of genetic material delivered by the CGIAR institutes.	Arbitration: in France, the New Civil Code of Procedure governs international arbitration in its articles 1492 to 1507 (India)	illegal use of another's genetic resources or TK. Once wrong patents or IP are issued, it becomes a very long winding	the provider country. Compliance with MAT should be embedded in the contractual arrangements under which the MAT functions, using the
	Rome 1980, Convention on the Law Applicable to	(India) Bonn Guidelines	Regional instruments: Andean Community Common	and expensive affair for the	provisions of civil law. (India)
	Agency, The Hague,	(provide details of	Regime 1996	original holders	Regional and

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Convention.

^{19/} Please refer to the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the Convention.

Elements <u>17</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD <u>18</u> /	Relevant provisions of existing international instruments within the framework of the CBD <u>19</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	1978), conciliation (Resolution 57/18 UNGA) (India) ITPGRFA, Annex II deals with arbitration and conciliation mechanisms. (Japan) ITPGRFA, art. 21 (Norway) ITPGRFA, art. 12.5 and art. 21 (IPGRI) ITPGRFA: Issue of non- compliance with Standard Material Transfer Agreement being considered by Contact Group for the Development of the SMTA and subsequently by the first meeting of the Governing Body of the Treaty in June 2006. Under FAO-In Trust Agreements, see IPGRI submission in Inf. Doc for further details on non- compliance.	essential elements of PIC and MAT) CBD has various mechanisms for dispute settlement. (Japan) Bonn Guidelines (Norway) CBD art. 27 Bonn Guidelines, section V, B, C, E, F. (USA) Bonn Guidelines	African Model Law Draft ASEAN Framework Agreement National law: BDA 2002 and BDR 2004 follow strictly PIC and MAT procedures in line with BG and CBD provisions. Art. 21(1) NBA approval required for benefit-sharing. Section 55 addresses enforcement (certain offences punishable under law) BDA 2002, Art. 50 provisions of settlement of disputes between State biodiversity board and NBA or among state biodiversity boards (SBB). Central Government authority to examine dispute between NBA and SBB, whereas NBA is authority to settle disputes between SBBs. (Japan) MGL 2005, especially pp. 26- 29 (USA) CRADAS; NIH Research grant award terms; Health and Human Service (HHS); US court system/contract law.	as has been observed previously. The basic associated problem is the identification of owners which makes it very difficult to enforce such rights. (Japan) No gaps identified. Japan will continue to accumulate experience with MGL 2005. (Norway) Lack of cost effective measures to monitor and ensure enforcement.	international authorities for ensuring that these mechanisms function with equity is necessary. Also a provision in TRIPs Agreement that mandates patent applicants to disclose source of origin, evidence of PIC and compliance with benefit-sharing will ensure that the TRIPs and CBD are implemented in a mutually supportive manner. (Norway) Need to develop how e.g. certificates and disclosure requirements may form part of a comprehensive benefit-sharing system. Dispute settlement procedures between parties to an MTA should be agreed upon in the MTA (leave it up to the parties whether this should be solved by national law or in accordance with international law).

Elements <u>17</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD <u>18</u> /	Relevant provisions of existing international instruments within the framework of the CBD <u>19</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Measures to ensure compliance with the	(Canada) ITPGRFA: Model MTA	(Canada)	(Canada)	(Costa Rica)	(Costa Rica)
mutually agreed terms on which	to ensure compliance with provisions and principles	CBD: art. 8, 10, 15, 16 18, 20 and 21.	In the process of elaborating national policies and	Monitoring and enforcement	At international and national levels
genetic resources were granted and to prevent the	of IT WIPO/IGC and WTO/TRIPs Council:	Bonn Guidelines: section IV, D.	regulations consistent with relevant provisions of the CBD and the BG.	measures are weak in the majority of	In applications for IPRs must request the disclosure of the origin
unauthorized access and use of genetic	ongoing discussions.	(Costa Rica) Issue addressed in	Raise awareness among stakeholders and indigenous	legislations (Switzerland)	(Norway)
resources consistent with the Convention	(Costa Rica) WTO/TRIPs	WG-ABS	communities with regards to the negotiation of MAT and	See section above on	Compliance with the provisions of PIC
on Biological Diversity; (xi)	ILO Convention No 169 and other human rights	(EC) Same as above	granting of PIC.	"ensuring benefit-sharing"	should be a matter for both provider and user
Measures to ensure	treaties (EC) (Norway)	(India)	(Costa Rica) Biodiversity Law No. 7788	beliefit sharing	countries. There is a need to address
compliance with national legislations on access and	Judicial cooperation at the different procedural	CBD and Bonn Guidelines	Executive Decree No.31-514 MINAE of 15 December		compliance with PIC and MAT at the
benefit-sharing, prior informed consent and	stages: <u>Investigation</u> through the	(Norway)	2003, entitled "General Standards for access to genetic		multilateral level within the context of the international regime.
mutually agreed terms, consistent with	Convention on the Taking Evidence Abroad in Civil	CBD, art. 15.7 Bonn Guidelines,	and biochemical resources and elements of biodiversity."		User countries need to adopt measures to
the Convention on Biological Diversity;	or Commercial Matters (the Hague, 1970)	section II, par. (b) and (d), section V.F.	(EC) (Norway)		ensure compliance with national legislation in
(ix)	Notification of judicial actions, through the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or	(Switzerland) See section above on "ensuring benefit-sharing"	National or regional regimes of judicial assistance helping legally and financially poor stakeholders to get access to national courts (exists in all EU members, and organized		provider countries. This is also a matter for international IPR regimes (e.g. TRIPs and WIPO PCT)
	Commercial Matters (The Hague, 1965) Enforcement of arbitral awards through the United Nations Convention on the	(USA) Bonn Guidelines	through an EU network; in France, judicial assistance is defined by law no 91-1266, 18 December 1991, and open to non-nationals).		This could be dealt with at the national level by introducing legislation to enforce ABS legislation by both user and provider

Elements <u>17</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD <u>18</u> /	Relevant provisions of existing international instruments within the framework of the CBD <u>19</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	Recognition and Enforcement of Foreign Arbitral Awards (New York, 1965) (India) ITPGRFA, art. 12.1, 12.2, 12.3 (IPGRI) Same as above		Regional laws: Andean Community Common Regime 1996 addresses transfer to third parties. Draft Central American Agreement, art. 19(b) (terms for transfers to third parties) Draft ASEAN Agreement (addresses transfer to third parties) National laws: BDA 2002, art. 20 BDR 2004, rules 9, subrules 1-6 (address third party transfers) (Switzerland) See section above on "ensuring benefit-sharing" (USA) CRADAS; NIH Research grant and contract award terms; Health and Human Service (HHS); Lacey Act; US court system/contract law and other protections; Smithsonian collection and loan policies and procedures; USG supported extramural research grants and programs; BIO Code of conduct; PIIPA.		countries and measures to deal with violations of ABS legislation. This question of enforceability should also be dealt with in the context of the international regime. (Switzerland) See section above on "ensuring benefit-sharing"

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7. Functioning of the international regime

Elements <u>20</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/	Relevant provisions of existing international instruments within the framework of the CBD 22/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Functioning of the	(Canada)	(Canada)	(Costa Rica)	(India)	(EC)
international regime	ITPGRFA:	CBD: Art. 8, 10, 15, 16,	Do not exist	Absence of national	These may be key
Measures to facilitate the functioning of the	MTA to be elaborated	18, 19, 20, 21, 23, 24 and 25.	(India)	legislations in many of the CBD Parties.	components of any international regime
regime at the local, national, subregional, regional and international levels, bearing in mind the transboundary nature of the distribution of some <i>in situ</i> genetic resources and associated traditional knowledge; (viii) Means to support the implementation of the international regime within the framework of the Convention; (xix) Institutional issues to support the	by Governing Body. Art. 18 (funding strategy to be implemented) ITPGRFA, UNCLOS, Antarctic Treaty and other relevant international agreements contain institutional provisions to support implementation. (Costa Rica) Do not exist (India) ITPGRFA Multilateral System:	Bonn Guidelines (Costa Rica) Do not exist The financial instrument of the GEF (element (xix)) (India) CBD Working Group on ABS negotiating international regime Bonn Guidelines (Japan) (USA) Bonn Guidelines	LMMC are actively working on the development of a legally binding international regime within the framework of the CBD. The Biological Diversity Act: Biodiversity management committees for documentation and chronicling of knowledge relating to biodiversity (section 41) (Japan) MGL 2005 (USA) US Plant Varieties Protection Act (PVPA)	Mere guidelines do not ensure that mechanisms are in place to put a check on biopiracy since most countries do not require origin/source disclosure of TK/GR in IPR. (Japan) No gaps identified. Japan will continue to accumulate experience with MGL 2005. (IPGRI)	Institutional issues: the CHM could have an enlarged role for example, as recipient of the notifications of disclosure of origin in patent applications. (India) National and international level. Implementation measures for ITPGRFA and proposed international regime need to be harmonized and implemented at local, subregional, regional, national and international levels.

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Please take into account the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the

Convention.

22/ Please refer to the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the Convention.

Elements <u>20</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/	Relevant provisions of existing international instruments within the framework of the CBD <u>22</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
implementation of the international regime within the framework of the Convention; (xxii)	- to be implemented through national node in each member party to the ITPGRFA - regional and subregional implementation need to be streamlined international cooperation emphasized in art. 7 art. 15 addresses implementation of ITPGRFA by IARCs of CGIAR. (Japan) ITPGRFA, art. 10-13. (USA) ITPGRFA UPOV 1991 Paris Convention WTO/TRIPs World Organisation for Animal Health (OIE) International Plant		Patent Act Plant Patent Act CRADAS Bayh-Dole Act (tech transfer) State Department sponsored regional training on ABS Support and participation in the Global Biodiversity Information Facility NIH Research Grant Award terms Health and Human Service (HHS)	The Global Crop Diversity Trust seeks to raise a 260 million US\$ endowment of which circa 42 million is currently pledged. The Trust does not support in situ conservation. For the time being it is focussing on Annex 1 crops and forages.	(Norway) Such measures could be components of an new international regime on ABS. (IPGRI) Continue fund raising for the Global Crop Diversity Trust. Other sources of funds will be necessary for conservation efforts under the Treaty's funding strategy for non-Annex 1 and in situ PGRFA.

Elements 20/	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/ Protection Convention (IPPC) Global Biodiversity Information Facility (IPGRI) The Global Crop Diversity Trust – part of the funding strategy pursuant to Art. 18 of the ITPGRFA.	Relevant provisions of existing international instruments within the framework of the CBD 22/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge; (xiii)	(Canada) ITPGRFA: Model MTA could serve the purpose of identifying origin of GR. (Costa Rica) WTO TRIPs (Norway) CITES (art. VI) (IPGRI) ITPGRFA: The SMTA to be used within the MLS,	(Canada) Bonn Guidelines: elaboration of voluntary certification schemes for institutions to be considered, Appendix II. (Costa Rica) Issue under discussion in WG-ABS	(Costa Rica) Biodiversity Law No. 7788 Executive Decree No.31-514 MINAE of 15 December 2003, entitled: "General Standards for access to genetic and biochemical resources and elements of biodiversity."	(Canada) Need for focussed discussion on the feasibility of such a system: considering the level of resources available varying from one country to another; determination of the certificate's object (origin, source or legal provenance and their respective definitions). (Costa Rica)	(Costa Rica) At international and national levels (Norway) The CHM could have a role as receiver of notifications of disclosure of origin in patent applications and unique identifiers of genetic resources under a system for international certificates of origin/legal provenance. An international certificate of origin/legal provenance as part of the international

Elements <u>20</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/	Relevant provisions of existing international instruments within the framework of the CBD <u>22/</u>	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	functions, de facto, as a certificate of source.			Has not been defined. (IPGRI) The ITPGRFA and the SMTA does not oblige the recipient of material to provide a certificate of source when applying for a patent.	regime could be a useful tool in building trust, increasing transparency and traceability of the origin of the genetic resources. (IPGRI) If national law requires the provision of a certificate of source, presumably the SMTA could be deemed to satisfy that condition.
Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights; (xiv)	(Canada) WIPO Budapest Treaty, art. 3 (deposit of microorganisms for patent purposes) UPOV 1978, art. 7 (breeder to provide relevant information for examination purposes) WIPO and WTO/TRIPs Council: ongoing discussions (Costa Rica)	(Canada) Bonn Guidelines, par. 16(d) (ii) (Costa Rica) Same comment as above under Costa Rica Bonn Guidelines (Switzerland) CBD decision VI/24C Bonn Guidelines	Patent Rule 29 (1) (a) (identification of prior art) Patent Act, art. 38.1 (deposit of biological material for patent application purposes) (EC) Databases held by national patent offices (where the origin of the genetic resource is part of the description of the invention). (India) Disclosure of origin/source of	(Costa Rica) Compatibility with the system of protection of IPRs – issue not required at the international level (India) Disclosure of the source and the country of origin in a patent application would play a significant role in preventing biopiracy and	(Costa Rica) At international level (EC) The EU proposal to WIPO to include the disclosure of origin in patent applications as a formal condition is a very important element facilitating the possibilities for the sharing of benefits arising from the source of genetic resources. (India) It is imperative that

Elements 20/	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/	Relevant provisions of existing international instruments within the framework of the CBD 22/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	WIPO/IGC (EC) (Norway) The Patent Law Treaty (PLT) and the Patent Cooperation Treaty (PCT) governed by the WIPO are relevant for the disclosure of origin/source/legal provenance. Potential amendments to these agreements are currently being debated in WIPO/IGC Paragraph 19 of the Doha Declaration instructs the TRIPs Council to continue the review of Article 27.3(b) and to examine the relationship between TRIPs and CBD and TK. (Switzerland) WIPO/PCT: proposal by Switzerland on the declaration of the source – outstanding		genetic resources and TK is required under Indian Patent Act section 10. (Norway) Disclosure provisions can be found in patent laws/ABS laws in inter alia Brazil, Costa Rica, Denmark, Egypt, India and Norway. (USA) Lanham Act (trademark) USPTO databases	misappropriation. (Norway) Only a few countries have introduced disclosure provisions in their national patent laws. In addition, these provisions vary widely amongst countries. The existing treaties like the PCT does not allow international disclosure requirements (only as a requirement for national patent applications). (Switzerland) No international provisions concerning the disclosure of source of GR and associated TK (IPGRI)	disclosure of origin/source be made mandatory to avoid biopiracy. This will avoid the pursuing of legal remedies in other countries, which may be complicated and not economically feasible for many aggrieved countries. Also at the international level there is an urgent need to harmonise the provisions of CBD and TRIPS, in the interest of all parties, namely, the stakeholders of biological material/TK, the consumer and intellectuals. Art. 7 of TRIPs Agreement clearly emphasises that the "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation in a manner conducive to social and economic welfare and to a balance of right and obligation." (Norway) Proposals in WIPO (eg the
	issue (see				EU proposal) to include the

Elements <u>20</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/	Relevant provisions of existing international instruments within the framework of the CBD 22/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	PCT/R/WG/7/13, par. 135(i)) WIPO/IGC: Draft technical study on disclosure requirements related to			See above	disclosure of origin in patent applications as a formal condition is an element that could lead to triggering of benefitsharing.
	genetic resources and TK (WIPO/GRTKF/IC/5/1 0)				Such a disclosure requirement at the international level could result in a level playing field for users of genetic
	(USA) WIPO Budapest Treaty on the				resources and could lead to more predictability in this field.
	international recognition of micro deposit UPOV TRIPs				The CHM could have a role as receiver of notifications of disclosure of origin in patent applications
	TKIIS				(Switzerland)
					National and international
					Swiss proposal to amend the PCT to explicitly enable the national legislator to require patent applicants to declare the source of GR and TK in patent applications.

Elements 20/	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/	Relevant provisions of existing international instruments within the framework of the CBD 22/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed? (IPGRI) See above
Capacity-building	(Canada)	(Canada)	(Costa Rica)	(Norway)	(Costa Rica)
measures based on country needs (xvii)	ITPGRFA, art. 13.2 (sharing of benefits), 18 (resources for capacity-building). UNCLOS, (promotion of the development and transfer of the marine scientific and technological capacity of States) (Costa Rica) Do not exist (India) ITPGRFA: capacity-building measures, art. 13(c) and 14. (Japan) ILO 169, art. 26-31 (Switzerland) ITPGRFA, art. 13.2	CBD, art. 18, 20, 21 Bonn Guidelines (Costa Rica) Bonn Guidelines (Norway) CBD Action Plan for capacity-building on access and benefit-sharing (COP Decision VII/19 F) CBD art. 16, 17 and 18 (Switzerland) CBD, art. 12, 13, 25 Decision VII/16 and VII/19F Bonn Guidelines, par. 20(b), 44(d)	Biodiversity Law No. 7788 (Japan) National Strategy for the Conservation and Sustainable Use of Biodiversity ODA Charter (USA) USPTO international training	More resources and capacity-building is needed in order to implement the Action Plan for capacity building on ABS.	At international and national levels (EC) Capacity-building measures at national level with international contributions will be a key element to raise awareness among officials and operators. Need to set up necessary mechanisms to have a coherent ABS strategy in every Party, though it should not be necessary to legislate for this. (Norway) Mechanisms for capacity-building and technology transfer will be important elements of an international regime. Capacity-building activities should be based

Elements <u>20</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 21/	Relevant provisions of existing international instruments within the framework of the CBD 22/	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
					on elements of the Action Plan for Capacity-building on ABS.

8. **Poverty eradication**

Elements <u>23</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 24/	Relevant provisions of existing international instruments within the framework of the CBD <u>25</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Poverty eradication	(Canada)	(Canada)	(Costa Rica)	(India)	(Costa Rica)
Measures to promote access and benefit-sharing arrangements that contribute to the achievement of the Millennium Development Goals, in particular on poverty eradication and environmental	UNCLOS provisions on development and transfer of marine technology, in particular art. 244 highlights strengthening the "autonomous marine scientific capabilities" of developing countries – education	CBD, art. 18 BG, par. 11(k) (Costa Rica) Several processes underway in the CBD relating to the conservation and sustainable use of	Several processes within the United Nations. (India) Provisions of BDA indirectly facilitate poverty eradication through benefit-sharing mechanisms. (Japan)	The absence of specific laws and mechanisms in place make the achievement of this goal a hard task. (Japan) No gaps	At international level (EC) National authorities should set up the mechanisms so that the benefits from the granted access revert to conservation of the environment of the local communities. These could

^{23/} 24/ The Roman numerals in parenthesis following each element refer to the numbering of that element under heading (d) of the annex to decision VII/19 D.

Please take into account the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the

Convention. Please refer to the list of instruments and processes in paragraph (d) (xxiii) of the annex to decision VII/19 D of the Conference of the Parties to the Convention. <u>25</u>/

Elements <u>23</u> /	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD 24/	Relevant provisions of existing international instruments within the framework of the CBD <u>25</u> /	Relevant provisions of existing regional and national instruments, and relevant processes	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
sustainability; (vii)	and training are two important priority areas. (Costa Rica) Summit of Johannesburg (Japan) ITPGRFA (Switzerland) ITPGRFA, ABS provisions (USA) ITPGRFA	biodiversity. Several processes in the United Nations (India) Poverty alleviation particularly in developing and least developed countries is an objective of BG (E. par. 11(k)) and provisions related to benefit-sharing and sustainable development will indirectly serve this purpose. (Japan) BG (Switzerland) CBD ABS provisions Bonn Guidelines (USA) Bonn guidelines	MGL 2005, especially p. 3. (Switzerland) ABS provisions (USA) Many programs, for example, those managed by USAID, US Forest Service, USDA, Peace Corps and the Smithsonian indirectly link ABS and poverty eradication by developing information, systems and markets for sustainably sourced goods and products, by encouraging better stewardship of lands in production, innovating new, higher yield and lower risk management systems and empowering local communities through programs of sustainable natural resource management.	identified.	cover, for example, environmental education programmes, sustainable projects which would help in the fight against poverty. (India) International and regional mechanisms should be evolved in mutual cooperation. (Norway) National legislation/mechanisms should be designed so that the benefits arising from the use of genetic resources are channelled to the conservation and sustainable use of biological diversity, taking into account the welfare and environments of indigenous and local communities.
