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THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING OF GENETIC RESOURCES: ANALYSIS AND IMPLEMENTATION OPTIONS FOR DEVELOPING COUNTRIES

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LIST OF ACRONYMS

ABS	Access and benefit sharing
ASEAN	Association of South East Asian Nations
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
COP	Conference of the Parties
COP/MOP	Conference of the Parties serving as the Meeting of the Parties
CPB	Cartagena Protocol on Biosafety
EU	European Union
GRULAC	Group of Latin American and Caribbean Countries
IARCs	International Agricultural Research Centres
ILCs	Indigenous and local communities
IPR	Intellectual Property Rights
LM-APAC	Like-Minded Asia Pacific Countries
LMMC	Like-Minded Megadiverse Countries
MAT	Mutually agreed terms
PIC	Prior informed consent
TK	Traditional Knowledge
UNEP	United Nations Environment Programme
WHO	World Health Organisation
WTO	World Trade Organisation

1. INTRODUCTION

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation to the Convention on Biological Diversity ('the Protocol') was adopted in the wee hours of 30 October 2010. It marked the conclusion of a long and arduous negotiation process based on a mandate established at the 7th meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) held in Kuala Lumpur in 2004. This in turn was prompted by the call by the World Summit on Sustainable Development in 2002 at Johannesburg for the establishment of international rules to ensure that benefits flowed to mainly developing countries that provided genetic resources. Benefit sharing had remained an empty promise since this highly subscribed environmental treaty - the Convention on Biological Diversity (CBD) - came into effect a decade earlier. The negotiations stretched over 6 years and were conducted through a wide variety of rather creative modes. Finally it was a text crafted by a small unelected group that was presented for adoption by the Japanese Presidency in the closing hours of the deadline given for the adoption of the Protocol. At best it may be described as a partially negotiated text.

The Protocol opened for signature by parties to the CBD on 2 February 2011 and comes into effect after 50 States ratify it.

This paper analyses the key components of the Protocol and presents the options for implementing it for developing countries. Their concerns may be secured through decisions of the Conference of the Parties serving as the Meeting of the Parties (COP/MOP). COP/MOP is explicitly mandated to keep under regular review the implementation of the Protocol and must make decisions necessary to promote its effective implementation (Article 26.4). In addition, or alternatively, their interests may be expressed in their national ABS law. Indeed, the Protocol requires national action to implement its substantive obligations.

2. THE KEY COMPONENTS

2.1 Objective

The objective of a Protocol provides the reason for which the Protocol was enacted. More specifically it provides the context for interpreting the rest of the specific operative clauses. The objective thus helps to resolve cases of divergent interpretation, possible conflicts between different provisions and assists in dispute settlement. This provides important guidance for those charged with implementing the Protocol at the international level - COP/MOP (Article 26); as well as national implementing authorities. Certain provisions in the Protocol measure the validity of an action by reference to whether or not it is in accord with its objective. For example, any other specialised international instruments or agreements dealing with access and benefit sharing ('ABS') which Parties enter into must 'be supportive of and not run counter to the objectives of the Protocol' (Article 4.2, 4.3 and 4.4). Finally, the objective provides the basis upon which the mandatory evaluation of the effectiveness of the Protocol may be accomplished under Article 31.

There is a single objective established - the fair and equitable sharing of the benefits arising from the utilisation of genetic resources (Article 1). Every obligation or decision taken in the implementation of the Protocol must be directed to achieving the objective. It would not, for example, be in conformity with this Article to pursue policies of access to genetic resources without ensuring the fair and equitable sharing of benefits derived from their utilization.

Important legal consequences also flow from this Article for those who sign the treaty but have not ratified it; as well as those who ratify it but for whom the treaty has yet to enter into force. Article 18 of the Vienna Convention on the Law of Treaties obliges a state that has signed a treaty or expressed its consent to be bound by it, to refrain from acts that would defeat the object and purpose of the treaty, pending the entry into force for it of the treaty.

The Article also states the prime ways by which the objective is expected to be achieved, namely: by appropriate access to genetic resources, by appropriate transfer of relevant technologies and by appropriate funding. This requires adequate and specific provisions in the Protocol obliging Parties to give effect to the fulfillment of these important facets.

2.2 Access

The CBD does not require a country to enact any law or regulation requiring its prior informed consent (PIC). It states quite simply that *'access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party'* (Article 15.5). This establishes an absolute obligation on those wishing to access genetic resources to obtain the consent of the Contracting Party unless that Party waives that right. The Protocol seems to require the enactment of such a law as a precondition for the PIC of the provider country. Some developing countries had sought to exclude such a condition as it implies that if a country has no specific ABS law or regulatory requirements, access could proceed legitimately without the PIC. This could well condone and promote biopiracy. The Protocol thus imposes a requirement additional to that in the CBD, which could have ramifications. Provider countries that do not develop any specific law or requirements to regulate access may not be able to require countries to enforce user country compliance measures. Further a Party may need time to enact an ABS law even after the Protocol comes into force for it. This, especially in the case of developing countries, could be because of a lack of capacity in formulating a law as well as in setting up the necessary infrastructure in support of its implementation. The Protocol recognizes the need to support capacity building measures in developing countries. One such measure includes legal and institutional development (Article 22.5(a)). The experience of countries in implementing the CBD is instructive. More than a decade after the CBD came into force only some 27 countries (of which 19 are developing countries) had informed the secretariat of the establishment of a national competent authority (http://www.cbd.int/doc/lists/nfp-abs-cna.pdf; accessed on 27/2/2011). Although some 54 Parties have established ABS measures – which also includes strategic and action plans (http://www.cbd.int/abs/measures; accessed on 27/2/2011) it appears that a minority of developing countries have binding and operational ABS laws. If Parties to the Protocol, especially provider developing countries, are slow to enact a law either access may not be facilitated or access may continue without the PIC of these countries. The objective of the Protocol - to ensure benefit sharing - will be undermined, with deleterious consequences for the conservation and sustainable use objectives of the Protocol (Article 1) and the CBD (Article 1).

This situation needs to be addressed by a Conference of the Parties serving as a Meeting of the Parties to the Protocol (COP/MOP) once the Protocol is ratified.

Developing countries that do not have, or cannot enact for the time being, an ABS law should formally establish a policy or administrative measure that states that PIC and MAT along the lines of the Nagoya Protocol and the CBD is required for any access to their genetic resources, biochemical components derived from genetic resources and traditional knowledge (TK) associated to genetic resources. This should also be notified to the ABS Clearing-House. In the meantime they should work speedily towards enacting an ABS law or other regulatory requirement or a more comprehensive administrative or policy measure.

The latitude in the CBD for a country to determine conditions for access (Article 15.1, CBD) as it deems fit in the exercise of its sovereign right seems to have been curtailed. The Protocol was intended to confirm and expand on the rights already secured by the CBD. What it now provides are elaborate procedural requirements to facilitate access.(Article 6). These requirements must be included in the law, administrative or policy measures of provider countries. The following must be reflected in such law or other measures:

a. An obligation to ensure that the law fulfils the general criteria of legal certainty, clarity and transparency. Developed countries justified this requirement on the ground that only then could user countries be able to enforce the laws of the provider country. The transparency requirement may be satisfied by posting the law and other requirements on the ABS Clearing House established by the Protocol. However, the other general requirements of legal certainty and clarity are less amenable to an objective assessment. Who decides whether a country's law satisfies this requirement? The Protocol neither sets out the criteria nor the mechanism by which this may be objectively determined. This provides for legal uncertainty.

It is important for developing countries to ensure, through a COP/MOP decision, that the determination as to what constitutes such criteria is not left to the subjective discretion of the country of the user ('user country').

b. An obligation to supply information on how to apply for PIC.

c. An obligation for the competent national authority of the provider country to give:

(i) a 'clear and transparent written decision';
(ii) … in a cost effective manner, and,
(iii) … within a reasonable period of time.

d. An obligation to set out the criteria and/or processes for obtaining the PIC, or the approval and involvement, of indigenous and local communities for access to genetic resources, if this is a requirement of domestic law.

e. An obligation to provide for fair and non-arbitrary rules and procedures on access. The genesis of this provision was the proposal by Canada made in Working Group 7 in Paris in 2009 for foreign applicants for access to be treated in the same way as nationals; and for all nationals of all foreign countries to be accorded the same favoured treatment given to any other foreign national. In WTO parlance, these are known as the 'national treatment' and 'most favoured nation treatment' principles that underpin this trade treaty. The EU couched it differently but to much the same effect. Its proposal, made at Working Group 6 in 2007 was:

An international commitment of parties to ensure that their national access rules apply in a non-discriminatory way. Developing countries, right from the outset, questioned the relevance of these trade-related provisions in an ABS Protocol, and its encroachment on the sovereign right of countries to determine conditions for access. At Working Group 9 in Cali in March, 2010 a compromise text was suggested by the Co-Chairs as follows:

> (an obligation) *'to set up clear and fair rules and procedures that do not arbitrarily distinguish between national and foreign users.'*

It was rejected by developing countries for much the same reason. Developed countries, in particular the EU at the ABS International Negotiating Group in Montreal in September 2010, then metamorphosed it into the present formulation:

> (an obligation) '*to provide for 'fair and non-arbitrary rules and procedures on accessing genetic resources;'*

This terminology masks the continuing intent of developed countries to reach their objective by other means. During the final lap of negotiations at Nagoya in October 2010, the EU confirmed that this referred to no more than a reference to procedural justice.

That should be the meaning accorded to this provision. A provider Party is entitled in its national law to establish different classes of applicants, such as local researchers, foreign researchers, public research institutions or foreign research institutions. The rules and procedures for dealing procedurally with applications for access may differ according to any such classification. However, the substantive decision on whether or not to grant access remains the prerogative of the provider Party.

f. An obligation to issue a permit or equivalent at the time of the access. Such a permit or equivalent is evidence of the decision of a country to grant PIC and of the establishment of MAT (Article 6.3(e) and Article 14.2(c)). The permit or equivalent also forms the basis of an internationally recognised certificate of compliance. Once the permit is made available to the ABS Clearing House, it automatically acquires the status of such an international certificate (Article 17.2). As there is a mandatory requirement to notify the issuance of the national permit to the Clearing House (Article 6.3(e)), all national permits issued and notified would thus convert to the status of internationally recognised certificates. It is restated that such a certificate shall serve as evidence that the genetic resource which it covers has been accessed in accordance with PIC and that MAT has been established as required by the legal requirements of the Party providing the resource (Article 17.3).

g. An obligation to establish clear rules and procedures for requiring and establishing MAT: mutually agreed terms will invariably be included in a contract. There is a short list of some of the terms which may be included. These are: a dispute settlement clause, terms on benefit sharing - including in relation to IPRs, terms on subsequent third party use, and terms on change of intent. These latter two terms are of considerable importance to provider countries. They may provide for the need to secure a fresh PIC and/or MAT if there is any intent to transfer the resource to a third party, or any intent to change the use of the resource from that for which the access was initially granted.

h. Finally, Parties must inform the Secretariat of their designated focal point and national competent authority or authorities no later than the date when the Protocol enters into force for that Party (Article 13). The focal point is obliged to make information available on

the procedures for obtaining PIC and MAT for both genetic resources as well as TK associated to these resources. The competent authority also has the same function - providing information on procedures and requirements for obtaining PIC and MAT. There is no corresponding requirement applicable to the obligation or responsibility of the competent authority in a user country. Additionally, the competent authority is responsible for granting access or issuing the written evidence for the grant of access and advising on applicable procedures and requirements for obtaining PIC and entering into MAT. Detailed information about the national focal point and the national competent authority must be conveyed to the secretariat which must make it available through the ABS Clearing House (13.5). Such information includes: where there is more than one such national authority, the specific responsibilities of each such authority, also which authority is responsible for the genetic resources sought and changes of any focal points or competent authority (Article 13.4).

These are elaborate and detailed obligations designed to facilitate access. Developing countries started the negotiations with a clear position that there could be no compromise of their sovereign right to act in accordance with their sovereign right to decide upon the establishment, if any, of conditions for access through their national law. As access was one of the first components to be negotiated, developing countries felt that their flexibility in conceding to some aspects relating mainly to transparency and legal certainty (making and communicating access decisions on time, providing information of their rules on access) would result in reciprocal concessions on compliance. Developing countries were prepared to concede that the benefit sharing objective of the Protocol necessitated the grant of appropriate access and the establishment of clear procedural requirements. The quid pro quo – as set out in the objective - was the establishment of adequate and equally elaborate user measures to ensure compliance with the PIC and MAT of provider countries, the appropriate transfer of technology and appropriate funding. This would hold the balance evenly between provider countries and user countries.

Hence, developing countries need to ensure that these specific access obligations are balanced with similar detailed provisions on compliance, transfer of technology and appropriate funding through an appropriate COP/MOP decision. (These provisions are discussed later in the following section.)

In the meantime, developing countries should incorporate these specific rules required by the Protocol in accordance with the preceding discussion in a law, or administrative or policy measure. They also must notify the Clearing-House of their focal point and/or the national competent authority.

2.3 Compliance

For developing countries, compliance was at the 'core of the core' of the Protocol. Recurring reports of cases of biopiracy underlined their concern of the continuing expropriation of their resources without any sharing of benefits. At all stages of the negotiations, developing countries maintained that weak compliance provisions would mean an insignificant and unacceptable Protocol. The opening statement at Nagoya by Brazil on behalf of the Like Minded Mega Diverse Countries (LMMC), the Like Minded Asia Pacific Countries (LM-APAC) and the Group of Latin American and Caribbean Countries (GRULAC) expressed commitment to a Protocol that would be ' ... significant in stopping biopiracy and efficient in benefit-sharing. Therefore, a Protocol that includes derivatives, and a Protocol with strong compliance measures'.

What developing countries had maintained throughout the negotiations with respect to compliance were: clear obligations by countries with users in their jurisdiction to take effective measures against misappropriation, a specification of the measures, the establishment of monitoring and tracking measures in support of compliance, designated checkpoints to monitor and track the use of genetic resources, derivatives and TK, patent offices as one such checkpoint, and finally sanctions for non-compliance.

What the Protocol finally provides for is now examined in greater detail.

Parties are obliged to take 'appropriate, effective and proportionate legislative, administrative and policy measures' to ensure that genetic resources utilized within their jurisdiction have been accessed in accordance with the prior informed consent and that mutually agreed terms have been established, as required by the domestic ABS law or regulatory requirements of the other Party (Article 15.1). These are known as ‘user country measures’, or simply as 'user measures'. The obligation relates to ‘utilisation of genetic resources’ within the user country. This term is defined by the Protocol to mean research and development of the genetic resource and/or its biochemical component (that is, derivatives). As benefits must be shared arising out of the utilisation of the genetic resource as well as subsequent applications and commercialisation (Article 5.1), user country measures must necessarily extend to such applications and commercialisation.

This is a novel obligation and for the first time meets the demand by provider (mainly developing) countries for user (mainly developed) countries to establish such mandatory compliance measures. This is buttressed by the further obligation to take appropriate, effective and proportionate measures to address situations of non-compliance with the user measures established (Article 15.2). The effect is that user countries must ensure that users within their jurisdiction who carry out research and development of the genetic resource and derivatives do so in compliance with the law and other regulatory requirements of the provider country. **Research and development is not defined. It is open to national law to define it widely to cover the whole chain - any stage of research, development, modification, innovation, pre-commercialisation and commercialisation in relation to the resource acquired.** They must put in place 'effective, appropriate or proportionate' measures that ensure that the resource has been legally accessed and its utilization in compliance with the provider’s country’s laws and legal requirements; and that benefit sharing provisions are in place. Further they must also establish ‘effective, appropriate or proportionate' sanctions for failure to comply with the measures they have established.

However the Protocol does not set out the criteria for what constitutes such 'effective, appropriate or proportionate' measures.

Developing countries need to establish, through a COP/MOP decision, clear and objective criteria for such measures.

National law could also provide for such measures in support of compliance with domestic law or regulatory ABS requirements of provider country Parties. An example is the Norwegian law which provides that 'the import for utilization in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent. The state may enforce the conditions by bringing legal action on behalf of the person that set them. (Nature Diversity Act No 100, 2009, section 60).

A generic provision could be in these terms:

a. Every biological resource obtained from the jurisdiction of a Party to the Protocol which requires by its law or regulatory requirements a valid permit or equivalent issued by the said Party for access to such resource shall be accompanied by such valid permit or equivalent.

b. The National Competent Authority shall establish measures aimed at preventing the use within the country of the biological resources which do not have such a permit or equivalent.

c. A notification by a competent authority of the Party to the Protocol that it has not issued a permit or equivalent for access to its biological resources shall be prima facie evidence of this fact.

A further provision in the law or policy could provide for denial of access to users of countries that have not established such effective measures.

Further, the laws or regulatory requirements that must be adhered to must be that of the *'other Party'*. This last qualifier departs from the language elsewhere in the Protocol (for example in Article 5.1), based on Article 15.3 of the CBD, that the resources accessed must be those that are provided by the countries of origin of such resources or the Parties that have acquired the resources in accordance with the CBD. Concerns have been raised that departing from this CBD formula may countenance biopiracy as the following example shows. Resources may have been accessed illegally from a country of origin X, by another country Y. If a user accesses these from country Y ('the other Party') in compliance with the ABS law of country Y, the user country may argue that it does not have to ensure compliance with the ABS requirements of the country of origin X. **Developing countries must ensure that a COP/MOP decision brings this provision in line with the provisions of the CBD and the other provisions of the Protocol as to the country whose ABS law must be complied with.**

The law of a provider Party may require any subsequent third party use and/or change of intent of use to be subject to fresh PIC and MAT. This will most probably be reflected in MAT. The Protocol requires Parties to establish clear rules for MAT which may include such terms - Article 6.3(g)(iii) and (iv). If the law or other regulatory requirement of the provider Party requires PIC and MAT in these situations, then the user measure must provide for this as is made obligatory by Article 15.1 - to take measures to provide that genetic resources utilised within its jurisdiction have been accessed in accordance with PIC and that MAT has been established, as required by the domestic ABS law or regulatory requirements of the provider Party. Operationalising this provision, however, may be problematic. Requiring the checkpoint to peruse the contents of the contract to ascertain its terms may not be practically feasible and impose an onerous burden. Article 17.1(a)(i) requires the checkpoint to do no more than collect/receive information as to the establishment of MAT. The only practical solution is for the provider Party to set these terms in the international certificate of compliance - that is the use for which the access was granted, and/or the consequences of a transfer of the resource - for example whether the transfer is allowed or prohibited; as well as the terms for any such transfer – such as the need for PIC and/or MAT. The Protocol allows for the inclusion of such additional terms (Article 17.4).

Developing countries should enact in their law a provision as to whether or not fresh PIC and/or MAT is required for subsequent third party use and/or change of intent of use.

If they require fresh PIC and/or MAT, this fact should be clearly stated in the permit or equivalent that they issue - which upon posting on the Clearing-House becomes the international certificate of compliance. The use for which the permit is granted should also be stated; as well as the fact that no subsequent third party use is allowed and that the permit is only issued to the person or entity named.

A final clause requiring Parties to cooperate in cases of alleged violation of the domestic ABS laws, although qualified - only *'as far as possible and as appropriate',* is nonetheless of value. It envisages a situation where a wrongdoer has been identified and a remedy or sanction is being sought. A country called upon to cooperate in such a case and refusing to do so may be required to justify its refusal. Any unreasonable refusal may be the subject of non-compliance with the Protocol under procedures and mechanisms to be established by COP/MOP at its first meeting (Article 30).

2.3.1 Monitoring and Checkpoints

The Protocol establishes a clear obligation for the designation of one or more checkpoints to support compliance and to monitor and to enhance transparency about the utilisation of genetic resources (Article 17.1). The checkpoints will collect or receive relevant information related to PIC and the establishment of MAT and/or the utilisation of the genetic resource, including derivatives ((Article 17.1(a)(i)). Parties must also establish mandatory disclosure requirements by users at these checkpoints. Any failure by users must also be addressed by appropriate, effective and proportionate measures (Article 17.1(a)(ii)). Further the information will be provided to the Party providing the PIC as well as to the Benefit Sharing Clearing-House. These new plethora of compliance and monitoring measures are useful additions to protect against biopiracy.

However some concerns of developing countries articulated during the negotiations have been sidelined.

A key area of serious contention between developed and developing countries, was the prescribing of the checkpoints. Developing countries consistently argued throughout the negotiations that user countries must establish effective checkpoints. These would be places which a user would need to go to with regard to the research and development of the resource or for claiming a right in relation to the innovation made from such R&D, or for the commercialisation of any resultant product. The user would be obliged to provide pertinent information at such checkpoints. This information would include: the country of origin of the resource or the associated TK, that the prior informed consent of that country had been obtained, that MAT had been established and its essential terms adhered to, such as, whether the user had the right to the particular resource and whether a particular use was permitted by the grant of the access. Without such a checkpoint(s), developing countries asserted that compliance could well be rendered ineffectual and illusory.

For these reasons, developing countries proposed mandatory disclosure of information at intellectual property examination offices, at offices regulating products or giving marketing approval, to research institutions subject to public funding and entities publishing research results relating to the utilisation of genetic resources. These checkpoints were recommended

by an Expert Technical and Legal Group set up by the 8th Meeting of the CBD's Conference of the Parties (COP8) in Curitiba in 2006. The disclosure requirements at these checkpoints could be met by furnishing an internationally recognised certificate of compliance.

Developed countries resisted the requirement for these checkpoints. As a final compromise some developing countries proposed that: there be an indicative list of checkpoints; there should be clear criteria for what would constitute effective checkpoints; there be a time limit for Parties to notify the Secretariat of the checkpoints they designate; and that Parties that had included IP offices as checkpoints in their national law must name such offices as their designated checkpoint under the Protocol.

Almost all of these proposals by developing countries have been watered down substantially in the Protocol.

First, there is an obligation to set up 'one or more' checkpoints (Article 17.1(a)). So countries can designate just one checkpoint. The developing countries had proposed that, in such a case, the patent office be a mandatory checkpoint. This proposal has been deleted from the Protocol; as has been the proposal of an indicative list of checkpoints. Of concern is the fact that some countries made clear during the negotiations that they intended the national competent authority to be the single checkpoint. The functions assigned by the Protocol to a national competent authority is to be responsible for granting access or to advice on procedures for obtaining PIC and entering into mutually agreed terms (Article 13.2). Further, the Protocol requires the information collected from a checkpoint to be passed on to the national competent authority of the user country (as well as the ABS Clearing House and to the country providing the resource). The national competent authority, being the recipient, could hardly also be the generator of the information collected from a checkpoint. In any event, it is difficult to envision how such a checkpoint will be supplied such information and/or be able to pick up the information in relation to the use of the genetic resource as it is not a critical point at which any product, research result or other right is being presented or claimed by the user.

However developing countries succeeded in securing Article 17.1(a)(iv), which reads as follows:

Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (relating to the designation of checkpoints).*They should be relevant to the utilisation of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialisation or commercialisation'.*

This establishes the criteria for the checkpoint to be designated. Developing countries agreed to this formulation in a last ditch attempt to at least incorporate the essential elements of the effective checkpoints they had proposed. They made it clear that these criteria would capture the whole gamut covering situations when any new genetic resource or TK-based product is patented, placed on the market or otherwise dealt with: offices processing IPR applications, authorities dealing with product registration/licensing or other non-licensing marketing approvals, and public bodies that fund research and development involving genetic resources (Business week 2005: many products are brought to the market without patents and only 0.2 percent of all patents are commercially viable). These checkpoints have functions relevant to the collection of relevant information at specified stages of the utilisation of the genetic resource – as is spelt out in the subparagraph. If any doubt still subsists as to whether these are the checkpoint(s) contemplated by this provision, recourse to the negotiating history

will help clear this doubt. Such supplementary means are legitimate to interpret a particular provision in a treaty where the meaning is in doubt: Vienna Convention on the Law of Treaties, Article 32.

Developing countries should through COP/MOP require Parties to designate checkpoints that are effective. COP/MOP should make an assessment of 'effectiveness'. In particular checkpoints should be clearly places or authorities whose normal function is to collect or receive information relating to the utilisation of the genetic resource, derivatives or associated TK.

Developing countries should also designate checkpoints and include in particular IPR offices as one such checkpoint. This would have a salutary effect on users who wish to patent their innovation arising from the R&D on the resource, derivatives or associated TK; or who wish to market their resultant product. Clearly, developing countries would constitute a large market for such products.

Finally, developing countries should consider having in their national law, administrative or policy measure, a provision that no access would be given to users from jurisdictions that do not have effective monitoring measures, including effective checkpoints.

Secondly, there is no obligation to inform the secretariat or the clearing house of the designation of the proposed checkpoint. This stands in stark contrast to the requirement for the immediate notification of the appointment of a national focal point and national competent authority to facilitate access, and the elaborate related obligations (Article 13), as discussed earlier. Developing countries had proposed that Parties inform the secretariat within a prescribed time period of their designated checkpoints.

Developing countries should move for a COP/MOP decision to prescribe a reasonable period of time for such designation, taking into account the capacity of a Party.

Thirdly, the obligation for the user to disclose information at these checkpoints is couched in language that uses a notorious euphemism in international treaties - 'as appropriate' (Article 17.1(a)(ii)). This could be read as leaving it to the discretion of a Party to decide whether or not to implement the particular provision. A closer reading, however, suggests that disclosure is mandatory. The provision reads as follows:

'Each party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified ... at a designated checkpoint'.

This expression 'as appropriate' does not qualify the obligation to disclose. After all, the purpose of the checkpoint is to collect or receive information as a monitoring measure to support compliance. Without mandatory disclosure, the designation of a checkpoint would be simply quite pointless.

A COP/MOP decision should make this clear. Additionally, developing countries should include mandatory disclosure requirements in their national law or administrative or policy measure.

Fourthly, the checkpoint is entitled to refuse to supply 'confidential' information it receives to the national competent authority, the clearing house or the country requiring PIC and MAT. Who decides what information qualifies for exclusion on this ground is left open. **It is crucial that developing countries seek to restrict the kind of information for which confidentiality may be claimed through an appropriate COP/MOP decision.** The Cartagena Protocol on Biosafety is instructive. It has elaborate provisions on confidential information (Article 21) which sets out when, and how, confidential information may be claimed. The Party of import of the Living Modified Organism (LMO) can permit the exporter to identify information that is to be treated as confidential. The exporter must justify its claim. This claim may be refused, and the information disclosed, subject to certain procedural safeguards. Finally, there is also set out information that cannot be considered as confidential. The Nagoya Protocol, in stark contrast, has a bare provision vide a statement that provides for the protection of confidential information that a checkpoint will provide to national relevant authorities, the ABS Clearing-House and the Party providing PIC (Article 17.1(a)(iii)). Also the internationally recognized certificate of compliance must contain specified minimum information 'when it is not confidential' (Article 17.4). The paucity of specificity as to when and how such a claim of confidentiality can be validly raised gives rise to legal uncertainty and could become a potentially fertile ground for disputes.

Developing countries should include in their national ABS law or administrative or policy measure provisions along the lines of the Cartagena Protocol on Biosafety as to when and how confidentiality claims can be made.

Fifthly, the reference to monitoring the use of TK associated to genetic resources has been deleted from any monitoring measures including disclosure requirements. This is a serious flaw as most cases of biopiracy relate to the unlawful use of such TK. However, a preamble of the Protocol recognises:

> *'the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities'.*

Further, Parties providing the resource are obliged to take measures with the aim that TK associated with the resource is accessed with the PIC or approval or involvement of indigenous and local communities (ILCs) and that MAT have been established (Article 7). Finally the Protocol requires Parties to take measures to provide that TK utilized within their jurisdiction has been accessed in accordance with PIC or approval and involvement of ILCs and that MAT have been established as required by domestic law or other regulatory requirements (Article 16.1). Article 17.1(a)(i) requires checkpoints to collect or receive relevant information related to PIC or establishment of MAT; and sub paragraph (ii) requires users to provide this information at the checkpoints. A cumulative reading of these provisions imply that if a country requires PIC or MAT of ILCs, then this information must be supplied by the user to the checkpoints in support of compliance measures.

Developing countries should ensure that a COP/MOP decision clarifies this crucial compliance obligation. They should also require disclosure requirements at checkpoints of the TK associated with the genetic resource accessed in their national ABS law or administrative or policy measure.

Finally, there are no specific sanctions prescribed for failure to disclose the information at the designated checkpoints. Developing countries had, as a compromise, proposed that the application by users should not be processed if the applicant fails or refuses to disclose *after* being provided an opportunity to remedy the situation. Even this weak compromise proposal has been deleted from the Protocol. There is instead, however, an obligation for parties to take appropriate, effective and proportionate measures to address situations of non-compliance (Articles 15.2 and 16.2). COP/MOP is enjoined at its first meeting to approve procedures to, inter alia, address cases of non-compliance (Article 30).

Developing countries should pursue the development of such measures by COP/MOP to deter, or even punish where appropriate, the failure to provide relevant, complete and accurate information to the checkpoints.

Developing countries should also include in their ABS law or administrative or policy measure that, at the very least, the application of a user who fails to provide such information to the checkpoints will not be processed.

2.3.2 Compliance with MAT

MAT implies a negotiated contractual agreement between the provider and the user. Parties may wish to bring an action for breach of the contract in the jurisdiction of the user. This would especially avoid any problem relating to the recognition and enforcement of judgments if the action was brought in a jurisdiction foreign to the user. Hence developing countries proposed that Parties with users in their jurisdiction should grant access to justice. This would include granting access to courts or other impartial adjudication bodies in the jurisdiction, based on procedures that are fair and that provide effective remedies; and where possible, appropriate assistance mechanisms to remove or reduce financial or other barriers to such access. Developing countries sought to reflect this by adding the adjectival term 'facilitated' access to justice. Developed countries opposed this - arguing first that they did not understand the term ‘access to justice’. Later when explained that the concept was derived from the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters negotiated in the UN Economic Commission of Europe region, as well as several other international treaties to which the EU and other developed countries were a Party, the EU argued that the term had implications that they could not agree with. Some other developed countries argued that employing this term would mean according preferential treatment to litigants of provider countries over their own (user country) citizens. The final provision deletes the term 'facilitated' access. The Protocol now provides that each party must ensure that they give an opportunity to seek recourse to the courts of their country (Article 18.2). However the other facilitative measures are not specifically stated; neither does the word 'facilitated' preface 'access to justice'.

Nonetheless the term 'access to justice' does encompass these several facets. The Aarhus Convention is instructive. Widely recognised as the world's foremost international instrument promoting, inter alia, access to justice in environmental matters' (UNEP, Your Right to a Healthy Environment, 2006), it elaborates on the integral components of such access. These include an obligation to provide access to administrative or judicial procedures to challenge breaches of national law; giving the right to a wide category of persons to challenge any violation of national law in court or any other independent and impartial body, such as an ombudsman. This would include NGOs and indigenous and local communities. Importantly, access to justice also obliges a state to ensure that costs in bringing an action are not prohibitively expensive. In other words, States must provide an inexpensive, accessible

forum. All these aspects are an integral component of 'access to justice'. The Protocol obliges Parties to take effective measures to provide access to justice (paragraph 3(a) of Article 18); and requires parties to ensure opportunity to seek recourse under their legal systems (Article 18.2). However in the light of the intense objections by developed countries in the negotiations to acknowledge these facilitative components of 'access to justice', **it would be prudent for developing countries to have a decision by COP/MOP that spells out the components as universally acknowledged.**

Finally the effectiveness of this Article shall be reviewed by COP/MOP in accordance with Article 31 of the Protocol (Article 18.4). Article 31 already provides for an evaluation of the effectiveness of the Protocol beginning from 4 years after the entry into force of the Protocol. The special repeat of a seemingly superfluous provision has its justification. The issue of an ombudsman was raised by some developing countries, primarily the African Group in ABS Working Group 7 in 2009 and, later, by Peru. The text proposal however has been deleted from the Protocol. **Developing countries can pursue this proposal (for the establishment of an ombudsman) on a priority basis under this review process through COP/MOP.**

For ease of reference, the text proposal for an ombudsman by the African Group was as follows:

'The IR (International Regime) on ABS shall establish an international ABS ombudsman's office. The ombudsman's office shall be responsible for provider countries, ILCs to identify breaches of their rights and to provide aid in seeking fair and equitable resolution of disputes. The ombudsman's office shall be empowered to take action on behalf of ILCs through the binding Dispute Resolution Mechanism. The ombudsman's office shall also where necessary represent ILCs in proceedings in foreign jurisdiction, take deposition from ILCs and provide evidence of customary law and practice as and where appropriate'. *(UNEP/CBD/WG-ABS/7/5, at p. 45)*

2.4 Scope

2.4.1 Derivatives

a. Derivatives and scope

On the final day, when a text was presented to the Parties on a 'take it or leave it' basis by the Japanese Presidency of the Conference of the Parties (Nijar 2011), developing countries insisted on changing the definition in this text of the term 'utilisation of genetic resources' from *'research and development on the genetic and/or biochemical composition of genetic material'* to *'genetic resources'*. This proposed change was accepted. To reiterate: genetic material as defined by Article 2 of the CBD is limited to materials that contain functional units of heredity, hence excluding derivatives. 'Biochemical composition of genetic resources' is wide enough to include all material whether or not it includes such functional heredity units.

The final question that arises is whether this extension of the scope of the Protocol to derivatives is inconsistent with the CBD. When the CBD was negotiated the issue of derivatives was not a live issue and not considered by the negotiators. Hence the restrictive formulation of the definition of the term 'genetic resources' in the CBD. Since then –

especially in the course of the negotiations - it became clear that an ABS protocol would be emptied of its value if derivatives were not included. To reiterate, industry accesses and utilizes derivatives as it is primarily their utilization that yields benefits. And a protocol without derivatives would thus undermine the conservation and sustainable use objectives of the CBD. All this implies that when developing the Nagoya Protocol the expressions - such as 'genetic resources' – must be given an evolutionary and not a static interpretation. This is countenanced by international law and jurisprudence.

In the *Shrimp Turtle* case the Appellate Board (AB) of the WTO was required to interpret Article XX(g) of GATT which allows contracting parties to take measures relating to the conservation of exhaustible natural resources. If 'exhaustible natural resources' was interpreted in accordance with the meaning contemplated by the GATT negotiators in 1947, it would mean non-living mineral resources such as petroleum or coal reserves. They could not extend to sea turtle species. However the Board held that the term had to be interpreted in the light of evolving international legal instruments and policies to promote sustainable development. Article XX(g) and the interpretation of the term should not be frozen in time to 1947, it declared. A new interpretative context was developed when GATT was incorporated into the WTO framework in 1998. A preamble to the WTO Agreement referred to sustainable development as an objective of the WTO system.

And so in the case of the NP. It seeks to develop the ABS provisions of the CBD in accordance with its original intent to ensure benefit sharing as a crucial component that would lead to conservation and sustainable development that then further leads to more benefit sharing. Not to include derivatives would lead to an empty protocol and an absurd result – no benefits and an undermining of the CBD's objectives. The Protocol seeks to ensure that this does not happen by including within its scope the term 'utilisation of genetic resources' and defining this term to include biochemical composition of genetic resources. This is an expression that it says is in addition to the (limiting) definition in the CBD.

A treaty can be likened to the Constitution of a country. It is considered a live and dynamic document that has to be interpreted in the light of changing and evolving circumstances. Freeze it in time and you render it otiose and useless for future generations.

b. Derivatives and PIC for access

Article 5.1 states that

'...access to genetic resources for their utilization shall be subject to the prior informed consent of the Party ...'

Again applying the definition of *'utilisation of genetic resources'* which refers to '*genetic and/or biochemical composition of genetic resources',* derivatives which do not contain functional units of heredity are also included in this Article. This means that there must be PIC obtained for access to such derivatives. The argument to the contrary by the European Union cannot be sustained. (Council of the European Union, DS 1803/10, Brussels, 12 November 2010 at p. 3: *'Importantly, the Protocol does not support self-standing prior informed consent requirements for access to biochemicals that are not anymore contained in genetic material'.)*

To reiterate, the term 'utilisation' when referenced directly or indirectly to genetic resources has a special meaning under the Protocol. This was what the Parties intended. This special

meaning must then be given to the term, according to the rules of interpretation of treaties (Vienna Convention on the Law of Treaties, Article 31.4). The expression read in its normal English usage seems to suggest that the purpose of the access is for their use. However the term employed is 'utilisation' not use. This term has been given a specific meaning. It does not mean 'to use' the genetic resources as defined in the CBD. That the Article does not reproduce the term exactly as it appears in the definition (*'utilisation of genetic resources'*) matters not. Working Group 9 *bis* meeting agreed when developing an understanding of the term that it may be expressed in varied grammatical ways depending upon the context in which it appears. The person who first extracts the biochemical composition of the genetic resource would no doubt have to obtain the PIC of the provider country that is the country of origin. Similarly, any person accessing the extract from wherever – the naturally occurring biochemical composition (and not the genetic resource) – for R&D would need to ascertain the country of origin and obtain PIC. Note that 'naturally occurring' derivatives excludes products

c. Derivatives and benefit sharing

Article 5.1 states that

"Benefits arising from the utilization of genetic resources as well as subsequent applications and commercialisation shall be shared in a fair and equitable way with the Party providing such resources …'

Again clearly the benefits arising from derivatives are included by the definition of the term *'utilisation of genetic resources'* as explained earlier. The use of the expression 'as well as' should not be construed as indicating a difference between R&D and the subsequent applications and commercialization. As discussed earlier, utilization of genetic resources refers to R&D and this term could be interpreted to include all stages of the research and development on the genetic resource and the derivatives right up to the stage of commercialization of any product developed, although it is acknowledged that this may well be going beyond the ordinary meaning of the term. It is noted that the R&D involved in the 'utilization' includes through the application of biotechnology, and 'biotechnology' means 'any technological application'. It should thus be interpreted that 'utilisation' covers the commercial use of derivatives. This is also made abundantly clear by the reference in the chapeau to Article 17.1 that the measures are to monitor compliance in relation to the *utilization of genetic resources*. Subparagraph (a)(iv) of the same article then states that checkpoints must be effective and should have functions relevant to the implementation of this Article. The functions that are identified are expressly stated to include *'any stage of research, development, innovation, pre-commercialisation or commercialization'*. The implication is that these are an amplification of what is covered by the term 'utilisation' and by extension, 'research and development'.

2.4.2. Pathogens

Very early on in the negotiations, at the resumed 9th Working Group meeting in Montreal in July 2010, the European Union (EU) quite unexpectedly introduced a special provision on access to genetic resources that are pathogens. The proposal obliged Parties when developing their national ABS laws to:

(i) Provide immediate access to pathogens that

- also fall under the purview of other international organizations (such as the WHO, IPPC, World Animal Health Organisation); and

- which are of particular public concern for the health of humans, animals or plants.

(ii) ... in ways and for uses provided for in existing and future rules, procedures or practices by these international organisations and conventions ...

(iii) ... on the sharing of pathogens and related benefits established by these organisations and conventions.

This meant that Parties had to agree, through their own law, to give up on their rights and guarantee immediate access to pathogens on the basis of existing and *future* rules *and practices* as are, and may be, determined now and *in the future* by these other international *organisations* and conventions. (emphasis added)

This exclusion of a valuable resource from the ABS Protocol was rejected by developing countries. Some developed countries too rejected the wide and far reaching cast of the provision.

The context

Developing countries have been providing pathogens to the 5 collection centres of the WHO all of which are located in developed countries. The WHO then grants access to these pathogens to others, including industry which patents the virus, its components or vaccines created out of the use of the virus and supplies the vaccines to those, mainly developed countries, which can afford the high prices. The deposit of the pathogens implies the PIC of the provider country. And the rules and practices of the WHO states that the provider country also gives a *carte blanche* PIC to whoever wishes to subsequently access this material from the centres.

This state of affairs came to a head in 2008 when Indonesia complained that its supply of the avian flu virus resulted in no benefit sharing, nor access to the vaccines; nor transfer of technology to develop the vaccines in the future. A vigorous debate ensued in the WHO and developing countries are presently actively involved in negotiations at this forum to rectify this inequitable situation. They have proposed a standard material transfer agreement (SMTA) that seeks to include access based on fair and equitable benefit sharing terms and access to the vaccines as well as to technology transfer. This has been rejected by developed countries.

The proposals by the developed countries were hence seen as an attempt to preempt the outcome of the WHO negotiations. And to lock developing countries into a position that would perpetuate an inequitable situation. The provision also violated the fundamental principle that it was for countries in their national interest to determine when an emergency exists or needs to be declared. The EU proposal requires the national law to take measures in cases of '*present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally'*.

Developing countries also argued that this should be addressed under a non-derogatory provision that had already been provisionally agreed to. It permitted parties to develop and implement other specialised ABS agreements provided they did not run counter to the objectives of the Protocol and the CBD.

The provision that now appears in the Protocol (Article 8(b)) is as follows:

> *In the development and implementation of its access and benefit sharing legislation and regulatory requirements, each Party shall:*
>
> *(b) pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally.*
>
> *Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially developing countries.*

By and large developing countries succeeded in diluting the original proposal that made it obligatory to grant immediate access to pathogens in language that virtually required countries to sign away their sovereign rights without the commensurate sharing of benefits. The provision relating to expeditious fair and equitable sharing of benefits and access to affordable medicines was proposed to balance the expeditious access provisions. However, there may be a barrier to expeditious access if the vaccines are the subject of patents; such patents may also create difficulties for securing fair and equitable benefit sharing. Further, the question of access to and transfer of technology, including that protected by patents, remains unaddressed.

Complicating the issue is another article on relationship with international agreements and instruments (Article 4.3). It requires that due regard be paid to *'useful and relevant ongoing work or practices under such international instruments (relevant to this Protocol) and relevant international organisations provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol'.*

Developing countries had strenuously argued against the inclusion of the underlined words. First, this is a relationship clause with other international instruments. Hence the reference to international organisations appeared inappropriate as these are not of the same status as international instruments. Secondly, it is also inappropriate to refer to any ongoing work or practices under such organisations. This adds to legal uncertainty. 'Ongoing work' is always in a state of flux and reflects work that has not been concluded. Further 'practices' have no status in international law as a source of law. Practices of international organisations may be 'created' in all kinds of ways: through use, custom, decisions, and such like.

Except for the proviso, and the permissive nature of the obligation (*should),* developed countries sought to reassert by this provision what they lost in the earlier article 8(b) dealing specifically with pathogens.

For example, the Council of the European Union now states (DS 1803/10, Brussels, 12 November 2010) that when developing and implementing national ABS legislation the first sentence of Article 8(b) requiring that due regard be paid to cases of present or imminent emergencies that threaten or damage human, animal or plant health as determined nationally or internationally - gives explicit support to WHO decisions establishing different levels of pandemic threats and related national and international responses. Secondly, the EU states that the enabling clause in the second sentence of the Article indicates that the benefit sharing

for pathogens is to be approached differently from the general principle of benefit sharing established in Article 5.1.

The position of the EU is, with respect, untenable for the following reasons (Nijar, March 2011). First, the first sentence of Article 8(b) says no more than that due regard must be paid to cases of present or imminent emergencies as determined nationally or internationally. The determination is, as is almost always the case, within the province of national governments. Further, Article 4.3 clarifies, due regard - and no more - should (and not must) be paid to useful and ongoing relevant work or practices going on under relevant international organizations. However this is subject to an overriding proviso: that the work is supportive of and does not run counter to the objectives of the CBD and the Protocol. Secondly, the second sentence of the Article does not establish an approach to benefit sharing for pathogens that is different to that established for other genetic resources. The Article states that Parties *may***,** when developing and implementing their national ABS law, take into consideration the need for expeditious access and expeditious fair and equitable sharing of benefits arising from the use of such resources. This allows parties to consider whether or not to establish different procedures for access. This of course allows Parties to the Protocol to arrive at solutions within the WHO on issues relating to ABS for pathogens. However, these must be consistent with and not run counter to the objectives of the Protocol, in particular those relating to the fair and equitable sharing of benefits, including by appropriate access and by appropriate transfer of relevant technologies and affordable access to the vaccines.

The position taken by the US in the WHO forum is, with respect, even more farfetched (Nijar, March 2011). It argues in a non-paper issued for the ongoing WHO negotiations on pathogens that the Protocol excludes pathogens from its scope. It argues that pathogens with pandemic potential are excluded because they are not directly linked to the overall objective of conservation and sustainable use of biodiversity; and that the virus is accessed to develop a vaccine to eradicate the virus itself. However there is nothing in the CBD or the Protocol that excludes this particular category of genetic resource, and especially so on the basis of this qualification. If the resource is subject to utilisation as defined then the Protocol applies. Such a contention also ignores the negotiating history of Article 8(b). The original several proposals during the negotiations explicitly referred to pathogens. A preambular paragraph also refers to the importance of ensuring access to pathogens. Such a reference would be purposeless if pathogens were outside the ambit of the Protocol. Finally the EU, which made the proposal in the first place, acknowledges that pathogens are within the scope of the Protocol.

The US non-paper also argues that even if pathogens are within the scope of the Protocol, the WHO assembly resolutions and the Pandemic Influenza Preparedness Framework are specialized instruments dealing with access and benefit sharing and hence would replace the Protocol under its Article 4.4. This argument is unacceptable for the following reasons. First, the resolutions and Framework are not of the same status as a treaty. Further, Article 4.4 contemplates a dedicated international treaty on ABS such as the International Treaty on Plant Genetic Resources for Food and Agriculture of the UN-FAO, enacted pursuant to a resolution of the CBD. In any event any specialized instrument of the WHO must provide for fair and equitable sharing of benefits. (The US argument that the preamble dealing with pathogens only speaks of ensuring ‘access’ and makes no reference to benefit sharing, ignores the clear provisions in the operative part of the Protocol requiring both access and benefit sharing.) This must also include making available vaccines developed from these viruses at affordable prices to provider developing countries, as expressly required by Article 8(b). Else the instrument will run foul of, and violate, the provision in the Protocol

that requires any specialised instrument to be consistent with and not run counter to its objective - the fair and equitable sharing of benefits. Even the due regard (and no more) that should (and not must) be paid to the work or practices of relevant international organizations – and this could include the resolutions and Framework of the WHO – are subject to the same overarching consistency requirement.

A cumulative reading of Article 8(b) and Articles 4.3 and 4.4 of the Protocol makes clear the following:

a. A country can develop a national law that deals with pathogens as a genetic resource and subject it to the ABS requirements.

b. Countries may also collectively enter into any obligation - including a standard material transfer agreement in international fora such as the WHO -- that reflects the ABS objective of the Protocol. The agreement must therefore include fair and equitable sharing of benefits arising from the utilisation of the viruses, (which should be expeditious if access to the viruses is expeditious), access and the transfer of relevant technologies in relation to developing vaccines for pathogens. The vaccines must be made available to developing countries at affordable prices.

c. Parties to the Protocol in developing their national law or administrative or policy measures are not bound to take into account any ongoing work or practice in the WHO relating to pathogens. They need only to consider taking into account any such work or practices.

2.4.3. Temporal Scope

Does the Protocol apply to genetic resources (and derivatives and TK) acquired before the entry into force of the Protocol? Two completely divergent views were expressed throughout the negotiations. Some countries (largely, developing) proposed their inclusion while others countries proposed that the Protocol apply only to genetic resources acquired after the entry into force of the Protocol. The Protocol includes neither of these formulations. What then is the position?

The CBD makes it mandatory for access to be based on PIC, unless a Party otherwise determines: Article 15.5, CBD. Parties must also take measures to ensure benefit sharing arising from the utilisation of the genetic resources: Article 15.7, CBD. If the Protocol applies only to resources acquired after the entry into force of the Protocol, this may be implied as condoning access in violation of these two articles of the CBD. Such an interpretation would countenance an illegality and would be unacceptable. It would merely encourage Parties to delay ratification so that they could access the genetic resources with impunity in the interim.

However, to suggest that the Protocol apply to situations before it entered into force would be against the principle of retroactivity. This principle simply stated means that no new legal consequences or obligations can be applied by a new instrument in respect of actions or situations before the entry into force of the instrument, unless clearly intended.

This principle operates differently when applied to a national law; and when applied to an instrument in international law.

Obligations imposed by national law will depend upon its provisions. Generally a national law will not make a law that has retroactive effect. In the ABS context, requiring access (PIC) and benefits to be shared (MAT) after these benefits have been created for genetic resources accessed and before the law came into existence, would clearly be making a retroactive law. However, a national law can require new rules to apply to new situations. Thus a law may require that access and benefit sharing rules apply for new uses of resources acquired before the entry into force of the law. An example would be where a pharmaceutical company acquires a genetic resource or derivative for use as a particular drug before the entry into force of the law. It then changes its use of the resource for a different drug after the law enters into force. This does not make the law retroactive. The time when the resource was accessed would be irrelevant.

Thus a Party can enact a law with such a provision. Similarly a law may be created to require that access and benefit sharing rules apply for continuing uses after the entry into force of the Protocol. This is applying new legal consequences for ongoing uses for resources acquired prior to the entry into force of the Protocol. This also does not violate the rule against retroactivity.

The further question that arises is whether the Protocol, which authorises Parties to make such a law, is legal in international law? Article 28 of the Vienna Convention on the Law of Treaties 1969 deals with non-retroactivity of treaties. It reads:

> *'Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.'*

Applying this rule, the Protocol will not apply to situations which ceased to exist before the entry into force of the Protocol. By the same token, it would apply where the situation has not ceased to exist. So if a situation arose in the past (resources acquired before the entry into force of the Protocol) but continues to exist under the new Protocol (new or continuing use of the resource) the provisions of the Protocol can apply without violating the retroactivity rule in international law.

However this is subject to two provisos. First, if the resource has been accessed with the PIC of the provider, then the terms of the access will govern the new or continuing use of the resource. Secondly, for the historically acquired resources for which no PIC was, or could have been, obtained, the Protocol acknowledges indirectly that these are not within the scope of the Protocol and establishes a process to address this problem.

Article 10 obliges Parties to consider the need for and modalities of a global multilateral benefit sharing mechanism in respect of the benefits arising from the utilisation of genetic resources *'for which it is not possible to grant or obtain prior informed consent.'* COP/MOP is required to address first the need for a mechanism before the modalities can be worked out. In discussing this, developing countries should be particularly mindful of the reality of the proliferation of exchanges in the past –some undertaken by their colonial masters - and the complexity of identifying the country of origin when a resource has crisscrossed boundaries and territories. This should not, however, affect the recognition of a country as a 'country of origin' where the domesticated genetic resource has acquired distinctive properties. This is provided for in the CBD (Article 2).

Ex situ collections

Importantly, the *ex situ* resources taken from developing countries pre-CBD need also to be addressed. Many such resources now reside in collection centres in developed countries. These include the Kew Gardens in London, the Leibniz Institute of Plant Genetics and Crop Plant Research (IPK) in Berlin, the Smithsonian Institute in Colorado, USA and the genebank in St Petersburg in Russia. These resources are being accessed without reference to the PIC and MAT of the country of origin. This has the effect of depriving countries of benefits and may ultimately undermine the ABS requirements of the Protocol.

Developing countries should hence establish a process in COP/MOP to develop a regime to regulate these *ex situ* resources.

The Protocol provides a basis for their regulation. Article 6.1 states that *access to genetic resources for their utilization shall be subject to the PIC of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.* Article 15.1 requires user country Parties to enact compliance measures that regulate genetic resources utilized within its jurisdiction, in particular that they have been accessed in accordance with the PIC and MAT, as required by the domestic ABS law or requirements of the other Party.

So if a researcher wishes to access a genetic resource (or derivative or associated TK) he must obtain the PIC and establish MAT. This must be with the Party that provides the resource which is the country of origin or the country that has acquired the resource in accordance with the Convention (referred to as 'country of origin') - as per Article 6.1 of the Protocol. Now if the researcher goes to an *ex situ* source that particular person or entity cannot be the 'provider' because that source does not fall into any of the categories of providers under the Protocol - that is a country of origin etc. Any utilisation without the PIC and MAT of the provider prescribed by the Protocol would clearly be unlawful if it violates the law or regulatory requirements of that particular provider. It is noteworthy that *ex situ* centres, like the Kew Gardens, maintain a data base as to the country from which the particular genetic resource was collected. The Gardens will have to direct the researcher to that particular country and he or she will have to abide by the ABS law or administrative or policy measure of that country. The same situation obtains with regard to the acquisition of a resource from wherever, say a supermarket shelf, for utilization (research and development) within the meaning of the definition of the Protocol. The researcher will have to seek out the country that is the provider of that resource. '*Ex situ* sources are referred to in the CBD. The CBD defines a 'country providing a resource' as *'a country supplying genetic resources ... taken from ex situ sources, which may or may not have originated in that country'* (Article 2). However there is no reference in the operational provisions of the CBD to this expression. The omission is significant as it implies that resources taken from such sources are to be dealt with under the ABS provisions of the CBD, which now are dealt with under the Protocol.

A pragmatic solution may be for the *ex situ* centre supplying the resource to agree to notify the country of origin Party, dispensing with its PIC; and the centre requiring the user to share benefits upon utilization with that Party. For this a scheme for benefits to be shared or provided will need to be established either bilaterally or through COP/MOP. If the country of origin cannot be identified, or if it is not a Party to the CBD or the Protocol, the benefits could be paid into the potential Global mechanism (Article 10) for biodiversity-related purposes as provided for in the Protocol (Article 9). This could, incidentally, provide a positive incentive

for countries to join the Protocol. An example of a scheme exists under FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (Nijar et al 2009). It is also instructive that the 12 International Agricultural Research Centres (IARCs) of the CGIAR voluntarily signed agreements placing their collections of germplasms under the Multilateral System of ABS of the International Treaty. This was pursuant to Article 15 of the Treaty which calls on the IARCs of the CGIAR to sign agreements with the governing body to bring their collections under the terms of the Treaty. Such agreements are necessary as the IARCs have their own legal personality and governance system and cannot be bound by the Treaty's terms without their consent (Moore and Tymowski 2005).

Developing countries should include within the scope of their ABS law or administrative or policy measure, genetic resources (including biochemical components and TK associated to genetic resources) that are in *ex situ* sources and of which they are the country of origin or that they have acquired in accordance with the CBD.

Developing countries should move the COP/MOP to address the issue of *ex situ* collections to ensure that there is fair and equitable sharing of benefits arising from the utilisation of genetic resources (derivatives and associated TK) with provider countries as set out in Article 15.3 of the CBD.

2.4.4. Commodities

Are commodities within the scope of the Protocol? This is an important question to address and resolve as a huge volume of these commodities - such as maize, corn, soya bean, and the like - are traded globally everyday. The price for the commodity is almost always determined by the market or mutually agreed between the supplier and the buyer, or, sometimes, through specialised commodity exchanges. The answer lies in the purpose of the acquisition. The Protocol only deals with acquisition for the purpose of its 'utilization'. This has a special meaning under the Protocol - to conduct research and development on the genetic and/or biochemical composition of genetic resources. Acquisition for any other purpose falls outside the scope of the Protocol. Commodities for direct use as commodities including for consumption or for non-breeding purposes (which does not thus involve R&D) are not accessed for research and development. They clearly are not covered by the Protocol. It follows that if the resource is accessed from wherever (such as a supermarket) for research and development purpose, then the Protocol would require that the PIC and MAT of the provider be obtained, as discussed earlier.

Some developing countries expressly provide for the exclusion of commodities from their ABS law. Some others reserve the power to exclude biological resources 'normally traded as commodities': India, Biological Diversity Act 2002, section 40.

Developing countries may wish to consider whether or not explicitly provide for the exclusion of commodities in trade from their national ABS law or administrative or policy measure.

2.5 Benefit Sharing

The Protocol obliges each Party to take legislative, administrative or policy measures to share benefits in a fair and equitable way with the Party providing the resource. This is the country of origin or a Party that has acquired the genetic resources in accordance with the Convention.

The sharing must be upon mutually agreed terms. These provisions faithfully reproduce the provisions of Articles 15.7 and 15.3 of the CBD. The benefits that may be included are also set out in the Protocol and are largely a reproduction of those set out in the Annex to the voluntary Bonn Guidelines. The benefits to be shared are those arising from the '*utilisation of genetic resources'*. This term appears in Article 15.7 of the CBD but is not defined there. It is, as discussed earlier, defined in the Protocol to include derivatives and settles the perennial dispute between developed and developing countries on this issue. The Protocol also states that the benefits include those arising from subsequent applications and commercialisation. This is, in any event, implicit in Article 15.7 of the CBD and the definition of 'utilisation' in the Protocol.

In the CBD access is expressly made subject to the provisions of Article 15 - which includes the sharing of benefits. In the Protocol the link between access and benefit sharing is not explicit. If benefit sharing is delinked, it could imply that so long as benefits are shared, even for unauthorised access or where access is not possible for some reason, the Protocol is complied with (Union for Ethical Biotrade 2010). This could condone biopiracy and may place provider countries in a rather difficult position of having to negotiate terms based on a violation of their sovereign right to grant or refuse access. This interpretation is not acceptable for this reason. It will be recalled that the objective of the Protocol makes a direct link between benefit sharing and appropriate access.

However, it could be argued that this is not a case about access but about the utilisation of the genetic resource or a derivative? This would imply that where there is R&D on a genetic resource or a biochemical composition, there will be no non-compliance of the Protocol if benefits are shared through MAT in respect of any product created - independent of whether there was compliance with access provisions or not (Union for Ethical Biotrade 2010). This argument may be used to reinforce the view of some developed countries that no PIC is required for derivatives, but only benefit sharing. However this argument would violate the general tenor of the CBD and the Protocol. The spirit and thrust of these two instruments is to provide for benefit sharing that ensues upon the grant of access. This is made clear by the objective: the fair and equitable sharing of the benefits arising from the utilisation of the genetic resources, including by appropriate access ... 'Appropriate access' encompasses access in accordance with the terms of the Protocol. Hence legal access under these two instruments is upon PIC and benefit sharing through MAT. If access is not obtained, any subsequent dealing with the genetic resource, derivative or TK associated with the GR would be a violation of the Protocol.

The only useful value of this delink is to solve cases of temporal scope. Where a resource has been accessed a long time ago, in any event before the entry into force of the Protocol, then as access is not possible, the benefits - at least for new and continuing uses (see earlier discussion) - must still be shared. This is the only reason the provision in the Protocol relating to benefit sharing has been crafted to deal with utilisation and not access. Similarly the potential setting up of a Global Multilateral Fund under Article 10 is to deal specifically with the exceptional situations where access is not possible.

As discussed earlier, the benefits arising from R&D applies to the whole chain from research up to commercialisation. This also includes the benefits accruing from the information and new knowledge from the research and development. That the whole chain is covered is implicit in the term 'development' but has in any event been made clear by the addition of the term 'subsequent application and commercialization' that completes the chain of development. This may raise a particular problem. A product may be developed by others

not involved in the initial access application and in a different jurisdiction. An extract of a genetic resource may, for example, be sent by a local researcher to a foreign company which then develops and manufactures a product. The initial access by the local researcher will be subject to PIC and MAT. The obligation to share benefits arising from subsequent applications and commercialization still continues and applies to the foreign company. The difficulty is of ensuring that these benefits accrue to the country of origin providing the resource. **The MAT with the initial researcher should be framed such as to capture these benefits. More specifically, the MAT agreement should be drafted to oblige not only the initial researcher but as well all others in the chain to share benefits. It could even be drafted to require PIC when the foreign company accesses the extract (the biochemical composition or the derivative) from the local researcher.**

Even prior to the Protocol, the ABS laws of some countries provide for a PIC and MAT when the resource is transferred to another. This is countenanced by the Protocol which requires Parties to establish clear rules for MAT which may include, inter alia, terms on any subsequent third party use as well as any change of intent - Article 6.3(g)(iii) and (iv). Such terms need to be supported by an ABS law or administrative or policy measure. In such a case, user country measures on compliance must ensure that subsequent transferees of the genetic resource or derivatives, as well as those who change the use, comply with the PIC and MAT of the provider country. The practical problem of ensuring that the checkpoint is able to pick up such information has been discussed under 'compliance'. **In any event, developing countries should include a provision in their national law requiring the transferee of any genetic resource or derivative and/or where there is a change of intent of use, to obtain PIC and MAT.**

In addition, developing countries should consider developing a menu of minimum terms for inclusion in MAT that would guarantee fair and equitable sharing of benefits. This would also be useful when resources are endemic to a region. However, developing countries must be cautious in agreeing to allow COP/MOP to 'take stock' of their contractual clauses as this could impair their flexibility to determine the terms on which access is to be granted.

2.6 Traditional Knowledge (TK)

The scope states explicitly that the Protocol also applies to TK associated to genetic resources within the scope of the CBD and to benefits arising from the utilisation of such knowledge (Article 3). Although a cross-cutting issue in the Protocol, TK has been dealt with under stand-alone provisions. These are examined in greater detail.

2.6.1 PIC

The Protocol provides for two distinct situations where Parties must take measures in relation to ILCs. The first relates to access to genetic resources (Article 6.2). The second relates to access to TK of ILCs associated to genetic resources (Article 7).

First it is noted that the Protocol deals with the right of ILCs in relation to both genetic resources and TK associated to it. This is an enhancement of their rights as the CBD only deals with TK of ILCs (Article 8(j)). Secondly, access in both cases may be secured upon the PIC *or* the approval and involvement of ILCs. These are two options. Is there a difference between them? The first expression involves prior and informed consent. The latter seems to

suggest a lesser right and could mean that there is no need for the consent to be obtained prior to the access; nor is there an obligation for 'informed' consent.

In the case of access to genetic resources of ILCs, however, it is only where ILCs have an established right to grant access that Parties need to take the measures for the PIC or approval and involvement the provision applies. It cannot be assumed that the right must be established by the Party or by legislation. As is trite, rights of ILCs can be established by a variety of ways. Customary or native rights of indigenous peoples are not established by, and indeed often precede, any legislation. It is significant that, in contrast, Article 5.2 uses the term *'in accordance with domestic legislation regarding the established rights of these ILCs over their genetic resources'*. Judicial decisions in common law jurisdictions have routinely declared the existence of these rights, often in the face of state opposition. (See for example the Australian High Court decision: *Mabo* case; and the Malaysian Federal Court decision: *Kerajaan Negeri Johor v Adong Kuwau*). The right may also be established by customary international law. The Expert Group on TK established by the ABS Working Group to provide input to the negotiations concluded that the right of ILCs had been established by, or was fast becoming part of, international customary law (UNEP/CBD/WG-ABS/8/2). The Expert Group based its conclusion on a plethora of international instruments, including the UNDRIP, numerous national laws and decisions of the CBD. A preambular paragraph in the Protocol notes the existence of the UNDRIP.

Further, the Protocol recognises the inseparable nature of genetic resources and TK in a preambular paragraph. The TK Expert Group reached a similar conclusion. This inextricable link of TK to the genetic resource implies that any application for access to the genetic resource would trigger the provisions in the Protocol relating to access to TK as well (UNEP/CBD/WG-ABS/8/2). Several commentators have also commented that resources cannot be appropriated without the concomitant appropriation of knowledge (Coombe 1998).

As regards the difference between 'PIC' and 'approval and involvement', Parties to the CBD have consistently considered the latter expression as meaning PIC. For example, COP5 adopted General Principles (Decision V/16) clarifying that *'access to TK, innovations and practices of ILCs should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices'*. (CBD 2003). The Bonn Guidelines, developed by the Parties in 2002 to assist Parties and governments to develop legislative administrative or policy measures on ABS, suggest that Parties establishing a system of PIC in accordance with Article 15.5 of the CBD should abide by basic principles of a PIC system. One such principle is that the *'consent of relevant stakeholders, such as ILCs ...should also be obtained'* (CBD 2002). The conclusion is that there is no appreciable difference between the two expressions. Further as regards access to TK, it appears that Parties would have to take into consideration PIC if this is required by community protocols (Article 12.1). Indeed Parties must 'endeavour to support' the development of such protocols in relation to access to TK (Article 12.3(a)).

In both situations, Parties are required to take measures with *the aim of ensuring* that the genetic resource and/ or the TK of ILCs are accessed with their PIC or approval and involvement. This strengthens the provision in the CBD - Article 8j - which only requires the promotion of the wider application of TK with the approval and involvement of ILCs.

However, in both cases, the requirement is *'in accordance with domestic law'* and the measures to be taken by each Party *'as appropriate'*. This may be interpreted to qualify the obligation to enact measures where there is an established right of ILCs over the genetic

resources. Then it is in the absolute discretion of a Party. An alternative reading of these phrases could be that an obligation is established and has to be implemented in accordance with its law - by appropriate measures. Indeed some countries stated during the negotiations that subjecting the regulation of TK to accord with domestic law was to provide flexibility for countries to deal with issues relating to TK especially in view of the diverse ways TK is approached, in different countries.

The further question arises –whether the right of ILCs must be 'established' by domestic legislation? This is the terminology used in article 5.2 when dealing with the same subject matter in relation to benefit sharing. However this expression does not appear in this Article dealing with access. The implication is that there is no precondition for the right to be established through a specific legislation. It can come into existence through other means – for example, as declared by courts of law – as discussed earlier. This will be especially true for countries with a common law tradition. Indeed the term law in those jurisdictions is defined to include written law, common law and customs and usages (see for example the Federal Constitution, Article 160). The position may be different for civil law countries that only recognize legislation that is specifically enacted.

Parties may/must* include PIC requirements for access to genetic resources and/or the TK associated to genetic resources in their national law or administrative or policy measure.

*This depends upon which interpretation is advanced for 'in accordance with law'.

2.6.2 Benefit Sharing

Parties are required to take legislative, administrative or policy measures with the aim of ensuring that benefits arising from the utilisation of genetic resources held by ILCs are shared in a fair and equitable way with the communities, based on MAT. The obligation is 'in accordance with domestic legislation regarding the 'established rights'. As the earlier discussion clarifies, this right must be established by the state through legislation. It cannot be established by other ways. If the right is so established then there is an absolute obligation to share benefits. The obligation with regard to TK is, however, unqualified and mandatory. It obliges Parties to take the appropriate measures in order that the benefits are shared upon MAT. This is an improvement on the provisions of the CBD which only *encourage* the equitable sharing of the benefits (Article 8(j)).

Parties must provide for benefit sharing, through MAT, arising out of the utilization of TK associated with genetic resources in their national law or administrative or policy measure.

Parties must provide for benefit sharing, through MAT, arising out of the utilization of genetic resources that are held by ILCs in their national law or administrative or policy measure where this right is established by legislation.

Parties may provide for benefit sharing, through MAT, arising out of the utilization of genetic resources that are held by ILCs in their national law or administrative or policy measure.

2.6.3 Compliance

The compliance measures referred to earlier as 'user country measures' also apply to compliance with the domestic law or regulatory requirements of the Party where the ILCs are located in respect of ABS for TK associated with genetic resources (Article 16.1). They are in fact a mirror image of those provisions. The user countries must also address cases where their measures are not complied with (Article 16.2). This provision is also identical to that for user country measures as discussed earlier. The same comments as made earlier apply to these provisions as well. What is a significant omission, however, is that the monitoring provisions make no reference to associated TK. Although therefore the checkpoints could pick up information on the use of the associated TK that has been accessed without PIC and MAT of the provider, yet there is no obligation to do so. Nor is there then an obligation to report this fact to the national competent authority, the ABS Clearing House or the provider country. The internationally recognised certificate that must be shown to the checkpoint as evidence of lawful access, only relates to the genetic resource and not the associated TK. It is further noted that the minimum information proposed for the certificate, although referring to subject matter, makes specific reference to the genetic resource but makes no reference to the associated TK.

As the monitoring measures are to support compliance, and there is a specific Article 16 obliging the provision of effective user country measures for compliance with domestic law on ABS for TK associated with genetic resources, it simply does not make sense to exclude such TK from these monitoring measures. This sends a wrong signal and may encourage misappropriation of TK. This could not have been intended. The monitoring only relates to how the compliance measures may be effectively implemented.

Developing countries should at COP/MOP develop the implementing monitoring measures for TK as well. This is of crucial importance as most cases of biopiracy relate to TK associated with genetic resources.

2.6.4 Other Provisions

i. Parties are also required to take into consideration in implementing obligations under the Protocol, as applicable: customary laws, community Protocols and procedures, with respect to associated TK of ILCs. This is again *'in accordance with domestic law'*. (Article 12.1)

ii. Parties must also establish mechanisms to inform potential users of TK associated with genetic resources of their obligations for its access and the fair and equitable sharing of benefits arising from its utilisation. This must be accomplished with the effective participation of ILCs. The measures must be posted on the Clearing House. (Article 12.2)

iii. Parties must also endeavour to support the development by ILCs of

- Community Protocols relating to access to and the fair and equitable sharing of benefits from the utilization of TK;
- Minimum requirements for MATs to secure fair and equitable sharing of benefits; and
- Model benefit sharing contractual clauses for benefit sharing. (Article 12.3)

iv. Parties are required not to restrict the customary use and exchange of genetic resources and associated TK within and amongst ILCs (Article 12.4). This is *'as far as possible'* and in accordance with the objectives of the CBD. This renders the provision subject to the discretion of the Party with no objective criteria established for assessing whether the discretion has been properly exercised.

v. There are provisions for Parties to *'endeavour to cooperate'* with the involvement of ILCs where applicable, where the same genetic resources are located across boundaries (Article 11.1). Note that the 'effective participation' of ILCs for developing mechanisms to inform potential users of their obligations, referred to earlier, is in this Article reduced to mere 'involvement'.

vi. This also applies where the same associated TK is shared by one or more ILCs in several Parties (Article 11.2).

These provisions need to be strengthened at COP/MOP.

2.6.5 Publicly Available TK

There were intense and prolonged negotiations with regard to publicly available TK. Developing countries, led by China, India and Nepal, argued that such knowledge was not freely accessible and the PIC and MAT requirements should also apply; and further, where the knowledge was diffused and/or there was no identifiable holder of the TK, PIC had to be obtained from, and MAT established with, the Party. Developed countries opposed this. Some of them argued that the State had no role; others that this was outside the scope of the CBD as it only dealt with holders of TK, namely ILCs. The developed countries' reliance on the 'public domain' concept to deny the right to PIC and MAT was rejected by developing countries. First, this 'public domain' concept was to show prior art to defeat claims of innovation in patent applications. Secondly, the obligations in the CBD related to benefit sharing when TK was accessed and utilized. This has nothing to do with IPRs or the public domain.

Proposals were put forward by developing countries to deal specifically with two scenarios. One, where the knowledge was not obtained directly from ILCs. The other, where there was no identifiable owner of the resource as the TK was passed down from generations ago. These were as follows:

Article 9.5

> *Parties shall take appropriate legislative, administrative or policy measures so that users of TK associated with genetic resources, whether oral or documented or in other forms, obtained from a source other than directly from ILCs, to enter into fair and equitable benefit sharing arrangements with the rightful holders of such knowledge as may be determined by the provider Party.*

Article 9.5 *bis*

> *Where TK is held by a Party on behalf of ILCs and the original holders within these communities cannot be identified, such Parties may take legislative, administrative or policy measures, as*

> *appropriate, so that users of such TK enter into fair and equitable benefit-sharing arrangements with that Party for the benefit of the ILCs.*

There was recognition of the diversity of circumstances in which TK was held or owned by ILCs as well as the unique circumstances where TK is held in countries. China, Nepal and India explained at great length that TK was held at 3 levels in their countries - the ILCs, the individual (such as traditional healers) and at the national level (where held at neither of the 2 earlier levels or spread across a diffuse number of communities).

In the end, all references to these provisions were simply eliminated in their entirety. All that remains now in the Protocol are references in the preambular paragraphs to the recognition of unique and diverse circumstances whereby TK is held.

However, it is open to developing countries, through their national ABS law to provide for these situations. The phrase earlier referred to 'In accordance with domestic law, each Party shall take measures, as appropriate..' provides the necessary opening and flexibility to do so.

2.7 Transfer of Technology

It must be recalled that the grand bargain underpinning the CBD was that resources would be provided - mainly by developing countries - in return for access to and transfer of technologies by those who utilised those resources - mainly developed countries (Lyle Glowka 1994). The expectation of developing countries was that the Nagoya Protocol would operationalise the provisions in the CBD on technology transfer by including specific provisions, in much the same way that Article 5 of the Protocol operationalises the access provisions of Article 15 of the CBD. This is especially as Article 1 of the Protocol identifies appropriate transfer of technologies as one of the key ways for attaining its objective of the fair and equitable sharing of benefits.

The CBD has elaborate and specific provisions under its Article 16 for access to, and transfer of, technologies that, make use of the genetic resources accessed. Parties are obliged to provide or facilitate access to, and transfer of, relevant technologies, including biotechnology, to provider countries. This must be under fair and most favourable terms, including on concessional and preferential terms. Where necessary, the financial mechanism of the CBD shall help to pay for such technology. Contracting Parties have to take the necessary legislative, administrative or policy measures with the aim that developing countries providing the resources are provided access to and transfer of technology which makes use of those resources; as well as to get the private sector to facilitate access to, joint development and transfer of, technology - for the benefit of both governmental institutions and private sector of developing countries. Parties must also take legislative, administrative or policy measures to provide for the effective participation in biotechnological research activities by developing countries that provide the genetic resources for such research; and take practicable measures to promote and advance priority access on a fair and equitable basis by developing countries to the results and benefits arising from biotechnologies based upon the resources provided. (Article 19 CBD).

However, the Protocol provides merely for Parties to 'promote and encourage' access and transfer of technology to developing and least developed country Parties (Article 23). In

recognition of the fact that those with the technologies would be the private sector rather than the country Party, developing countries proposed earlier on in these negotiations - as an add on to these CBD provisions - that Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities. And that this must include measures by developed country Parties to provide incentives to the private sector within their jurisdiction to promote and encourage access and transfer of technology to developing countries to help them establish a sound and viable technological and scientific base.

The Protocol has excised the underlined words. This clearly subtracts from the existing provisions of the CBD. This undermines the fundamental construct upon which the CBD was negotiated. It also creates a fundamental imbalance in the Protocol as the access provisions build upon and advance those in the CBD, while, in stark contrast, the technology transfer provisions detract from the CBD provisions.

Article 23 however starts off with the following:

> *'In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol'.*

This makes clear that this Article is built upon Article 16 - 19 of the CBD and must necessarily advance it through collaboration and cooperation in the appropriate research and development. This would also include Articles 16.4 and 19.1 of the CBD which requires Parties to take legal, administrative or policy measures for the private sector to facilitate access to and transfer of technologies to developing countries; and for the effective participation of the provider countries in biotechnological research. Further the advancement of the objective of the Protocol would require the sharing of benefits (Articles 1 and 5.1). The non-monetary benefits identified by the Protocol include: sharing of R&D results and transfer of technology under fair and most favourable terms, and strengthening capacities for technology transfer (Annex).

Developing countries should establish these benefit sharing obligations through a COP/MOP decision as well as include these measures in their national law, or administrative or policy measures. They should also provide for these obligations by users in MAT.

2.8 Non-Commercial Research

The Protocol requires Parties to provide for simplified access for non-commercial research purposes in their national law (Article 8(a)). This is merely one of the measures that Parties are obliged to take to create conditions to promote and encourage research. The research must contribute to the conservation and sustainable use of biological diversity, particularly in developing countries. It must be noted that simplified procedures do not exempt a user from the PIC and benefit sharing requirements. It merely does away with the more elaborate access requirements for commercial research.

The Protocol also states that Parties take into account 'the need to address a change of intent for such research' - that is, from non-commercial to commercial research. As has been oft repeated, the line between non-commercial and commercial research is invariably blur. Much of the research that starts off as non-commercial ends up being used or accessed by industry for commercial ends. It is practically difficult to monitor when the intent changes. Some countries require a periodic reporting of the research. Others require, in addition, the applicant to swear a statutory declaration of the intent and an undertaking to inform of the change of intent. Any false declaration is punishable with imprisonment.

Developing countries can provide in their national law for simplified procedures for pure and non-commercial research that contributes to the conservation and sustainable use of biological diversity.

There must be an obligation to inform the authority when there is a change of intent to commercial research, in which case there must then be fair and equitable sharing of benefits through MAT. To ensure this is complied with countries could require the applicant to swear a statutory declaration of the intent and an undertaking to inform of the change of intent. One of the obligations undertaken in this declaration could be periodic reporting of the research results. Any false declaration should be punishable with imprisonment.

2.9 Non-Parties

A rather short article deals with non-Parties (Article 24). It reads as follows:

> *'The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing House.'*

This is an adaptation of Article 24.2 of the Cartagena Protocol on Biosafety. It requires Parties to encourage non-Parties to apply the principles and further the objective of the Protocol, namely the fair and equitable sharing of benefits for the utilization of genetic resources, derivatives and associated TK. How this is to be effected is left open. The Article also encourages States that are non-Parties to provide information to the Clearing-House on access dealings that they are involved in. The object is to gather as much information as possible and make it available to all Parties.

However, an earlier proposal - which paraphrased Article 24.1 of the Cartagena Protocol - has been deleted from the Protocol. It reads as follows:

> *'Activities and transactions regarding access and benefit-sharing related to genetic resources and derivatives between Parties and non-Parties shall be consistent with this Protocol and the Convention.'*

The deletion of this provision is unfortunate. Such a provision would have ensured that Parties adhere to, and advance the objectives of, the Protocol when dealing with non-Parties. Since the protocol cannot create obligations for non-Parties, this Article would have made it the responsibility of any Party conducting dealings with a non-Party to ensure consistency with the objective of the Protocol. This would ensure fair and equitable sharing of benefits by appropriate access and transfer of technology. Any dealing with a non-Party would be on the

basis of equivalent measures in the Protocol to achieve its objective. This ensures that such dealings do not undermine the Protocol; do not set up a dual standard for transactions related to genetic resources, TK and derivatives; and ensures that non-Parties do not have a competitive advantage by remaining outside the Protocol. It is to prevent such situations from arising that treaties usually allow Parties to engage with non-Parties provided that the transaction is consistent with the objectives of the treaty.

2.10 Global Multilateral Benefit-Sharing Mechanism

As adverted to earlier, the Protocol also requires future work for Parties to consider the need for and modalities of a global multilateral benefit sharing mechanism (Article 10). This is to deal with benefits derived from the utilisation of genetic resources and TK that occur in transboundary situations or for which it is not possible to grant or obtain PIC.

Two transboundary situations are described in the Protocol:

(a) where the same genetic resources are found in-situ within the territory of more than one Party; and

(b) where the same TK associated with genetic resource is shared by one or more ILCs in several Parties.

The establishment of this mechanism was consistently proposed by the African Group since Working Group 5 in Montreal in 2007.

Whether the need for the Global Mechanism must await a COP/MOP discussion and outcome, Article 10, quite strangely pre-empts this and provides for the purpose for which, and with whom, the benefits are to be shared, namely, through this mechanism and to support the conservation and sustainable use of the components globally. This implies a sharing not among the countries where the 'transboundary' resource is found or shared as adverted to in Article 11. This Article says that where such resources are found *in situ* in more than one Party they shall cooperate with a view to implementing the Protocol - that is, the benefit sharing objective. This implies that these Parties are to cooperate on the sharing of benefits and that these benefits are to accrue only to them. The same applies in respect of TK that is shared by one or more ILCs in several Parties. Some regional ABS laws attempt to provide for a collective mechanism to resolve the benefit sharing in cases where the resource is endemic to the region (see for example the Draft ASEAN Framework Agreement on Access to Biological and Genetic Resources, 2004, Article 7.4: *'whenever biological or genetic resources are indigenous to two or more Parties'*). Additionally, the Parties are free to apply the benefits as they wish. Article 9 merely encourages users and providers to direct any benefits towards conservation and sustainable use purposes. However, Article 10 requires that the benefits must be used to support the conservation and sustainable use purpose.

The other situation for considering the need for this Global Mechanism is where it is not possible to grant or obtain PIC. What are the scenarios envisaged by this provision?

First, as regards Parties to the CBD it cannot cover pre-CBD collections. This is because the Protocol is enacted under the CBD and the CBD does not apply to pre-CBD collections. The Protocol also states that it covers genetic resources within the scope of Article 15 of the CBD. Article 15.3 of the CBD restricts genetic resources covered to only those:

a. provided by Parties that are countries of origin as defined by its Article 2; or

b. provided by Parties that have acquired the genetic resources in accordance with the CBD. Only these two categories of genetic resources entitle a provider to benefits under the Convention.

As regards the latter category, two distinct cases are excluded:

a. resources acquired before the entry into force of the CBD; and

b. resources acquired illegally from the country of origin after the entry into force of the CBD (Lyle Glowka 1994).

Secondly, this may also mean the exclusion of *ex situ* collections from the purview of the CBD (Lyle Glowka 1994, p. 79; Moore & Tymowski 2005, p. 9). The Centres named earlier and located primarily in, or under the control of, developed countries, collected these resources primarily from farmers' fields and from developing countries and which predate the CBD. These collections represent unique germplasm that are usually concurrently obtainable from provider countries. There is hence a need to deal with access and benefit sharing in relation to these resources. Article 10 provides an opportunity to consider whether there is a need to do so to provide a solution to this outstanding problem; and if so, how this should be done.

A similar situation existed when the CBD was finalised. There were then large *ex situ* collections of genetic resources collected before the entry into force of the CBD held in gene bank collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) as well as many national collections. In adopting the agreed text of the CBD in Nairobi in May 1992, Parties called for a solution to be found for access to these *ex situ* collections not acquired in accordance with the Convention and to the question of farmers' rights. Negotiations for these commenced under the FAO and culminated in the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture in 2001 and came into force in 2004. The Treaty took 10 years to materialise.

A similarly worded provision in the CBD (Article 19.3) calling upon Parties to consider the need for and modalities of a protocol, led to the creation of the Cartagena Protocol on Biosafety (CPB). It took 6 long years, six working group meetings, a failed Extraordinary COP, three informal consultations and a resumed COP to conclude the CPB.

Parties may also in the context of the discussion of Article 10 seek to resolve the issue of benefits arising from continuing uses after the entry into force of the Protocol of genetic resources acquired before its entry.

In the interim, as regards *ex situ* collections a solution could be advanced at COP/MOP based on the earlier discussion (under 'Temporal Scope') seeking the agreement of these centres to refer any access applications to the country of origin, where known, for their PIC and MAT. This will preserve the integrity of the Protocol.

Learning from the arduous process of resolving the *ex situ* collections issue, developing countries should, through COP/MOP, resolve the question of the need for the Global Mechanism; and work on the modalities expeditiously if the need is established.

This should also apply to cases of continuing uses of resources acquired before the entry into force of the Protocol.

In the meantime, they should seek an interim solution at COP/MOP where access is sought from *ex situ* centres where the country of origin is known.

3. A SUMMARY

The various options with regard to some key components may be summarised as follows.

3.1 Scope

- **Derivatives.** The term 'utilisation of genetic resources' provides a clear basis for extending the scope of the Protocol to biochemical components of genetic resources. This includes derivatives that no longer are part of the genetic resource and therefore do not have functional units of heredity. This term also appears in the provisions on access, benefit sharing and compliance. Hence these provisions also extend to derivatives. Importantly, access provisions apply to stand alone biochemical components of genetic resources. Finally, the research and development aspect in the definition of 'utilisation of genetic resources' covers the whole chain - from research on the genetic resource and/or the biochemical component right up to their commercialization. This would also include the genetic resource, its modification and the results of any R&D including any information and know-how.

- **Temporal scope.** The inclusion of new and continuing uses of genetic resources and derivatives accessed before the coming into force of the Protocol does not violate the retroactivity principle. This interpretation is consonant with international law. Hence countries may provide for such uses in their national law.

- Pathogens. Pathogens, which are a subset of genetic resources, are clearly within the scope of the Protocol, as evidenced by a specific reference in preamble 16, and the benefit sharing provisions apply for any access. A cumulative reading of paragraphs 3 and 4 of Article 4 and Article 8(b) suggests the following conclusions:

  a. A country can develop a national law that deals with pathogens as a genetic resource and subject it to the ABS requirements.

  b. Countries may also collectively enter into any obligation - including a standard material transfer agreement in international fora such as the WHO -- that reflects the ABS objective of the Protocol. The agreement must therefore include fair and equitable sharing of benefits arising from the utilisation of the viruses, (which should be expeditious if access to the viruses is expeditious), access and the transfer of relevant technologies in relation to developing vaccines for pathogens. The vaccines must be made available to developing countries at affordable prices.

  c. Parties to the Protocol in developing their national law or administrative or policy measures are not bound to take into account any ongoing work or practice in the WHO

relating to pathogens. They need only to consider taking into account any such work or practices.

3.2 Benefit Sharing

Article 5 of the Protocol provides for benefit sharing arising from the utilization of genetic resources as well as subsequent applications and commercialisation. This is no more than an amplification of 'utilisation' as referred to earlier. The sharing must be fair and equitable. Parties are at liberty to determine what constitutes such sharing according to their needs through mutually agreed terms. Countries may stipulate minimum terms that ought to be included to fulfill the fair and equitable criteria in their national ABS law. Some of these terms are indicated in Article 6 paragraph 3(g) of the Protocol. Developing countries could consider drawing up a menu of model clauses for easy reference. This may be particularly helpful where genetic resources are endemic to a region so as to avoid any downward spiralling of such terms.

3.3 Compliance

There is a clear obligation for countries with users in their jurisdiction to establish 'effective, appropriate and proportionate' measures for compliance. Developing countries can, through national law and a COP/MOP decision, establish clear and objective criteria for what constitutes 'effective, appropriate and proportionate' measures. Further national law could provide for the denial of access to users where their countries have not established measures that match the criteria.

The Protocol obliges countries to establish one or more checkpoints to monitor compliance. The choice of the checkpoint is in the discretion of Parties. Developing countries could seek to secure the following decisions at COP/MOP:

a. that the checkpoints be those that are effective for purposes of monitoring compliance;

b. that Parties inform the Secretariat of their designated checkpoints within a prescribed timeline;

c. the COP/MOP will evaluate whether the checkpoints are effective for purposes of monitoring and transparency in relation to the utilization of the genetic resources including derivatives, bearing in mind the criteria specified in paragraph 1(a)(iv) of Article 17;

d. if the check points are considered not to meet the said criteria, the Party will be required to re-designate an appropriate checkpoint;

e. if a Party fails to designate an acceptable checkpoint, it will be deemed to be in non-compliance;

f. countries that already require disclosure requirements at intellectual property rights offices must be obliged to name such offices as a checkpoint;

g. other countries should be required to endeavour to designate such offices as a checkpoint;

h. there must be mandatory disclosure requirements at the checkpoints by the production of the international certificate.

Parties may also prescribe in their national law that access will be denied to users unless and until their countries have designated checkpoint(s) acceptable to COP/MOP. Until such a

decision is made by COP/MOP, Parties may deny access to users in countries that have no effective checkpoints.

3.4 Access to Justice

Developing countries should, through decisions of COP/MOP and their national law, elaborate on the content of 'access to justice' in Article 18 of the Protocol. This Article requires user countries to take effective measures to ensure that provider countries have recourse to their legal system to obtain redress when there has been a breach of the mutually agreed terms for the grant of access. The concept 'access to justice' encompasses several facets as the Aarhus Convention instructs. It includes an obligation to provide access to administrative or judicial procedures to challenge breaches of national law as is provided for by Article 18.2 of the Protocol. The concept also envisages giving the right to a wide category of persons to challenge any violation of national law in court or any other independent and impartial body, such as an ombudsman. This would include NGOs and indigenous and local communities. Importantly, the term also obliges a State to ensure that costs in bringing an action are not prohibitively expensive. States must therefore provide an inexpensive and accessible forum.

3.5 Traditional Knowledge

The Protocol advances the CBD provisions on TK. However, these provisions are made subject to national law. It should be clarified that this is to allow countries to reflect the diversity of the ways in which TK is held and treated in different countries. A preamble to the Protocol recognizes 'the unique circumstances where traditional knowledge associated with genetic resources is held in countries'. The qualifier should not be construed to thwart the rights of indigenous and local communities. Further, it should be clarified through COP/MOP decisions and national law, that nothing in the Protocol allows for access to publicly available TK or TK that is diffused and has no identifiable holders (and that is consequently held by the State) without PIC and MAT. Work in other fora - such as WIPO - should not be allowed to undermine this requirement as this would clearly run counter to the objectives of the CBD and the Protocol.

3.6 Technology Transfer

The Protocol subtracts from the provisions of the CBD on technology transfer. It is of crucial importance for COP/MOP to restate that the provisions in the Protocol are built upon the existing obligations in Article 16 of the CBD. This should include, inter alia, a clear obligation by Parties to provide incentives to the private sector within their jurisdiction to promote and encourage access to and transfer of technology to developing countries to help them establish a sound and viable technological and scientific base. This will be operationalising Article 16.4 of the CBD.

4. CONCLUSION

As is common knowledge, the Nagoya Protocol was rushed through in the final hours of COP10 in an attempt to secure a binding instrument on ABS. As a result the Protocol represents, at best, a partially negotiated instrument. In the process, transparency, legal certainty and balance seem to have been sacrificed. The silver lining, however, is that the generalised provisions, crafted in an attempt to accommodate seemingly polarised positions, provide considerable flexibility. It is for developing countries to exercise the options open to them as a result, as outlined in this article, through national law as well as through COP/MOP at the crucial implementation stage after the Protocol is ratified. Hopefully, this will finally provide the world with an instrument truly supportive of national ABS laws and policies to end biopiracy and restore fairness and equity in the exchange of genetic resources across the globe. For, ultimately, only on the basis of fair and equitable sharing of benefits can the conservation and sustainable use objectives of the CBD be finally realized.

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ANNEX

NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

NAGOYA PROTOCOL
ON
ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION
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TEXT AND ANNEX

NAGOYA PROTOCOL

ON

ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION

TO THE

CONVENTION ON BIOLOGICAL DIVERSITY

TEXT AND ANNEX

SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY
MONTREAL

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Introduction

The Convention on Biological Diversity was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit") and entered into force on 29 December 1993. The Convention is the only international instrument comprehensively addressing biological diversity. The Convention's three objectives are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

To further advance the implementation of the third objective, the World Summit on Sustainable Development (Johannesburg, September 2002) called for the negotiation of an international regime, within the framework of the Convention, to promote and safeguard the fair and equitable sharing of benefits arising from the utilisation of genetic resources. The Convention's Conference of the Parties responded at its seventh meeting, in 2004, by mandating its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing in order to effectively implement Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge) of the Convention and its three objectives.

After six years of negotiation, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity was adopted at the tenth meeting of the Conference of the Parties on 29 October 2010, in Nagoya, Japan.

The Protocol significantly advances the Convention's third objective by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. Specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing genetic resources and contractual obligations reflected in mutually agreed terms are a significant innovation of the Protocol. These compliance provisions as well as provisions establishing more predictable conditions for access to genetic resources will contribute to ensuring the sharing of benefits when genetic resources leave a Party providing genetic resources. In addition, the Protocol's provisions on access to traditional knowledge held by indigenous and local communities when it is associated with genetic resources will strengthen the ability of these communities to benefit from the use of their knowledge, innovations and practices.

By promoting the use of genetic resources and associated traditional knowledge, and by strengthening the opportunities for fair and equitable sharing of benefits from their use, the Protocol will create incentives to conserve biological diversity, sustainably use its components, and further enhance the contribution of biological diversity to sustainable development and human well-being.

NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,

Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,

Recalling further Article 15 of the Convention,

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Recognizing also the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

Article
1
OBJECTIVE

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Article
2
USE OF TERMS

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Convention" means the Convention on Biological Diversity;

(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Article
3
SCOPE

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article
4
RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Article
5
FAIR AND EQUITABLE BENEFIT-SHARING

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article
6
ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to

genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

Article
7
ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Article
8
SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Article
9
CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

Article
10
GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Article
11
TRANSBOUNDARY COOPERATION

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

Article
12
TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Article
13
NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall

forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

Article
14
THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION-SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

(a) Legislative, administrative and policy measures on access and benefit-sharing;

(b) Information on the national focal point and competent national authority or authorities; and

(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

3. Additional information, if available and as appropriate, may include:

(a) Relevant competent authorities of indigenous and local communities, and information as so decided;

(b) Model contractual clauses;

(c) Methods and tools developed to monitor genetic resources; and

(d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article
15
COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article
16
COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING FOR TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article
17
MONITORING THE UTILIZATION OF GENETIC RESOURCES

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

(a) The designation of one or more checkpoints, as follows:

(i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

(iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.

(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

(c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required

by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

(d) Unique identifier of the certificate;

(e) The person or entity to whom prior informed consent was granted;

(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

Article
18
COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

Article
19
MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article
20
CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Article
21
AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia*:

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

Article 22
CAPACITY

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia,* the following key areas:

(a) Capacity to implement, and to comply with the obligations of, this Protocol;

(b) Capacity to negotiate mutually agreed terms;

(c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia*:

(a) Legal and institutional development;

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

(c) The monitoring and enforcement of compliance;

(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

Article
23
TECHNOLOGY TRANSFER, COLLABORATION AND COOPERATION

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

Article
24
NON-PARTIES

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

Article
25
FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties

with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article
26
CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat

of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 27
SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

Article 28
SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article
29
MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

Article
30
PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

Article
31
ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

Article
32
SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

Article
33
ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article
34
RESERVATIONS

No reservations may be made to this Protocol.

Article
35
WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article

36

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired;
   (b) Up-front payments;
   (c) Milestone payments;
   (d) Payment of royalties;
   (e) Licence fees in case of commercialization;
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   (g) Salaries and preferential terms where mutually agreed;
   (h) Research funding;
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.
2. Non-monetary benefits may include, but not be limited to:
   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

   (c) Participation in product development;
   (d) Collaboration, cooperation and contribution in education and training;
   (e) Admittance to *ex situ* facilities of genetic resources and to databases;
   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
   (g) Strengthening capacities for technology transfer;
   (h) Institutional capacity-building;
   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
   (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
   (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
   (l) Contributions to the local economy;
   (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
   (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
   (o) Food and livelihood security benefits;
   (p) Social recognition;
   (q) Joint ownership of relevant intellectual property rights.