

**EU submission on
Access and Benefit-Sharing in preparation for the Fourth Meeting of the Ad-Hoc
Open-ended Working Group on Access and Benefit-Sharing**

1.- International Regime on Access and Benefit-sharing

In recommendation 3/1 on the “International Regime on Access and Benefit-sharing”, the Open-Ended Working Group *invited Parties to:*

1) submit to the Executive Secretary written comments and proposals on the items in Annex I of the recommendation (reproduced in Annex A of this notification), as soon as possible and no later than 1 October 2005, for consideration by the fourth meeting of the Open-Ended Working Group.

2) provide information to the Executive Secretary on the basis of the matrix contained in Annex II of the recommendation (reproduced in Annex B of this notification) and the potential additional elements and options, as soon as possible and no later than 1 October 2005, in order to facilitate further analysis of gaps in existing national, regional and international legal and other instruments relating to access and benefit-sharing.

1) EU comments and proposals on Annex A – Potential elements of an International Regime on Access and Benefit-sharing

The European Union welcomes the progress achieved at the Third Meeting of the Open-Ended Working Group on Access and Benefit-sharing. The EU is concerned, however, about the number of additional options and elements that have been added to an already long list of potential options and elements of the international regime. It seems to us that further discussions should focus on those aspects that – following an analysis of gaps in existing national, regional and international legal and other instruments - are fundamental to achieving a practicable, transparent, and efficient international regime to promote and safeguard the facilitated access to genetic resources and the fair and equitable sharing of benefits arising out of their utilization. In this context, the EU wishes to record that it supports the following options and elements listed in Annex A:

As regards Annex A, No. 2 on scope, the EU supports Option 6, as this is the closest to Decision VII/19, as copied above in italics before the new options.

With respect to Annex A, No. 3 on potential objectives, the EU supports Option 5.

As regards Annex A, No. 4 on elements to be considered for inclusion in the international regime, the EU notes that this section follows the same structure as the matrix contained in Annex B. The EU’s comprehensive views on these elements are included in the information provided in the matrix.

With respect to Annex A, No. 5 on potential additional elements and options identified, the EU does not support the addition of the further options and elements identified by the Third Opened-Ended Working Group, since the mandate given by COP-7 is sufficiently comprehensive.

The EU believes that the main emphasis should now be focussed on the gap analysis.

2) Information on the basis of the matrix in Annex B

The European Union attaches Annex B with contributions to the five columns for each of the elements identified by the Working Group. In doing so, it wishes to make the following observations:

- although the columns include relevant material identified by the Member States and the Commission, the material gathered is certainly not comprehensive.
- existing instruments that are relevant to more than one of the elements identified by the Working Group, are mentioned more than once in the matrix.
- the first three columns of the matrix¹ contain information of a largely factual nature.
- information provided in the final two columns of the matrix² is more subjective in character.
- in the second, and in particular in the third column of the matrix, instruments of relevance for specific EU Member States are presented in *italics*. The respective Member State(s) are identified when appropriate.

In the third column dealing with existing regional and national instruments and relevant processes, the EU has not included instruments adopted in or applying exclusively to regions/countries outside the EU: as we expect these regions / countries to mention them in their own submissions, unless they consider them inappropriate.

Overall, the matrix provides a detailed and complex picture of existing instruments and provisions at the international, regional and national levels and of potential gaps and measures to fill them. When combined with information provided by other Parties, Governments, indigenous and local communities, international organisations and relevant stakeholders, the information contained in the matrix will become even more difficult to access.

Against this background, and in order to assist the use of the wealth of information contained in the matrix, the EU has decided to add a summary assessment of its analysis of the matrix to this submission. This summary assessment identifies six areas where relevant gaps appear to exist and suggests possible solutions to address them. The EU sincerely hopes that this innovation is welcome and useful.

For convenience, this summary assessment is also shown below:

¹ i.e.: Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD; Relevant provisions of existing international instruments within the framework of the CBD; Relevant provisions of existing regional and national instruments, and relevant processes.
² i.e.: Identified gaps; At what level, national, regional or international, and how should the gaps be addressed?

Summary assessment of major gaps and possible manners of filling them based on the analysis contained in the matrix in Annex B of the SCBD Notification

Major gaps remaining:

1. Awareness raising and education of administrators and stakeholders in the public and private sectors at all levels and in the institutions of all Parties: lack of awareness on the concepts and requirements of ABS issues is a major impediment to driving forward implementation.

2. Overall there is a lack of transparency in relation to national legislation and/or procedures on ABS, accompanied by an insufficient use of existing available instruments: obvious examples, CBD lists of national focal points (NFP) and national competent authorities (NCA) are incomplete.

3. Where provisions exist, facilitated access (i.e. regulated/controlled access, promoting benefit-sharing and without hindering actual access) is rarely practical and effective. This fundamental element needs to be addressed since without facilitated access there are no benefits to share.
 Relevant reasons include:
 - a diversity of national authorities dealing with the various aspects of ABS leads to confusion, lack of effectiveness, etc and consequently intentionally or not, national legislation often impedes access due to delays, unnecessary bureaucracy, the lack of explicit procedures. It can even lead to legal uncertainty as regards authority of the different bodies and stakeholders involved in access granting procedures. These difficulties have hindered the

Possible manner of filling gaps:

1. Not generally amenable to legislation and regulation. Increased use of and awareness of CBD web-site, regional and national web-sites etc. Initiatives at national level to promote, encourage and educate through a range of instruments: publicity, stakeholder meetings, requirements of practicing institutions, etc.

- 2- Wide use of available mechanisms facilitated by the SCBD: website with lists of NFP and NCA.

- 3 - Legislation needs to be reviewed. Clarification and simplification of procedures should be encouraged. Best practice on PIC and MAT and government experience with administration of ABS should be shared., particularly:
 - cohesive arrangements and coordination among competent authorities, dealing with all elements should be encouraged to address these deficiencies;

<p>potential for benefit-sharing;</p> <p>- where indigenous and local communities are involved, identifying authorised representatives and relevant laws and customs can be an impediment to recognising the rightful entities to whom benefits might accrue.</p> <p>4. Current arrangements usually fail to link benefits with biodiversity conservation. In addition, regulations governing access rarely provide for measures to guarantee that bioprospecting will not be detrimental to biodiversity conservation.</p> <p>5. Often, there is no ready differentiation between the access of material purely for scientific research purposes and potentially for commercial purposes: this is currently discouraging scientific collaboration.</p> <p>6. Monitoring of PIC an MAT is hindered by the fact that from the process from the provision of genetic resources to the commercialisation of products is long and complex and the commercial products using genetic material do not allow for ready identification of the origin or source of material.</p>	<p>- the resolution of identification etc of indigenous and local communities is a matter for national/regional consideration.</p> <p>4. National regulation could be reviewed to take into account any detrimental effects of bioprospecting on biodiversity.</p> <p>5. Any new aspects of an international regime on ABS should address this fundamental issue: this would need to recognise the global implications of the distinction between access of genetic resources for scientific collaboration and for potential commercial gains the benefits of which need to be shared. They should also be consistent with the FAO International Treaty on plant genetic resources for food and agriculture with regard to the genetic resources covered by the Multilateral System of the IT.</p> <p>6. The EU proposal to WIPO to include the disclosure of origin in patent applications as a formal condition is an important element that could enhance benefit-sharing. The Clearing House Mechanism could have an enlarged role for example, as recipient of the notifications of disclosure of origin in patent applications.</p>
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Note: This table results from a technical analysis of the available information. It should not however be necessarily assumed that the EU will seek to promote these very provisional 'conclusions' at ABS 4. This will be dependent on a number of factors, particularly the matrix information provided by other Parties, etc.

Annex B

ANALYSIS OF GAPS

Elements ^{3/}	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD ^{4/}	Relevant provisions of existing international instruments within the framework of the CBD ^{5/}	Relevant provisions of existing regional and national instruments, and relevant processes ⁶ (see endnotes)	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
Access Measures to promote facilitated access to genetic resources for environmentally sound uses according to Article 15.2 of the Convention on Biological Diversity; (iv)	- Article 12 and Annex I of the International Treaty on Plant Genetic Resources for Food and	Information on national access legislation on the CHM Measures by the Provider: - CBD (Art.	- Designation of National focal points on ABS and National Competent Authorities. For example: Ministerial Declaration on	- Insufficient use of existing instruments (ABS NFP) - Lack of transparency on national ABS	- Access and MAT concerning genetic resources are under specific national legislations or under national ownership and contract laws. MAT are

^{3/} 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.

^{4/} 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.

^{5/} 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.

⁶ Additional information compiled by the Secretariat is available in documents UNEP/CBD/WG-ABS/3/2 and UNEP/CBD/WG-ABS/3/5.

⁷ In the context of the International Undertaking on Plant Genetic Resources for Food and Agriculture Art. 5(a) of FAO Conference Resolution 4/89 (included as Annex I of the IU) contains an agreed interpretation to clarify that “free access” does not necessarily mean free of charge but can embrace a range of transfers. Furthermore, the IT specifically deals with the processes necessary for facilitated access.

Elements ^{3/}	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD ^{4/}	Relevant provisions of existing international instruments within the framework of the CBD ^{5/}	Relevant provisions of existing regional and national instruments, and relevant processes ⁶ (see endnotes)	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
	Agriculture (IT-PGRFA) <ul style="list-style-type: none"> - FAO International Code of conduct for Plant Germplasm Collecting and Transfer - FAO Conference Resolution 4/89 (Art. 5a).⁷ Move explanation to	15.2, 15.5, 15.6) <ul style="list-style-type: none"> - Bonn Guidelines (Section IV A, B and C) Measures by the User: <ul style="list-style-type: none"> - Principles and Common Policy Guidelines for Botanical Institutions, sections on acquisition. In 	Access and Rights to Genetic Resources in the Nordic Countries 2003 paragraphs 3, 5, 8-15 and 18 (see www.nmr.dk) <ul style="list-style-type: none"> - Strategy for Genetic resources in the Fisheries, Agriculture, Forestry and Food Sectors of the Nordic Region 2005-2008 (see www.nmr.dk) <ul style="list-style-type: none"> - The Swedish Scientific Council on 	legislation and procedures <ul style="list-style-type: none"> - 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 	under the international civil laws and rules and shall also be considered as such. <ul style="list-style-type: none"> - International guidance, such as that provided by the Bonn Guidelines (see Section IV. A, B, C) might be useful. However, implementation efforts at the regional/ country-level need to reflect local conditions and requirements. - Section V.B of the

⁸ Available at: <http://bccm.belspo.be/mosaicc/docs/code.pdf>.

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	<p>footnote. Add also reference to the International Undertaking which the International Treaty has not superseded</p> <p>- The Consultative Group on International Agricultural Research (CGIAR) holds in public trust one of the world's largest ex-situ</p>	<p>particular: in order to obtain PIC a full explanation of how Genetic Resources will be acquired and used must be given.</p> <p>International Plant Exchange Network (IPEN) Code of Conduct on the acquisition, maintenance and supply of plant material for botanic gardens and similar collections</p>	<p>Biodiversity is currently preparing a Handbook on the collection of biological material, including the aspects of access and benefit-sharing, with the purpose to assist scientists avoiding legal pitfalls</p> <p>- National Access Legislation, for example: Philippine Executive Order n°247, Andean Pact Decision n° 391, Indian Biodiversity Bill, etc (non-exhaustive list; to be completed by other regions).</p>	<p>measures.</p> <p>-Intentionally or not national legislation has often impeded access due to delays, unnecessary bureaucracy, the lack of explicit PIC mechanisms and uninformed national authorities.</p> <p>- Access regulations rarely provide for measures to guarantee that bioprospecting will not be</p>	<p>Bonn Guidelines suggests mechanisms to promote accountability by all stakeholders involved in ABS.</p> <p>- Principles and Common Policy Guidelines for Botanical Institutions, sections on acquisition are examples on how to provide guidance on how the user should operate. Similar approaches could be introduced for other stakeholders/ in other fields (e.g. public research institutions, institutions funding research) at the</p>

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	collections. Draft Agreement between the ITPGRFA Governing Body and the International Agricultural Research Centres. Micro-Organism Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) ⁸	(Art. 1).		detrimental to biodiversity conservation.	international/ regional/ national levels. - Facilitated access does not mean uncontrolled access: this could usefully be clarified. Capacity building and financial resources for development co-operation is needed to

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	<p>International Agricultural Research Centres of the CGIAR.</p> <p>International Databases on plant (VIEWS) and animal (Dad-IS) genetic resources.</p>				<p>improve processes and decisions procedures on access to genetic resources at national level.</p> <p>National regulation could be reviewed to take into account any detrimental effects of bioprospecting on biodiversity.</p>
<p>Ensuring benefit-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</p>	<p>- Articles 12.4 and 13 of the ITPGRFA. - In the</p>	<p>- CBD (Art. 15.7) - Bonn G (Section IV.D.3 and Appendix II)</p>	<p>- The Nordic Ministerial Declaration on Access and Rights to Genetic Resources (para. 11)</p>	<p>- This fundamental element needs to be addressed in order for the provisions of the</p>	<p>- Bonn G set fair and practical conditions in Section IV.D.3 and Appendix II.</p>

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other utilization of genetic resources in accordance with Articles 15.7, 16, 19.1, 19.2. of the Convention; (ii)	<p>framework of the ITPGRFA the level, form and manner of benefit-sharing payments for using genetic resources taken from the Multilateral System is currently debated in negotiations on the standard Material Transfer Agreement..</p> <p>- The 1991 Act of the International Union for the</p>	<p>- Principles and Common Policy Guidelines for Botanical Institutions: section on Benefit-sharing. In particular, regarding examples of non-monetary benefits: “benefits in kind such as augmentation of national collections in the country of origin and support of</p>	<p>recommends the Nordic Gene Bank to consider the use of the provisional MTA, which now is used by international agricultural research centres, until the adoption of the standard MTA for the Multilateral System</p> <p>Council Regulation (EC) 2100/94 of 27 July 1994 establishing in line with UPOV a Community system of plant variety right protection</p>	<p>CBD to be achieved and for wider objectives such as the Millennium Development Goals to be realised.</p> <p>- Difficulties in access have resulted in minimal benefit-sharing. (See entry on ‘access’ above).</p> <p>-Often a diversity of national authorities dealing with the various aspects of ABS leads to confusion, lack</p>	<p>- 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.</p>

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Measures to ensure the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products, in the context of mutually agreed terms;	Protection of New Varieties of Plants (UPOV). Arts. 15.1 and 15.2. - The UPOV Convention provides a sui generis form of intellectual property protection which has been specifically adapted for the process of plant breeding and has been developed with the aim of encouraging breeders to	community development activities, training in science, conservation and management and IT administration. ” - The IPEN Code of Conduct for Botanic Gardens (Art. 2.3)		of effectiveness, etc: cohesive arrangements and coordination among the competent authorities , dealing with all elements should be encouraged to address these deficiencies. -Current arrangements fail to link benefits with biodiversity conservation. (An issue also identified relating to facilitated access).	

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<p>(vi)</p> <p>Measures for benefit-sharing 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)</p>	<p>develop new varieties of plants.</p> <p>Work of the WIPO in relation to disclosure of origin of genetic resources</p> <p>Micro-Organism Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)</p> <p>International</p>			<p>- Contrary to paragraph 48 of the Bonn Guidelines, some arrangements fail to link benefits with biodiversity conservation</p>	

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	<p>Agricultural Research Centers of the CGIAR International data bases on plant (VIEWS) and animal (Dad-IS) genetic resources</p> <p>Ditto</p> <p>Ditto</p>				

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<p>Promoting benefit-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)</p>	<p>- ITPGRFA (Arts. 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</p>	<p>- CBD (Art. 15.6 and 15.7) - Common Policy Guidelines for Botanical Institutions includes examples of written Material Transfer Agreements for non-commercial purposes. - IPEN Regulations</p>	<p>- 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 (France : CIRAD, IRD) - National or Regional funding for research in cooperation</p>	<p>- PIC and MAT processes rarely differentiate between acquisition for scientific purposes (e.g. taxonomy) and commercialisation. This provides a disincentive for partnerships, 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).</p>	<p>- National legislation needs to be framed in the light of these gaps and difficulties.</p>

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Measures to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources; (v)	As above.	As above.	As above. -See also Nordic Council of Ministers Declaration and Strategy above as well as 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 Multilateral system. No demands for benefit sharing will be made when handing out material	As above.	As above.
Recognition and protection of	- ILO	- CBD Art. 8(j)		-Identifying	- Governments should

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<p>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 of conduct/Models of prior informed consent or other 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</p>	<p>Convention No. 169 Concerning Indigenous and Tribal Peoples in Independent Countries (especially Articles 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.</p>	<p>and decisions related thereto. - Bonn Guidelines, para. 31.</p>		<p>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.</p>	<p>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 this procedures. - WIPO's work on recognition of prior art should be concluded.</p>

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indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j); (x)	ITPGRFA (Art. 9.2(a) on Farmers' Rights) WIPO's work on recognition of prior art in the use of genetic resources				
Derivatives Addressing the issue of derivatives; (xii)		A very specific and tailor-made definition only for their purposes is to be found in the Principles and Common Policy for		- There is no common understanding of what is meant by derivatives.	

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		Botanical Institutions Guidelines line: Derivatives includes, but are not limited to any progeny, extracts and compounds obtained from genetic resources and analogues of those compounds”			
Promotion and enforcement mechanisms of the international regime and compliance with PIC and MAT Monitoring, compliance and enforcement; (xx)	- Art. 12.5 of the IT.	- Bonn Guidelines Section V, (B,C,E,F) - CGIAR: policy	<u>Arbitration</u> : in France, the New Civil Code of Procedure governs international arbitration in its		- Disputes between parties agreeing on MAT must be resolved by domestic law. - Bonn Guidelines: relevant provisions

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Dispute settlement, and/or arbitration, if and when necessary; (xxi)	<p>- Dispute settlement/arbitration is likely to be covered in the standard MTA of the ITPGRFA</p> <p>International conventions on conflicts arising from international contracts : <u>conflict of laws and jurisdiction</u> (European Community Convention on the Law Applicable to</p>	<p>statements of ABS relevance of particular relevance are those that deal with aspects of third person use of genetic material delivered by the CGIAR institutes.</p> <p>ditto</p>	articles 1492 to 1507		<p>could be implemented nationally.</p> <p>- Compliance with the provisions of PIC should be a matter for the provider country.</p> <p>- Compliance with MAT should be embedded in the contractual arrangements under which the MAT functions, using the provisions of civil law.</p>

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	Contractual Obligations (Rome, 1980), Convention on the Law Applicable to Agency (The Hague, 1978)) ; <u>Conciliation</u> (Resolution 57/18 UNGA);				

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<p>Measures to ensure compliance with the mutually agreed terms on which genetic resources were granted and to prevent the unauthorized access and use of genetic resources consistent with the Convention on Biological Diversity; (xi)</p> <p>Measures to ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity; (ix)</p>	<p>Judicial cooperation at the different procedural stages:</p> <ul style="list-style-type: none"> - <u>Investigation</u> through the Convention on the Taking Evidence Abroad in Civil or Commercial Matters (The Hague, 1970); - <u>Notification of judicial actions</u>, through the Convention on the Service 	<p>Ditto</p> <p>Ditto</p>	<p>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 through an EU network ; in France, judicial assistance is defined by law no 91-1266, 18 December 1991, and open to non-nationals)</p>		

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	<p>Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters (The Hague, 1965);</p> <p>- <u>Enforcement of arbitral awards</u> through the United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York, 1965)</p>				

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<p>Functioning of the international regime</p> <p>Measures to facilitate the functioning of the regime at the local, national, subregional, regional and international levels, bearing in mind the transboundary nature of the distribution of some in situ genetic resources and associated traditional knowledge; (viii)</p> <p>Means to support the implementation of the international regime within the framework of the Convention; (xix)</p> <p>Institutional issues to support the implementation of the international regime within the framework of the Convention;</p>	<p>The Patent Law Treaty and the Patent Cooperation Treaty governed by</p>		<p>Databases held by national patent offices (where the origin of the genetic resource is part of the</p>		<p>- These might be key components/instruments of any new international regime on ABS.</p> <p>- Inst. Issues: The Clearing House Mechanism (CHM) could have an enlarged role for example, as recipient of the notifications of disclosure of origin in patent applications.</p>

Elements ^{3/}	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD ^{4/}	Relevant provisions of existing international instruments within the framework of the CBD ^{5/}	Relevant provisions of existing regional and national instruments, and relevant processes ⁶ (see endnotes)	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
<p>(xxii) Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge; (xiii) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights; (xiv) Capacity-building measures</p>	<p>the World Intellectual Property Organization (WIPO) are relevant for disclosure of origin/ source/ legal provenance. Potential amendments to these agreements are currently being debated in WIPO's Intergovernmental Committee on Intellectual Property and Genetic</p>		<p>description of the invention).</p>		<ul style="list-style-type: none"> - The EU proposal 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 use of genetic resources. - 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

Elements ^{3/}	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD ^{4/}	Relevant provisions of existing international instruments within the framework of the CBD ^{5/}	Relevant provisions of existing regional and national instruments, and relevant processes ⁶ (see endnotes)	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
based on country needs (xvii)	<p>Resources, Traditional Knowledge and Folklore (IGC)</p> <p>Paragraph 19 of the Doha Declaration, instructs the TRIPS Council to continue the review of Article 27.3(b) TRIPS, and to examine the relationship between TRIPS and CBD and (TK)</p>				strategy in every Party, though it should not be necessary to legislate for this.
Poverty eradication					- National authorities should set up the

Elements ^{3/}	Relevant provisions of existing international instruments, and relevant processes outside the framework of the CBD ^{4/}	Relevant provisions of existing international instruments within the framework of the CBD ^{5/}	Relevant provisions of existing regional and national instruments, and relevant processes ⁶ (see endnotes)	Identified gaps	At what level, national, regional or international, and how should the gaps be addressed?
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 sustainability; (vii)					mechanisms so that the benefits from the granted access revert to conservation of the environment of the local communities. These could cover, for example, environmental education programmes, sustainable projects which would help in the fight against poverty.

Summary assessment of major gaps and possible manners of filling them based on the analysis contained in the matrix in Annex B of the SCBD Notification

Major gaps remaining:

1. Awareness raising and education of administrators and stakeholders in the public and private sectors at all levels and in the institutions of all Parties: lack of awareness on the concepts and requirements of ABS issues is a major impediment to driving forward implementation.

2. Overall there is a lack of transparency in relation to national legislation and/or procedures on ABS, accompanied by an insufficient use of existing available instruments: obvious examples, CBD lists of national focal points (NFP) and national competent authorities (NCA) are incomplete.

3. Where provisions exist, facilitated access (i.e. regulated/controlled access, promoting benefit-sharing and without hindering actual access) is rarely practical and effective. This fundamental element needs to be addressed since without facilitated access there are no benefits to share.

Relevant reasons include:

- a diversity of national authorities dealing with the various aspects of ABS leads to confusion, lack of effectiveness, etc and consequently intentionally or not, national legislation often impedes access due to delays, unnecessary bureaucracy, the lack of explicit procedures. It can even lead to legal uncertainty as regards authority of the different bodies and stakeholders involved in access granting procedures. These difficulties have hindered the

Possible manner of filling gaps:

1. Not generally amenable to legislation and regulation. Increased use of and awareness of CBD web-site, regional and national web-sites etc. Initiatives at national level to promote, encourage and educate through a range of instruments: publicity, stakeholder meetings, requirements of practicing institutions, etc.

2- Wide use of available mechanisms facilitated by the SCBD: website with lists of NFP and NCA.

3 - Legislation needs to be reviewed. Clarification and simplification of procedures should be encouraged. Best practice on PIC and MAT and government experience with administration of ABS should be shared., particularly:

- cohesive arrangements and coordination among competent authorities, dealing with all elements should be encouraged to address these deficiencies;

<p>potential for benefit-sharing;</p> <p>- where indigenous and local communities are involved, identifying authorised representatives and relevant laws and customs can be an impediment to recognising the rightful entities to whom benefits might accrue.</p> <p>4. Current arrangements usually fail to link benefits with biodiversity conservation. In addition, regulations governing access rarely provide for measures to guarantee that bioprospecting will not be detrimental to biodiversity conservation.</p> <p>5. Often, there is no ready differentiation between the access of material purely for scientific research purposes and potentially for commercial purposes: this is currently discouraging scientific collaboration.</p> <p>6. Monitoring of PIC an MAT is hindered by the fact that from the process from the provision of genetic resources to the commercialisation of products is long and complex and the commercial products using genetic material do not allow for ready identification of the origin or source of material.</p>	<p>- the resolution of identification etc of indigenous and local communities is a matter for national/regional consideration.</p> <p>4. National regulation could be reviewed to take into account any detrimental effects of bioprospecting on biodiversity.</p> <p>5. Any new aspects of an international regime on ABS should address this fundamental issue: this would need to recognise the global implications of the distinction between access of genetic resources for scientific collaboration and for potential commercial gains the benefits of which need to be shared. They should also be consistent with the FAO International Treaty on plant genetic resources for food and agriculture with regard to the genetic resources covered by the Multilateral System of the IT.</p> <p>6. The EU proposal to WIPO to include the disclosure of origin in patent applications as a formal condition is an important element that could enhance benefit-sharing. The Clearing House Mechanism could have an enlarged role for example, as recipient of the notifications of disclosure of origin in patent applications.</p>
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Note: This table results from a technical analysis of the available information. It should not however be necessarily assumed that the EU will seek to promote these very provisional 'conclusions' at ABS 4. This will be dependent on a number of factors, particularly the matrix information provided by other Parties, etc.

2.- Use of terms, definitions and/or glossary, as appropriate

In recommendation 3/2 the Working Party recalled decision VII/19B of the COP on the use of terms, definitions and/or glossary, as appropriate, and noted that only few Parties had submitted the requested information and that further gathering of information was necessary.

The Working Group then urged Parties that had not already done so to submit to the Executive Secretary the information and views requested by the Conference of the Parties.....

The European Community and its Member States would like to take this opportunity to re-iterate the content of their previous submission under this item. This can be found in UNEP/CBD/WG-ABS/3/INF/1, p24. Furthermore, we continue to support the request to the Executive Secretary to prepare a glossary of definitions used in relation to access and benefit sharing.

3.- Other approaches, as set out in decision VI/24B, including consideration of an international certificate of origin/source/legal provenance

In recommendation 3/3, the Working Party recalled that existing other approaches could be considered to complement the Bonn Guidelines and are useful tools in assisting with the implementation of access and benefit-sharing approaches.

It also recognised that an international certificate of origin/source/legal provenance could be an element of an international regime on access and benefit-sharing, and deserved further examination.

Parties, Governments, indigenous and local communities, international organisations and all relevant stakeholders are invited to prepare further studies and pilot projects and to report thereon to the Executive Secretary, and to submit their views on the design of an international certificate of origin/source/legal provenance, including inter alia: (a) its rationale, need and objectives; (b) the desirable characteristics/features; and (c) the practicality, feasibility and costs at national and international levels.

The European Community and its Member States were among the Parties that responded to the invitation in decision VI/24B and, inter alia, submitted their views and relevant information on an international certificate of origin/ source/ legal provenance to ABS WG-3. The relevant part of this submission is found in UNEP/CBD/WG-ABS/3/INF/1, pages 25-26.

A certificate of origin could potentially be relevant to the ABS process under the CBD by bringing more transparency to transactions related to genetic resources and facilitating the monitoring of national access laws. However, core issues of this new concept still require a careful evaluation: the objective of such a certificate; exactly what should be certified; the relationship of such certificate with the CBD objectives on conservation and sustainable use; its practicality; and cost effectiveness, etc.

The EU is convinced that discussions on the concept and details of a certificate of origin will greatly benefit from practical implementation studies.

In this regard the European Commission is financing a project to test the feasibility of an integrated conveyance system to manage access and benefit sharing issues related to microbiological resources. The project develops tools to evaluate the economic value of microbial resources and model documents to enable the tracking of microbiological resources that can widely be used by microbiologists in the public and private sector. Results should be available by the end of 2005.

The German Environment Ministry has commissioned a comprehensive and informative study on the role of certificates of origin, source and legal provenance as one of the instruments under discussion within an International ABS Regime. The study has been sent to the CBD secretariat and has been made available to participants of WG ABS3.

4.- Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Parties providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users of such resources under their jurisdiction

In paragraph 1 of recommendation 3/4, the Working Group invited Parties and Governments, in preparation for its fourth meeting, to start or continue activities as spelled out in decision VII/19E.

Paragraph 3 invites Parties to submit information, analyses and views on the activities spelled out in decision VII/19E, in particular the measures outlined in paragraphs 2 (a) to (g) of decision VII/19E, and on the implementation of the Bonn Guidelines.

Paragraph 5 invites Parties to provide information on issues they identify related to the disclosure of origin/ source/ legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights.

As regards paragraphs 3 and 5 of recommendation 3/4, the EU already provided extensive information in its submission to ABS WG-3 (see UNEP/CBD/WG-ABS/3/INF/1, pages 22-23, 29-30).

Since then, further efforts have been undertaken at both the level of the European Community and at the level of Member States.

The European Community has successfully established an internet-based portal to information on access and benefit sharing⁹ as an integral part of the EC Biodiversity Clearing House Mechanism. The EC ABS Portal is used to disseminate information relevant to the implementation of the Bonn Guidelines to ABS focal points in Member States and to a growing group of registered stakeholders from governments, research institutes, private companies and NGOs.

Furthermore, the European Community and its Member States on 16 December 2005 formally submitted a proposal on the “Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications” to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization. This proposal (in the attached annex) calls for the establishment of a multilateral requirement for patent applicants to disclose the country of origin or, if it is not known, the source of genetic resources on which an invention is based. A patent applicant who refuses to disclose this information would simply not obtain a patent: its application would not be processed until he/ she discloses. In case a patent applicant disclosed but provided incorrect information, effective, proportionate and dissuasive sanctions would apply outside the field of patent law. The creation of such a requirement, when agreed internationally, would entail changes in two intellectual property rights treaties administered by the World Intellectual Property Organization.

⁹ The EC ABS Portal can be accessed at: <http://abs.eea.eu.int>.

Belgium has amended its patent laws with the aim to contribute to transparency with regard to the geographic origin of the genetic source on which inventions are directly based. The amended law include a new formal requirement “that patent applications must contain the geographic source of the plant or animal material, if known, that formed the basis for the development of the invention”.

In early 2005, the **United Kingdom** communicated to the CBD Secretariat and made available to the Parties at WG ABS3, copies of the ‘Review of the Experience of Implementation by UK Stakeholders of Access and Benefit Sharing Arrangements under the Convention on Biological Diversity’. The Review’s recommendations relate in particular to the advantages in the short to medium term of awareness raising of the concept ABS and its requirements, and they were endorsed by UK Environment Ministers. Later in 2005 a Working Party tasked with prioritising and implementing these recommendations, will meet.

A **French** review of existing judiciary mechanisms available to address potential cases of non-compliance with ABS mutually agreed terms was briefly mentioned in document UNEP/CBD/WG-ABS/3/5. It could be related to mechanisms existing in other countries.

In 2005, the **German Ministry for the Environment** published a study on “Users of genetic resources in Germany”, which was made available to participants of the WG ABS 3. The study is an analysis of the level of awareness and knowledge of ABS regulations of users of genetic resources in Germany and gives recommendations on how to improve stakeholders involvement. As follow-up, workshops with specific user groups will be held to offer them a platform to get in depth information and to exchange experiences.

Another project in **Germany** “Process-oriented development for a fair benefit-sharing model for the use of biological resources in the Amazon lowland of Ecuador” (ProBenefit, www.probenefit.de) aims at developing a suitable procedure for equitable benefit sharing for the use of biological resources and the associated indigenous knowledge in line with the principles of the CBD. To this end the project partners, together with the Ecuadorian government, the local Indian organisations and other relevant groups in society, as well as interested non-governmental organisations, will explore new models for the sustainable use of biodiversity in the Ecuadorian Amazon region.

Annex - Submission of EC and its Member States to WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore on 16 December 2004

Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications

Proposal of the European Community and its Member States to WIPO

1. Introduction

This document outlines the basic features for a balanced and effective proposal on the disclosure of genetic resources and associated traditional knowledge (TK) in patent applications.

The European Community and its Member States already agreed in the 2002 Communication to the TRIPs Council to examine and discuss the possible introduction of a system, such as a self-standing disclosure requirement, that would allow States to keep track, at global level, of all patent applications with regard to genetic resources.¹⁰ Since 2002, several developments in WIPO, WTO, FAO, the CBD and other relevant fora have contributed to the discussion. More recently, the Conference of the Parties of the Convention on Biological Diversity has invited WIPO to examine issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, inter alia, options for model provisions on proposed disclosure requirements.¹¹ The WIPO General Assembly of 2004 decided that WIPO should respond positively to this invitation. The present proposals reflect the position of the EC and its Member States on this issue.

¹⁰ Communication by the EC and its Member States to the TRIPs Council on the review of Article 27.3 (b) of the TRIPs Agreement, and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore (WTO document IP/C/W/383).

¹¹ See document WIPO/GRTKF/IC/6/13.

2. A binding disclosure requirement that should be applied to all patent applications

In the 2002 Communication to the TRIPs Council, the EC and its Member States expressed their preference for a requirement that should be applied to all patent applications. The EC and its Member States also consider that the disclosure obligation should be mandatory. This implies that the disclosure requirement should be implemented in a legally binding and universal manner. A global and compulsory system creates a level playing field for industry and the commercial exploitation of patents, and also facilitates the possibilities under Article 15(7) of the CBD for the sharing of the benefits arising from the use of genetic resources.

The introduction of such a scheme should take place in an efficient and timely way, and be related to the existing international legal framework for patents. In order to achieve such a binding disclosure requirement, amendment of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and, as the case may be, regional agreements such as the EPC will be necessary. The disclosure requirement then applies to all international, regional and national patent applications at the earliest stage possible.

3. The country of origin or, if unknown, the specific source of the genetic resource should be disclosed

It is suggested that, in order to provide patent applicants with a clear idea of what needs to be disclosed, the language used here should be the same as in the CBD definitions of country of origin, genetic resources and genetic material.¹²

First, the material that would be the subject of the requirement: Article 15 (7) of the CBD states that access and benefit-sharing objectives must be met with regard to “genetic resources”. It is therefore coherent to use the universally accepted CBD language. “Genetic resources” is defined in Article 2 CBD as “genetic material of actual or potential value”. The same provision states that “genetic

¹² This proposal does not include the disclosure of the source in patent applications based on genetic resources or traditional knowledge acquired before the entry into force of the CBD.

material” includes “any material, of plant, animal, microbial or other origin containing functional units of heredity”. In this context, human genetic resources are excluded¹³, and this exclusion should be carried over to the proposed system.

Second, the origin of the genetic resource: a disclosure of origin requirement would assist countries providing access to genetic resources to monitor and keep track of compliance with national access and benefit-sharing rules. On this basis, the applicant should be required to declare the country of origin of genetic resources, if he is aware of it. No additional research on his part would be required. It is the disclosure of the country of origin that paves the way for monitoring the respect of the rules on access and benefit-sharing, where such rules are in place.

The CBD defines the “country of origin” as the country which possesses those genetic resources in *in situ* conditions. Under the CBD, “*in situ* conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.¹⁴

It is clear that it may not always be possible for the patent applicant to indicate the country of origin. In these situations, it is suggested to make use of the broader notion of “source”. If the country of origin is unknown, the applicant should declare the source of the specific genetic resource to which the inventor has had physical access and which is still known to him. The term “source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a research centre, gene bank or botanical garden.¹⁵

Third, the connection between the material and the patented invention: the applicant must have used the genetic resources in the claimed invention. A notion should be applied that

¹³ As clarified by the CBD COP Decision II/11, paragraph 2.

¹⁴ Article 2.

¹⁵ This other source can include the “Multilateral System” as a source of genetic resources belonging to taxa included in annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture. According to Article 12.3 (b) of the International Treaty, “access shall be accorded expeditiously, without the need to track individual accessions”. The Multilateral System is the source of the genetic resources, as well as the beneficiary of the sharing of profits from their commercialisation.

makes it possible for the applicant to disclose the material used in the invention in an adequate way, without having the obligation to make further research on the origin of the resource, taking into account the interests of the applicant, the patent office and other stake holders. A good balance can be found by requiring that the invention must be “directly based on” the specific genetic resources. In such circumstances, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource. The inventor must also have had physical access to the genetic resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource that are relevant for the invention.¹⁶

4. Disclosure of associated traditional knowledge

In this specific case, there are good reasons for an obligation to disclose that an invention is directly based on traditional knowledge associated with the use of genetic resources. According to Article 8 (j) of the CBD, there is a commitment to respect, preserve and maintain traditional knowledge.¹⁷

Traditional knowledge is of intangible nature and the obligation to disclose cannot be based on physical access. It could therefore be proposed that the applicant should declare the specific source of traditional knowledge that is associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge. In this context, the European Community and its Member States refer to Article 8 (j) of the CBD where the notion “knowledge, innovations and practices” is used.

However, there are concerns about the possibly unclear scope of the term "traditional knowledge". In order to achieve the necessary legal certainty, a further in-depth discussion of the concept of TK is necessary.

¹⁶ See similarly the additional comments by Switzerland on its proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications, PCT/R/WG/6/11, paragraph 27.

¹⁷ The Bonn Guidelines adopted under the CBD to implement its Articles 15 and 8(j) address specifically all genetic resources and associated TK.

5. A standardised and formal requirement

In order to become effective, the way that the relevant information will be submitted from the patent applicant to the patent offices must be standardised. This should be organised in a non-bureaucratic and cost-efficient manner. An overwhelming majority of patent applicants do not base their inventions on genetic resources and/or associated TK and for them the burden should be limited to an absolute minimum.

Competent patent authorities, in particular patent offices, are not required to make an assessment on the content of the submitted information. They must also not be obliged to keep track whether the patent applicant has obtained the relevant material in a way compatible with benefit-sharing and prior informed consent provisions. Their role can be limited to checking whether the formal requirements are fulfilled, in particular, whether the applicant who declares that the invention is directly based on genetic resources and/or associated TK has subsequently disclosed information.

The EC and its Member States propose that the disclosure of the information be organised by including questions to be answered in the standard patent application form. The applicant then can give either a negative or a positive response to the question whether the invention is directly based on genetic resources and/or associated TK. If the answer is negative, the applicant does not need to fulfil any other administrative requirement on this issue. A positive answer triggers the requirement to disclose the country of origin or source as foreseen. In the exceptional case that both the country of origin and the source are unknown to the applicant, this should be declared accordingly.

If the patent applicant fails to give a negative or positive response, or if he fails or refuses to disclose information on the country of origin or source in cases where he claims that the invention is directly based on genetic resources and/or associated TK, the patent application is not shaped in accordance with formal requirements, except where the applicant has declared that the country of origin and the source are unknown to him. An applicant should be given the possibility to remedy the omission within a certain time fixed under patent law. However, if the applicant continues to fail to make any declaration, then the application shall not be further processed and the applicant will be informed of this consequence.

6. What should happen in cases of incorrect or incomplete information?

Meaningful and workable sanctions should be attached to the provision of incorrect or incomplete information. Where it is proved that the patent applicant has disclosed incorrect or incomplete information, effective, proportionate and dissuasive sanctions outside the field of patent law should be imposed on the patent applicant or holder. If the applicant provides supplementary information during the processing of the application, the submission of this supplementary information should not affect the further processing of the application. For reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers.

It must be left to the individual Contracting State to determine the character and the level of these sanctions, in accordance with domestic legal practices and respecting general principles of law. Both within WIPO as in other international fora means could be discussed to develop such sanctions.

7. Exchange of information

An indispensable measure that makes the disclosure requirement outlined in the previous sections an effective incentive to comply with access and benefit-sharing rules is the introduction of a simple notification procedure to be followed by the patent offices. The latter, every time they receive a declaration disclosing the country of origin or source of the genetic resource and/or associated TK, should notify this information to a centralised body. This could be done, for instance, by means of a standard form. That would facilitate the monitoring – by countries of origin and TK holders – of the respect of any benefit-sharing arrangements they entered into. The relevant information must be made available in accordance with the present rules on the confidential nature of applications.

The notification should be as simple as possible and must not lead to an unnecessary administrative burden for patent offices. The exchange of information should also be

managed in a cost-effective way and without unnecessary additional charges imposed on patent applicants. This could be achieved, for example, by using electronic means.

It would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the information available from the declarations on disclosure.

8. Summary

In summary, the EC and its Member States propose the following:

- a) a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications;
- b) the requirement should apply to all international, regional and national patent applications at the earliest stage possible;
- c) the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him;
- d) the invention must be directly based on the specific genetic resources;
- e) there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge; in this context, a further in-depth discussion of the concept of "traditional knowledge" is necessary;
- f) if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed;
- g) if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law;
- h) a simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

These proposals attempt to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system for disclosure in patent applications.
