

The Nagoya Protocol was adopted on 30th October 2010 - after 6 years of intense and rancorous negotiations. The final text was crafted by a handful of selected countries and virtually foisted on the rest of the world. This article traces the process leading up to the adoption. It analyses key features of the Protocol and examines whether the Protocol

- balances the interests of providers (mainly developing countries) and users (mainly developed countries),
- provides for legal certainty, and
- incorporates, adequately or at all, the concerns of provider countries.

A balance sheet along developing - developed country lines charts the outcome in terms of the negotiating positions.

The article highlights the challenges that developing countries may face in the implementation stage of the Protocol. It concludes with an outline of the options available to meet these challenges.

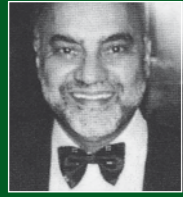
THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING OF GENETIC RESOURCES: AN ANALYSIS

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CEBLAW was established by the Government of Malaysia and the University of Malaya to foster research, development and training in matters relating to biological diversity and biosafety. It is a national, regional and international resource centre for biodiversity law. It assists the Government in the negotiations on international treaties relating to access and benefit sharing of genetic resources (under the Convention on Biological Diversity) and liability and redress (under the Cartagena Protocol on Biosafety).

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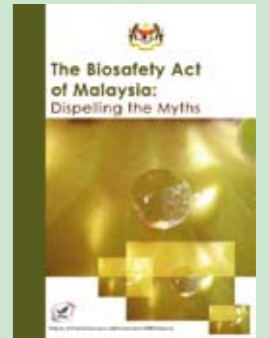
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A study prepared for the UN Food and Agriculture Organization in 2009 on whether, and how, national and regional laws, guidelines and other arrangements on access to genetic resources and benefit-sharing (ABS) may impact upon agriculture and food security.



Access and Benefit Sharing of Genetic Resources: A Record of the Negotiations of an International Regime, Vol. 1 (2010)

By Gurdial Singh Nijar and Gan Pei Fern

This publication provides:

- a comprehensive history of the negotiations from the 5th meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing of the Convention on Biological Diversity (WG ABS 5) until the WG ABS 9 (Part 1);
- a short description of the current elements being negotiated; and
- the positions of all participants (Parties, non-Parties, and NGOs from industry, universities, research groups and civil society organizations).

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ACRONYMS

ABS	Access and benefit-sharing
CBD	UN Convention on Biological Diversity
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
GR	Genetic resources
GRULAC	Group of Latin American and Caribbean Countries
ICG	Informal Consultative Group on ABS
ILCs	Indigenous and local communities
IP	Intellectual Property
JUSCANZ	Group constituting Japan, United States, Canada, Australia and New Zealand
LM APAC	Like-minded Asia Pacific Countries
LMMC	Like-minded Megadiverse Countries
MAT	Mutually agreed terms
PIC	Prior Informed Consent
TK	Traditional Knowledge
WHO	World Health Organisation



THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING OF GENETIC RESOURCES: AN ANALYSIS

1. INTRODUCTION

After a long wait of some six years - in the early hours of 30 October 2010 - an ABS Protocol with regard to genetic resources was finally adopted in Nagoya. It was a miraculous end to some 14 days of tumultuous and rancorous negotiations - marked by a break up of the solidarity of negotiating developing country groups, and secret deals. It was finally foisted, primarily upon developing countries, by the Japanese presidency of COP, in an atmosphere reminiscent more of a surrender ceremony than a triumphant outcome. The two Co-Chairs of the Working Group, who had presided over the process for more than the four preceding years, were conspicuously kept out of these final hours' parallel processes.

The Protocol that emerged eliminates some key concerns of developing countries, introduces vague and indeterminate provisions, and bristles with legal uncertainty. Significantly, it does not advance the CBD text in key areas and, in some crucial aspects, may even be CBD-minus. Notably, though, the provisions of importance to developed countries - relating to access - impose detailed and specific obligations on countries providing genetic resources.

The process

The final document that was presented for adoption came about through a rather unusual and unprecedented process. It was not arrived at through negotiations. What transpired is that well before Wednesday 27 October, Brazil and the EU initiated secret negotiations. As an EU negotiator disclosed quite inadvertently in the course of a small group negotiations the following day: *'In the course of the discussion subsequent to Montreal, we understand Brazil, representing other groups, has*

concerns. Therefore we undertook to start to talk to Brazil. We were speaking informally with Brazil to understand the concern of others, the concern on 'utilisation'.

The negotiators of EU and Brazil met and struck a deal. They had the blessings of Japan as well. They began to work on the text of a Protocol.

That was the moment in time when Brazil began its shift from the positions it held commonly with the rest of the developing world. It was working - tactically and strategically - as a leader of the LMMC and the rest of the developing world in the day but consorting with key developed country protagonists in secret in the night.

Late on Wednesday night 27 October 2010, two days before the meeting and the negotiations were scheduled to conclude, Japan, EU and Brazil roped in Namibia for a secret meeting. Norway was included too for good measure. The only negotiators present were those from the EU and Japan. Much later in the night, Namibia's negotiator also took part. At this very late night session a deal was struck on the issues that were key for these countries. Reportedly, it revolved around the following: a multilateral benefit sharing mechanism for genetic material and traditional knowledge (TK) acquired before the Protocol's entry into force, benefit sharing for derivatives linked with provided genetic resources and expeditious access to pathogens for health emergencies with accelerated benefit sharing. In return Brazil and Africa were happy to accede to all of the text as presented and negotiated by the developed world thus far.

Meanwhile, the rest of the negotiators were excluded. Blissfully ignorant of this development, they were still busy negotiating the difficult key issues!

Who precisely crafted or made a determination on the final text of those outstanding issues is a matter of conjecture and would require a confession from the Parties or negotiators involved. Nonetheless it is safe to assume that it was primarily the EU and Japan - with Brazil's agreement - that were certainly involved in drafting the crucial parts of the text, as is narrated later in this article. Two seasoned members of the secretariat staff were then directed to polish it up and spent the whole of Thursday 28 October doing so.

The following day – Thursday 28th October - a text relating to derivatives was presented by the Co-Chairs at a hastily convened closed-door noon meeting of key negotiators. The EU admitted that the text, although headed '*Proposal from Brazil, 28 October 2010, 14.15 pm*' (the meeting was held at noon!) was crafted by the EU and Brazil. The EU negotiator said, '*In Nagoya, experts sat between Brazil and the EU and looked at what could be that makes it work*'. Everybody else present condemned the undisclosed process leading to the text as non-transparent and non-inclusive. [See Box 1 for a summary of what transpired.] In response to these angry remonstrations, the Co-Chairs confirmed that they were kept out of this 'parallel process' and were not acting at the behest of any country or countries. A key negotiator, echoing the feeling of others, said that '*The way this was done is unacceptable. We did not know all this was going on behind our backs*'.

Colombia offered a text on derivatives as a solution which it said was based on, and more accurately reflected, the state of the open negotiations to-date. The meeting ended without any agreement. Parties decided to meet in the late afternoon and continue discussions primarily to resolve the issue of derivatives by focusing on the provision relating to use of terms.

Later that evening, when negotiations in a small group on 'utilisation of genetic resources' reached an impasse [see Box 2 of an account of the negotiations] pressure was being applied to countries. Ministers from some developing countries were receiving calls asking them to reign in their negotiators to relent. Even an

international NGO, the World Wide Fund for Nature (WWF), weighed in rather audaciously. This led a developing country negotiator to complain at the final IGC open meeting that night: '*There is extraneous pressure now being applied on developing country negotiators. It is based on a distortion of what is actually transpiring in the (closed) small group meetings. We ask for a formal assurance from our partners that they are not privy to these high handed techniques*'. No such assurance was forthcoming. Japan spoke of the great achievement and progress made. Its negotiator continued: '*The remaining task would be made much easier building upon your effort. We will just make additional work*'. He then said: '*We will make the final effort*'. To everyone's surprise, he announced that the following day all regional groupings would be invited to the Presidency room according to a time slot. On cue, the EU negotiator expressed the hope that the presidency would bring some good news the following day and said that he expected Parties '*who are reluctant to move forward today*' to respond favourably. By then, of course, as the earlier narrative discloses, Japan, the EU and Brazil had already crafted the Protocol. The time had arrived to put their secret deal into play.

And so, on the morning of the final day, Friday 29 October, this pre-crafted final version of the Protocol was distributed to Parties. At hastily convened meetings, the rest of the world tried to come to grips with its terms. The developing countries (except the Africa Group) too quickly met and rushed through a review of the provisions. They decided that they would only accept the Protocol if several important changes were made. [See Box 3 for a complete list of the proposed changes.] In the meantime the negotiators of the Africa Group informally informed some key negotiators of the LMMC and LM APAC that they were not accepting the Protocol and were going to bracket the strategic and the resource mobilisation plan. This then was the state of play just before the meeting in the Japanese COP President's room at 1 pm that day.

[See Box 4 for an account of the crucial LMMC Meetings]

BOX 1**MEETING OF SELECTED NEGOTIATORS WITH CO-CHAIRS ON 28 OCTOBER 2010 AT 12 NOON - EXCERPTS**

Co-Chair: We have to try to resolve the issue of derivatives, now or in an hour or two.

Switzerland: The main issue is scope of the Protocol. Everybody agrees that it covers genetic resources including biochemical components. Question is: does the protocol also address naturally occurring biochemical compounds derived from genetic resources and accessed independently of genetic resources? 90% to 95% of cases will be covered by provisions on access to genetic resources. A little bit might not be covered. If we want to cover everything, then we cannot find a solution in one hour.

Co-Chair: Those who want the remaining 5% to 15% to be covered, they need to determine whether we need it now. This can be done in the future. Otherwise the protocol will not be adopted.

Brazil: Derivatives is a crucial issue in this text. Three experts from Brazil discussing this issue and exchanged a few ideas with the EU. This can work for both of us. I have the language. For Article 4 (Benefit-sharing) include the word “as well as subsequent applications and commercialisation”. It is very straight forward and possible way out for you all to consider. We did not try to bypass anyone. It is honest work to get a protocol. I tell you this quite frankly.

EU: In the real world we want to get it 100% right. We want to strike a balance. Already come to a very good balance. Previous text and Montreal text cost us dearly. But we are ready to move in this direction. In Nagoya, experts from Brazil and EU sat down and looked at what could be that makes it work. We are very interested in going down that road. 97.5% to 98% would be covered and enable us to deliver the protocol we expect by today. Other pending issue is Article 6(b). Package involves new wording on “utilisation”. Do we still need the word “derivatives”? Article 4.1, we take out the bracket on “as well as subsequent applications and commercialisation”.

Australia: I will undertake to look at this (text) but we have concerns on your proposal.

Brazil: It's a package. So keep the word “derivatives”.

[Text by EU-Brazil distributed.]

Co-Chair: We will meet at 2pm for you all to respond.

Canada: There is not enough time to consult and decide.

Malaysia: This is quite unacceptable. We did not know all this was going on behind our backs. It appears that one or two countries have considered this fully and even formulated detailed text on it. The rest of the countries are expected to respond on the run. We are now presented with this, and told to do it this way in this time.

Colombia: I also express my concern. In fact I have another text to offer as a solution. It is based on the discussions we all had in the last several days.

Australia: I register my concerns about the process and the limited time. This Protocol will have big concerns and ramification and put us in a difficult position. It is a big ask. I am very concerned about the process.

EU: Some of us have been involved in this issue for 6 years. We understand each other. If this is not a workable solution, fine. But we are looking for a compromise.

[While EU is speaking, some countries shout: “But you do not do it this way! This process is wrong.”]

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Co-Chair: We did not ask you to come here on behalf of one or two countries. We did not come here to act on their behalf. Just that one or two countries have presented a solution.

Peru: 1. We appreciate the intention of EU-Brazil to build constructively on this, and will consider regardless of the source and will try to act positively.

2. We are not agreeing to any process that is not transparent and inclusive. Presenting us at the last minute with a proposal that they (EU-Brazil) have worked out in their own time, is not something we consider correct.

3. It is not the time to say we don't understand. All know what is at stake here. Is the coverage 95% to 97% - we are not sure. Who has made this calculation? It could perhaps be less, lesser, or even much lesser. We are not dealing with isolated, abnormal, out of bulk cases. For countries which have experience of cases of biopiracy, abnormal cases are the one which are most valuable commercially. We have not seen any economic assessment of the value of the derivatives not covered.

Other issues to consider: pathogens, scope.

Compliance very much linked to this, we need to see whether we agree to remove a portion of derivatives (from the scope). We need a linkage type of conversation. Need assurance that what we are going to discuss in the next few hours will not be interfered with by political negotiations in the Ministerial segment. There should be no parallel fora or process of any kind.

Co-Chair: We are building transparency. We are helping all of you, not some of you. We have not been working with any particular delegation. We have not been working in parallel.

Iran: We all understand that we cannot have a leak-proof protocol. This compromise is for both sides - provider and user. We need to have something that is a win for all of us and for biodiversity.

Australia: We need to find a workable solution on Article 6(b).

New Zealand: 1. We share the concern about the process. A lot of what we do is about process. If we don't get it right, even the best effort to explain to others will fall over.

2. We all understand the issues, but when it comes to utilisation, we need our experts at home to provide feedback. We are not trying to slow down the process but we can't make an announcement (agreeing to the proposal presented).

Philippines: We need a package as well. We also question the process. We need to consult and work in alliances and we need to do that very quickly.

Republic of Korea: We are ready to work on any constructive proposal.

EU: The solution is for everybody to adopt. Trying to provide a bridge for what is seemingly unbridgeable. Every party should have brought at least one expert for technical advice (for the negotiations at Nagoya).

Co-Chair: Be ready to compromise, otherwise there will be no solution. There will be a plenary but it will be difficult to open this issue at the plenary.

[Co-Chair announced that we meet at 4pm.]

BOX 2**THE SMALL GROUP NEGOTIATIONS ON 'UTILISATION OF GENETIC RESOURCES' HELD ON 28 OCTOBER 2010**

The EU-Brazil text presented was as follows:

“Utilisation of genetic resources’ means to conduct research and development on the functional units of heredity as well as on the naturally occurring biochemical compounds resulting from gene expression contained in genetic material accessed under Article 5 ...”

At the late afternoon meeting, developing countries rejected this EU-Brazil text as it clearly excluded derivatives - as was made clear by the use in the proposed text of the phrases ‘functional units of heredity’, and ‘gene expression’. To ensure that derivatives resulting from the metabolism of the genetic resource (secondary metabolites) would be included, developing countries proposed adding the words ‘*and metabolism of genetic resources*’ after the words ‘*gene expression*’. The proposal that was then presented by Iran, India, Malaysia, Colombia and Peru was as follows:

‘Utilisation of genetic resources means to conduct research and development on the genetic material as well as the naturally occurring biochemical compounds resulting from genetic expression and metabolism of genetic resources ...’

The EU rejected outright working on this proposal. Other developed countries and Brazil wanted this limited to genetic material accessed under article 5 of the Protocol. This again would have excluded derivatives. Iran lamented that ‘*It was disappointing to see that we are the only group conceding and trying to make compromises. We should strive for the middle ground, and both sides should make concessions.*’

The Co-Chairs too attempted to provide a solution by adding a further sentence to the developing country proposal, as follows:

‘The definition of ‘utilisation of genetic resources’ is without prejudice to any right of a Party to require PIC and MAT, in its domestic ABS regulatory framework, with respect to naturally occurring biochemical compounds.’

This was not accepted. The meeting thus ended in an impasse. It is noted that at this stage there was also no agreement on several other key issues as well, such as: publicly available TK, temporal scope, pathogens, relationship clause, checkpoints and mandatory disclosure requirements.

BOX 3**CHANGES AGREED TO BY LMMC, GRULAC AND LM APAC TO THE PRESIDENT’S TEXT AT THEIR MEETING ON THE MORNING OF 29 OCTOBER 2010**

(The changes are shown in tracked-form)

1. NAGOYA PROTOCOL (ANNEX I)**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:

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

ARTICLE 3 SCOPE

1. This Protocol shall apply to genetic resources within the scope of ~~Article 15~~ of the Convention

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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 3 *bis* RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

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.~~

ARTICLE 5 ACCESS TO GENETIC RESOURCES

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

(a *bis*) Provide for fair ~~and non-arbitrary~~ rules and procedures on accessing genetic resources;

ARTICLE 6 SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or 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 in developing countries.

ARTICLE 7 *bis* 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 utilisation of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is was 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 9 TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

5. Parties shall take legislative, administrative or policy measures, as appropriate, so that users of traditional knowledge associated with genetic resources in different forms, obtained from a source other than directly from indigenous and local communities, to enter into fair and equitable benefit-sharing arrangements with the rightful holders as may be defined in domestic law considering the uniqueness of the circumstances.

ARTICLE 12 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 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 13 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 and the traditional knowledge associated to genetic resources. Such measures shall include:

- (a) The designation of one or more checkpoints, as follows:
 - (i) Designated checkpoints ~~would~~will 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, according to national and international law.

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 and/or traditional knowledge associated to genetic resources covered by the certificate;
- (g) Confirmation that mutually agreed terms were established;
- (h *bis*) Confirmation that prior informed consent was obtained; ~~and~~
- ~~(h)~~ Commercial and/or non-commercial use;
- ~~(i)~~ Conditions of transfer to third parties; and
- ~~(h)~~(j) Permitted use.

ARTICLE 14 COMPLIANCE WITH MUTUALLY AGREED TERMS

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

- (a) ~~facilitated a~~Access to justice; and

ARTICLE 19 FINANCIAL MECHANISM AND RESOURCES

3. Regarding the capacity-building and development referred to in Article 18 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 and the small island developing States among them, and of Parties with economies in transition, for new and additional financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

2. WORK PLAN (ANNEX II)

B. Issues for consideration by the Intergovernmental Committee at its second meeting

- 13. Ex-situ collection.

3. DRAFT DECISION

~~Recognizing that the international regime is constituted of the Convention on Biological Diversity, the Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization, as well as complementary instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture and the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization~~

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I. Adoption of the Nagoya Protocol

6. ~~Decides that the first review under Article 25 of this Protocol shall assess the implementation of Article 12 bis in light of developments in other relevant international organizations, including, *inter alia*, the World Intellectual Property Organization, provided that they do not run counter to the objectives of the Convention and this Protocol;~~

6. Decides that the COP/MOP shall address the benefits of *ex-situ* collections regarding the provisions of the protocol.

BOX 4

BRAZIL AND THE MEETINGS WITH THE LMMC

On Wednesday 27 October 2010 morning the Ministerial Like Minded Mega Diverse Countries (LMMC) heard Brazil (which held the Chair for the group) say that their political assessment was that it was essential to conclude a protocol - even an imperfect one. Otherwise the momentum would be lost and there could be no protocol ever again. The Ministers of all the other mega diverse countries, however, rejected this view. [See below a Minister's response.] The LMMC, represents 17 developing countries holding the largest biodiversity in the world, and had been playing a central role in the negotiations since the mandate to negotiate an ABS protocol was established in 2004 at COP 7.

In fact Brazil had given an indication of its intention the day before (Tuesday 26 October 2010) at a strategy meeting of LMMC, Like Minded Asia Pacific countries and the Group of Latin American and Caribbean countries (GRULAC). Brazil said it was better to end the negotiations here in Nagoya with '*not an ideal protocol, but a framework protocol*'. Brazil's posture caught the rest of the group by surprise. It was a distinct departure from their firm position right from the outset of the negotiations that it was better to have no protocol than to conclude a weak or insignificant one. They even got the rest of the group to agree that without a significant protocol, LMMC should not agree to any strategic or resource mobilisation plan. However towards the end Brazil resiled from this position and was ready to accept any Protocol - no matter an imperfect one. And so the leverage for a strong Protocol in exchange for the strategic plan and resource mobilisation remained an empty self defeating negotiating stance. The meeting ended, however, with Brazil agreeing not to break ranks and to go along with the decision of the rest to: (1) reject a weak protocol; (2) reject a framework or hybrid (mix of framework with details as well) that does not secure the interest of developing countries; (c) secure developing countries' interest; (4) continue negotiations until developing countries achieve a meaningful protocol, including after Nagoya.

Statement by Malaysian Minister, Dato Douglas Unggah at the Ministerial LMMC Meeting. : 'Do not rush to adopt a weak protocol'

Malaysia would like to stress that ... we all want the negotiations to conclude here in Nagoya and for us to adopt a protocol but we must not rush to adopt a weak protocol. That will not be in our interest at all. We must adopt a protocol that is meaningful and balanced. I too urge that we should move as a group towards this end as we have over 60% of the world's biological resources.

An imperfect protocol now that compromises our interests will be detrimental to the long term interest of our nations. Let's move carefully. It is not now or never. We have made good progress on this ABS issue and let's capture and maintain this work. If in the next remaining days we do not capture our important interest, we should continue the negotiations. The process must have clear time table with deadlines.

If we are together in this endeavour as a group, this will certainly be possible.

BOX 5**MEETING CONVENED BY THE COP PRESIDENT WITH KEY SPOKESPERSONS OF ALL GROUPS HELD ON 29 OCTOBER 2010 AT 2 PM: EXCERPTS**

COP President: I am an old living creature as well as representing a new born baby.

Would like to hear views on proposal in the Protocol.

Brazil: The group of LMMC met this morning to consider your text. We consider your text with great respect. The group understands your attempt to move the process forward. The group had an opportunity to study the main elements of your text. Although under time constraint but able to look at the main point of your text.

I will try to be faithful to the spirit of the meeting.

The group understood we'll have to make sacrifices. With that spirit of compromise, we went through different parts of your text. I have to report that there are elements the group feel are fundamental positions they had not contemplated.

But the group also feels that we should have an opportunity of explaining them and try to reach consensus with all other members. We're convinced that consensus is really within reach. And we are ready to work in the remaining few hours that we have in order to fine tune those elements. There are not many elements we reopen, not into drafting exercise, but those we identified are really fundamental issues.

But would like to repeat all that in a good spirit, to have a protocol in Nagoya.

Mexico: GRULAC this morning we offer our commitment in good faith to try to include key points our region have been working on.

President: Don't think our proposal is perfect. But this is a product of all knowledge and wisdom, with all elements that were discussed and negotiated. Based on 18 years background. We're about to reach the peak. COP 8 resolution IR should be completed at COP 10. Activities before COP 10 - in New York, Montreal - many groups worked so hard. We know it is not perfect, inadequate. This is the final draft that I would like to present to you. So that you can accept it as a final draft. It includes all the views presented.

EC: We've also been engaged in these long negotiations in good spirit. Believe we are doing something which would benefit humanity. Work towards getting consensus. We worked in EU and studied the main elements of the text. With clear spirit will reach agreement and compromise. Accept in clear spirit of compromise. Many points included in the proposal are not easy to be accepted. But on the basis of thorough thinking, what we gain and what we lose, if we accept this compromise proposal, we are ready to accept as it stands now. The guiding principle we were following - to do our best for work in the future.

India (Vice- Minister): We still do have some concerns: derivatives and checkpoints. But at the same time we know today is the last day. Those concerns will stay with us - these are foundational concerns. As next COP hosts, we're strongly committed to the success of Nagoya. I was confident and did have a general idea that Nagoya would be a milestone. We've already arranged the happy hour at 6pm, that's how it is, that's life.

President: I promise - will make sure there'll be happy hour at 6 o'clock.

JUSCANZ: not speaking as a negotiating group. We had discussions this morning twice. There was a deep appreciation for the way shown by the Presidency, for having the courage of taking this step. We had a clear look at your text, it's a compromise, focusing on the main element and the main issues. There are some new elements for which a number of very important concerns raised. Some of us have to consult with capitals (on these). Some have serious concern. To be able to accept, the compromise has to be balanced - each of us have to accept issues that we are not happy with, perhaps. Clear indication, there'll be willingness to discuss some of these issues. Understand this would be the same for others and the same

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stance in the negotiations will be repeated. The members of our group are not convinced that we should add hundreds of hours more for this. The text as it is now not easy to accept.

CEE (Ukraine): Thank you for the draft protocol. We've gone through the proposals.

Our region recognises that the main elements reflect the position of the negotiations. At the same time, our region has different social ecological level, different substantial views of this protocol. We understand the President prepared this compromise protocol to help achieve our main goal on ABS. Renewing negotiations not help now. We welcome a consensus decision on this draft.

Malaysia: You have provided us with an important and positive document to move forward and hopefully for its conclusion. Mr president, together with LMMC who represent 17 developing countries that have the largest world's biodiversity - GRULAC, the Like Minde Asia Pacific countries, we have looked at various important aspects in your document that affect us. Since the Johannesburg World Summit in 2002, all governments - including yours and mine - agreed that benefit sharing has to be implemented in a way that would assist countries in achieving the third objective of the CBD, and as we all know, with benefit sharing will come the conservaiton and sustainable use of biodiversity and the saving of the planet for our, and our children's future. We are looking forward to, as LMMC and GRULAC have also said, to some adjustments in the document, to take account of this BS component in your doc. In our considered view, with some adjustments - adjustment of one word made in scope, we will ensure that the benefits we've been waiting for for so long for, will be dealt with in an adequate way. One word in the protocol, but a big step for developing countries and humanity at large. So we look forward very much, for a final look at the protocol, Believe everyone is on the same page for a balanced protocol. We look forward for this adjustment and compromise.

And there are also other amendments by developing countries which we would also like to get through. Our spokesperson would like to present these so that we can adjust - so that this can become a historic document - a historic step for biodiversity and for the planet itself.

President: Sincere appreciation for all of you to frankly explain to us your various views and situations of countries for the sake of compromise. However we could not reach the target 2010, set in 2002 that was supposed to substantially slow down the loss of biodiversity. We are all disappointed in not reaching the goal. We are now facing the future after 2010. Must do something to achieve the protocol so that we can launch a step forward. As you have mentioned, if this protocol is not adopted here in Nagoya, we may have to spend 100s of hours in future to start negotiations again. There are different opinions and views, the document is not perfect but urge you to accept the draft as it is.

Unfortunately we are missing the representatives of the Africa Group. Couldn't say all parties agreed to this proposal. Can we say there's consensus among the parties here?

Brazil: the group of LMMC do not agree to this text. We are very close in agreeing to this text. And we would like to have a last opportunity, maybe at the political level, to close this text. Very near in this text. So we request to you with all due respect - an opportunity to do that.

President: Thank you. As the president of COP 10, I would like to submit this original text as it is to the plenary.

Malaysia: Before this document is presented to the plenary, we have Brazil on behalf of LMMC and developing countries saying we need to have a final opportunity to look at some crucial aspects. Without looking at these, developing countries, as much as we would like to say yes, would find it hard to say yes. Without this opportunity, we couldn't say yes. A plea from developing countries. All the developing countries are speaking with one voice - we said we need your help, we are crying out to you, pleading to you, on the basis that as it is, it is not a balanced proposal.

Mexico: I have the responsibility to speak on behalf of GRULAC - to find a balanced solution. Would like

to ask you kindly to give us the opportunity.

EU: It is true that countries are trying to stretch their limits. Now would favour to look at the concerns of developing countries. We have stretched ourselves to the limit. Not easy what we've done, it's a chance that we wouldn't return to anymore.

President: *[To Brazil]* If you have any specific wording, could you please tell me specifically?

Brazil: We're all making sacrifices. My friend from Like Minded Asia (Malaysia) said that we have some points, but one specific point seems to be the most crucial for developing countries, and I would like to concentrate on that. That would be Article 2 on the use of terms. Although it has the meaning of utilisation of genetic resources (GR), but the second line refers to genetic material (GM). The main concern of developing countries: replace GM by GR.

GRULAC and Asia Pacific: support this change.

EU: I have a simple question. Is there consensus?

Brazil: Those who are here are asking for that. I cannot say for sure everybody would agree to this.

EU: If this is something that would lead us to sign, we say yes.

JUSCANZ: Not able to speak on behalf of the group. We are not a negotiating group. What was discussed within our group was based on a reflection of the discussion in good faith to try to find common ground. We have not been able to reach that common ground without your strong leadership on that. We would have been able to accept the proposal. My delegation would be willing to look at the proposal. Need a short moment to see whether we could reach out to other parties in our group.

A spokesperson: Australia, New Zealand and Canada can accept.

[A large number of members of the Africa Group begin to enter the room in large numbers while JUSCANZ is speaking. Others on the table have to make way for them to sit at the table.]

President: So now we want to share this view with them (Africa Group) now.

African Group (Minister from Namibia): Africa also wants to appreciate the manner, difficult as it may be, to come out with a document for our final adoption. And you've been working closely to conclude the work in time. From time to time the document was presented to us. Now it has to come back to you. We were not able to conclude. The time given to consider the document (the President's draft) is too short for us to say we feel the document could fulfil the minimum objective of what we are looking for. However, we refer to Article 25 of the document that provides for assessment and review in the future. On this basis at this point of time, Africa accepts the President's draft - with the understanding that at that time of review, we will get into the details of implementation, and of our concerns.

President: Before this, we had almost consensus on the draft protocol.

Secretariat: There was one change in p7 - use of terms - replace 'material' with 'resources'. Parties reached agreement on this change.

President: I confirm with that amendment we agree to this President's text.

At this meeting, with the spokespersons of various groups, the President formally presented the Protocol on a 'take it or leave it' basis. *[See Box 5 for an account of the proceedings at the meeting.]* A spokesperson for JUSCANZ said that it was not easy to accept the text but that they were not convinced that further negotiations would be

useful. Developing countries indicated that there were changes to be made before the Protocol could be accepted. The President insisted on submitting the original text to the plenary for adoption. A developing country spokesperson responded that adjustments were needed on some crucial aspects without which '*...developing countries, as much*

as we would like to say yes, would find it hard to say yes ... on the basis that it is not a balanced proposal.

Then the process took on a rather bizarre turn. Brazil, as the LMMC representative assigned to present the proposals for developing countries, stated that it would focus on only one change – the term ‘*utilization of genetic material*’ to be changed to ‘*utilization of genetic resources*’. This was an important change for developing countries as the Protocol would then include derivatives as a cross-cutting component. However no other changes, which developing countries had agreed to make, were presented. Indeed in their interventions earlier, the spokespersons for Like Minded Asia Pacific and GRULAC had clearly indicated that there were other key points that they wanted included or changed in the text. The EU agreed to the change; as did JUSCANZ. In that rather tense and brittle atmosphere, things suddenly moved rather swiftly. The Africa Group which was conspicuously absent throughout this meeting, then marched into the President’s Chambers in large numbers and, through the Namibian Minister, declared their unqualified support for the Protocol. In that atmosphere, and with the solidarity of developing countries now in disarray, the Protocol was agreed to. At the Plenary that started later in the evening and continued to the early morning hours of 30 October 2010 the Protocol was adopted

What follows is the background to the negotiations and an analysis of the main components of the Protocol.

Background: the meetings leading up to Nagoya

Historically genetic resources were accessed for free on the principle that these were the common heritage of mankind. However, with the increased recognition of intellectual property rights and private ownership over products of genetic resources, this view has changed. The 1992 Convention on Biological Diversity (CBD) introduced a new legal framework where sovereign rights of States over these resources was acknowledged and the authority to determine

access to genetic resources agreed to be a matter of national legislation which may need to be subject to benefit-sharing arrangements.

Nevertheless, the practice of free or illicit access continued and changed little even after the CBD came into force in 1993. This led to the call at the World Summit on Development in Johannesburg in 2002 for the benefit sharing provisions of the CBD to be implemented. A process was initiated that finally led to the establishment of the mandate at the 7th meeting of the Conference of the Parties to the CBD in 2004 at Kuala Lumpur for the development of international rules on access and benefit sharing (ABS) in relation to genetic resources.

The early Working Group meetings held variously at Bangkok, Paris, Granada and Montreal were marked by a sustained refusal by developed countries (where most of the users of genetic resources are coming from) to concede even the need for a binding instrument. Efforts by developing countries (which are mostly providers of genetic resources) to present text proposals were thwarted by the developed countries. The infamous Granada text - which developing countries sought to form the basis of the negotiations - was consistently repudiated by the developed countries. Finally in Geneva at Working Group 6 in January 2008, this Granada text was laid to rest when a ‘bricks and bullets’ approach to identify the essential and the preferable components for a Protocol made some progress. For the first time some developed countries hinted at the prospect of agreeing to a binding instrument.

But the following meetings yielded little result. At Cali in March 2010, Parties agreed to proceed with negotiations on the basis of a draft Co-Chairs’ text. However, for a number of reasons, little progress was made. Some light at the end of the tunnel emerged at Montreal in September 2010 when parties tackled the vexed question of including derivatives within the scope of the Protocol. An ‘understanding’ albeit with several qualifiers was reached. But, ominously, developed countries refused to subscribe to any text based on it. In the event, the negotiations at Cali and the

two subsequent ING meetings held in July and September ended merely with the acceptance of text on several marginal subject matters.

Hence Parties which came to Nagoya in October thought it well nigh impossible that a Protocol could be concluded by the designated deadline.

The competing interests

Access, benefit sharing and compliance have always been the three essential components of the Protocol – the ‘ABC of ABS’. Developing and developed countries laid different emphasis on these components. Developing countries emphasized the importance of securing benefit sharing and effective compliance measures; while developed countries stressed on access standards. The thrust of the developed countries’ strategy was to keep in tact as much as possible, the space afforded by the previous practice of uninhibited access. They argued early on that there was no need for a Protocol as private contracts between parties could deal with issues of access to genetic resources and the sharing of benefits arising from their commercial utilisation. Developing countries, on the other hand, stressed the need for effective compliance measures by countries to ensure that users in their jurisdiction did not misappropriate and commercialise genetic resources from provider countries. They also wished for clear rules that would curb, if not staunch, the continued biopirating of their genetic resources.

Did the Protocol strike a balance in meeting these different needs of developed and developing countries? There are rather specific and elaborate rules on access. In contrast, the compliance measures are vague, vacuous and lacking in specificity. Further, the scope of the Protocol, especially with regard to the inclusion of derivatives, and temporal scope are couched in language that could well be open to varied alternative interpretations. Additionally, matters of considerable concern to some key developing countries have simply been eliminated, such as the provisions on access to publicly available Traditional Knowledge (TK). Finally, the Protocol allows a carve-out from its ambit of genetic

resources to other fora on broad and vague basis (such as ‘ongoing work and practices’ of international organisations) that has no parallel in international law.

In the end there is now established a Protocol that is heavily tilted in favor of users of genetic resources most of which are biotechnological and other companies operating under the jurisdiction of developed countries. Providers, mainly developing countries are obliged to introduce elaborate access obligations that are not required by the CBD. The main Article in the CBD that deals with access to genetic resources merely states that parties exercise sovereign rights over their resources and have authority to determine access to genetic resources and this will be subject to national legislation. Further, there is no more than a voluntary best effort provision to create conditions to facilitate access to genetic resources for environmentally sound uses. This right now is severely curtailed by the Protocol.

What follows is an analysis of the key components of the Protocol. This article proceeds on the following basis:

1. An analysis of the provisions with a description, where useful, of the context and the evolution of the texts through the negotiations.
2. An assessment of whether the provisions are CBD minus or plus?
3. An assessment of whether the provisions serve the interest of developing countries?
4. Finally, whether, and if so how, developing countries may be able to maximize the flexibility in the Protocol to advance their interests.

This article relies upon the record of the negotiations undertaken principally by the author and his assistant at the Centre of Excellence for Biodiversity Law (CEBLAW). The author participated in the negotiations at various times as a spokesperson for the Like Minded Mega Diverse Countries, the Like Minded Asia-Pacific Countries and Malaysia. The assistant was a member of the Malaysian government delegation.

2. THE KEY COMPONENTS

2.1 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 shall be subject to the prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party*’. The Protocol seems to require the enactment of such a law as a precondition for the PIC of the provider country. 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, with serious ramifications. Provider countries that do not develop any specific law or requirements to regulate access – as has been the case for many countries since the CBD came into force - will be unable to require countries to enforce user country compliance measures.

Further, the law or regulatory requirements must set out elaborate specific requirements relating to access. The latitude in the CBD for a country to determine conditions for access (Article 15.1) as it deems fit in the exercise of its sovereign right no longer exists. The Protocol was intended to confirm and expand on the rights already secured by the CBD. The Johannesburg mandate was directed to securing benefit sharing. Ironically, instead, the Protocol produces a litany of clauses referring to access and other provisions that do not deal with benefit sharing. In sharp contrast there is a paucity of provisions on benefit sharing. The new access requirements that must be included in the law of provider countries include the following:

- 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.

- 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. In Cali 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 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. There was a proposal by developing countries to confine the ambit of this provision to procedural justice issues, as at one stage the EU argued that this provision was no more than a reference to these issues. Significantly, this proposal was rejected.

What does this provision mean in practical terms? The user country could refuse to act against a violator within its jurisdiction if it determined that the law of the provider country was not in conformity with this requirement. This action could be taken if the law or practice, previous or present, of the provider is held by the user country to be unfair or discriminatory. No external criteria have been established by the Protocol as to how, and when, these situations would arise. It is in the complete discretion of the user country to establish its own basis for the determination.

- f. An obligation to issue a permit or equivalent at the time of the access: Such a permit will be evidence of the decision of a country to grant PIC and establish MAT; and of the fact that the resource has been accessed in compliance with the legal requirements of a country. The permit also forms the basis of an internationally recognised certificate.

Once the permit is made available to the ABS Clearing House, it automatically acquires the status of such an international certificate. As there is a mandatory requirement to post the national permit on the Clearing House, all national permits issued would thus convert to the status of internationally recognised certificates.

- 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 an 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. 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 and issuing the written evidence for the grant of access. All this information must be posted on the ABS Clearing House. Detailed information about the national focal point and the national competent authority must be informed to the secretariat as well as notified to the Clearing House. 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.

These are elaborate and detailed obligations designed to facilitate access. They severely impair the right of countries given by the CBD to act in accordance with their sovereign right to decide upon the establishment, if any, of conditions for access through their national law. Developing countries started the negotiations with a clear position that there could be no compromise of their sovereign right to do so as accorded by the CBD. Instead they ended up with added obligations not contemplated by the CBD. As access was one of the first components to be negotiated, many 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. This did not come about, as is shown later in this article.

2.2 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 LMMC, the Like Minded Asia Pacific Countries and 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.

In the end, a co-engineered final text made possible a Protocol that contains compliance provisions of dubious value to developing countries.

These provisions are now examined in greater detail.

- a. Parties are obliged to take measures to ensure that users within their jurisdiction have accessed the resource in accordance with the prior informed consent and that mutually agreed terms have been established. These are known as user country measures, or simply as 'user measures'. These must be '*appropriate, effective and proportionate legislative, administrative and policy measures*'. However, the measures are not specified. Nor is criteria established for determining what constitutes such measures. It is entirely in the discretion of user countries to decide these. Finally, 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 4.1), 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. The language in the Protocol condones the legitimacy of access from countries that are not such countries. Hence if resources have been accessed illegally from a country of origin X, by another country Y, and a user accesses these from country Y in accordance with the ABS provisions of country Y, the user country does not have to ensure compliance with the ABS requirements of the country of origin X. This legitimizes biopiracy.

Developing countries tried, but failed, in the negotiations to bring this provision in line with the provisions of the CBD and the other provisions of the Protocol. Developed countries seemed to suggest that tracing such a country would be burdensome and add to legal uncertainty.

- b. Measures to address situations of non-compliance with these measures relating to access are also similarly worded with again no criteria established for ascertaining how the measures may be considered '*appropriate, effective and proportionate*'. A final clause requiring Parties to cooperate in cases of alleged violation of the domestic ABS laws is qualified - only '*as far as possible and as appropriate*'.
- c. A key area of serious contention between developed and developing countries relates to measures to monitor compliance. Developing countries consistently argued throughout the negotiations that user countries must establish effective monitoring, tracking and reporting requirements to support compliance. Without these, compliance would be rendered ineffectual and illusory. Monitoring requires the designation of checkpoints where the user must disclose pertinent information. This information would include: the country of origin of the resource or the associated TK, 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.

The checkpoints to be effective must be where applications, or reporting, regarding the use of the resource accessed would be made. Thus developing countries proposed mandatory disclosure of information at intellectual property examination offices, authorities involved in regulating products or giving marketing approval, 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 COP8 in 2006. The disclosure requirements at these checkpoints could be met by furnishing an internationally recognised certificate of compliance. A permit or equivalent issued by a national authority that was made available to the ABS Clearing House would constitute such a certificate.

As a final compromise some developing countries had 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 should designate such offices as their designated checkpoint under the Protocol.

All the proposals by developing countries in support of these compliance measures have been watered down so substantially as to weaken the core component of the Protocol. Instead the proposals by developed countries have been faithfully reproduced in the Protocol.

First, there is an obligation to set up no less than one ('*one or more*') checkpoint. The developing countries had proposed that the patent office be a mandatory checkpoint. This has been deleted from the Protocol. Even an indicative list of checkpoints has been deleted. 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 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). Hence 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.

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, as discussed earlier. Developing countries had proposed that Parties inform the secretariat within a prescribed time period of their designated checkpoints.

Thirdly, there is no mandatory obligation to disclose information at these checkpoints. Parties need only take measures to require users to make disclosure, 'as appropriate'. This is a notorious euphemism in international treaties that leaves the discretion to a Party to decide whether or not to implement the particular provision.

Fourthly, the information received by the checkpoint need not be supplied to either the national competent authority, the clearing house or the country requiring PIC and MAT (see earlier comments on this aspect), on the ground that it is confidential. Who decides this is also left open.

Fifthly, it is stated that the checkpoints '*must be effective and should have functions relevant to implementation of this subparagraph*'. This is as vague as language can be. What is a checkpoint that has functions relevant to the implementation of a paragraph that speaks of the role of checkpoints to collect/receive information, the obligation to optionally require disclosure of information, the protection of confidential information and the supply of the information to various authorities.

Sixthly, a general criteria is set out for such checkpoints. It is in these terms:

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.

Developing countries agreed to this formulation in a last ditch attempt to include the essential elements of the checkpoints set out in the

indicative list. They hoped that these criteria capture the reference to offices processing IPR applications, authorities dealing with product registration or marketing approvals, and bodies that fund research and development involving genetic resources. Yet the formulation is rather obtuse. Are the IPR offices relevant to the collection of information at the stage of innovation or pre-commercialisation? What is more worrying is that developed countries studiously fought to exclude any text that directly named these offices or bodies as checkpoints.

Seventhly, 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.

Finally, there are no 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. This provision has been deleted from the Protocol.

Compliance with MAT

MAT implies a negotiated contractual arrangement between the provider and the user. Parties may wish to enforce the contract for any breach of the terms in the jurisdiction of 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 provide effective remedies; and where possible, appropriate assistance mechanisms to remove or reduce financial or other barriers to such access. This was opposed by the developed countries. The Protocol now provides that each party must ensure that they give an opportunity to seek recourse to the courts of their country. However the other facilitative measures are not included. Developing countries fought to retain

the term ‘*facilitated*’ access to justice. Developed countries refused this - arguing first that they did not understand this term. Later when explained that the concept was derived from the Aarhus Convention 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 to. Some argued that this would accord preferential treatment to litigants of provider countries over their own citizens. The final provision deletes the term ‘*facilitated*’ access. This means that each party will take effective measures *regarding access to justice* without any facilitation. This article is to be reviewed by COP/MOP under the general review provisions.

2.3 SCOPE

(a) Derivatives

One of the longest contestations in these negotiations was the demand by developing countries to include derivatives within the scope of the Protocol. They argued that without this inclusion the Protocol would be emptied of its contents. This is because industry uses derivatives to create new and commercially valuable products. Whatever is required for agricultural use is covered by the Multilateral System of access and benefit sharing under the International Treaty on Plant Genetic Resources for Food and Agriculture. Thus no direct benefits flow from the access to these resources. The only real benefits will thus flow from the non-agricultural use of genetic resources by industry, in particular the pharmaceutical industry. This industry relies on biochemical compounds derived from genetic resource for developing new drugs. The biochemical compounds are the result of the metabolism of the genetic material. Once extracted, there is no need to access the natural material as its chemical structure can then be synthesized. These extracts or isolated material are the real marketable products of genetic resources and include all kinds of secondary metabolites such as gums, resins, or latex. These are not the direct product of genetic material.

Such biochemical compounds may be obtained by accessing the resource to obtain the extract, in which case PIC and MAT would be required. Alternatively, the biochemical compounds may be obtained directly from the extract without accessing the genetic resource. If derivatives are not included in the Protocol then no PIC and MAT would be required for this access. The resource would be accessed for free. This battle over derivatives hence formed the crux of the fight over the central theme of the CBD - benefit sharing ensuing upon the PIC requirement.

Does the scope in the Protocol cover derivatives? If so, for which component: access (PIC), benefit sharing and/or compliance?

Article 3 of the Protocol on scope reads as follows:

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilisation of such resources...

Article 2 of the Protocol states:

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

(c) “Utilisation 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

Developing countries are clear that derivatives are covered for access, benefit sharing and for compliance. This is based on the following:

1. Article 3 should be read as follows:

This Protocol shall apply to genetic resources and to benefits arising from the utilization of such resources. The expression ‘*within the scope of Article 15*’ is superfluous as the Protocol is being negotiated under the CBD.

However what is of critical importance is that the term ‘*utilisation of genetic resources*’ is defined. And it is stated in the chapeau of Article 2 that

this definition is '*In addition, for the purposes of this Protocol*' (to the terms defined in Article 2 of the CBD). This clearly means that this definition furthers the definition in the CBD where the context so admits. To reiterate, the definition reads as follows:

To conduct research and development on the genetic and/or biochemical composition of genetic resources, ...

The conclusion can be thus drawn that genetic resources to be covered are in relation to their utilization as defined. This includes the genetic and/or biochemical composition for purposes of conducting research and development thereon.

In the negotiations on derivatives on the penultimate day, as discussed earlier, developed countries insisted on including the expression '*R&D on the functional units of heredity as well as on the naturally occurring biochemical compounds resulting from gene expression contained in the genetic material ...*'

Developing countries wanted the words underlined removed as in their view that would have excluded derivatives. They proposed the addition of the expression: *any R&D done on metabolism of genetic resources*. Although this expression is not included in the final provision, the underlined words have also been removed. This implies that the expression wherever it appears in the protocol is not limited to '*functional units of heredity*' or to '*gene expressions*'. Further, the common understanding among all Parties was that this definition of '*utilisation of genetic resources*' held the key to determining whether the scope covered derivatives or not. For this reason the final few days and hours were spent negotiating this term.

[See Box 2 on a detailed account of the negotiations in a small group on the definition of the term 'utilisation of genetic resources'.]

2. 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*' that is in addition to the CBD definition of terms, derivatives are clearly included.

The term '*utilisation*' when referenced directly or indirectly to genetic resources has a special meaning under the Protocol. The expression is not used as a verb '*to use*'. That it may not be exactly expressed in the exact term used in the definition ('*utilisation of genetic resources*') matters not. As the Working Group 9 *bis* meeting agreed when developing an understanding of the term, the expression will be adjusted depending upon the context in which it appears.

3. Article 12.1 states that

'Each party shall take appropriate, effective and proportionate ... measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with the prior informed consent and'

These compliance measures again refer to the expression '*utilisation of genetic resources*' adjusted to the context in which it appears; and would by reference to the definition include derivatives.

Alternative interpretations

Arguments are beginning to be made, though, that the scope of regulated access does not extend to derivatives, that is those that do not necessarily contain functional units of heredity.

This is based on the following:

1. The first part of Art 3 reads:

'This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention...'

This, it is argued, does not extend to derivatives. Genetic resources is defined in the CBD as meaning genetic material of actual or potential value. Genetic material is in turn defined to mean any material of plant, animal, microbial or other origin *containing functional units of heredity*. This latter facet would exclude biochemical compounds as these do not contain such functional units of heredity or gene expressions.

2. The second half of the sentence in Article 3 reads:

‘... and to the benefits arising from the utilization of such resources’.

This, it is suggested, refers to the benefits that could be realized through the use of the genetic resources once they are accessed, including commercial exploitation of derivatives that may be created through the use of the accessed genetic resource.

As noted earlier, this line of argument does not take into account the fact that the chapeau mentions explicitly that for purposes of this Protocol, and additionally, the definition of the term ‘*utilisation of genetic resources*’ must be read into the text. Hence relying only on the CBD definitions flies in the face of this clear provision.

3. It is further argued that the reference in Article 5(1) to:

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

does not open up the scope of access regulated under the Protocol to derivatives. It is suggested only access to genetic resources per se is covered. And ‘*for their utilisation*’ refers to what you would do with the genetic resources after you accessed it legally under the Protocol. This argument suggests that the word ‘*utilisation*’ is to be read as a verb - ‘to use’ - completely ignoring the fact that the term has a specific meaning as defined and includes derivatives. It is further argued that the genetic resources could be utilized in a way that gave rise to a derivative that did not contain functional units of heredity, and the mutually agreed terms of an access agreement could specify that benefits derived from the commercial exploitation of such a derivative must be shared, or cannot be made the subject of patent applications, etc. And the argument goes that recognizing that derivatives can be the subject of benefit sharing agreements is not the same as making them the subject of the initial, regulated access under the Protocol.

The first draft presented

The original final text of the Protocol presented on

the morning of the final day defined ‘*utilisation of genetic resources*’ as:

To conduct research and development on the genetic and/or biochemical composition of genetic material, including through the application of biotechnology ...

Developing countries organized as the Like Minded Megadiverse Countries and the Like Minded Asia Pacific Countries reviewed this expression and concluded that the reference to genetic material relates back to the functional units of heredity. This implied that any biochemical compound that was isolated or the result of the metabolism of the genetic material would be excluded. This would effectively exclude genetic material and biochemical compounds derived from genetic material. Derivatives would thus be excluded. To allow for such derivatives to be included, the developing countries were of the view that there should instead be a reference to ‘*biochemical composition of genetic resources*’. This makes no reference to functional units of heredity. And would thus include any biochemical compounds isolated from the genetic material that is the result of the metabolism of the genetic material. [See Box 2 for an account of the negotiations on ‘*utilisation*’] This was the first change that developing countries wanted in the Protocol. As narrated earlier, at that final meeting in the COP President’s chambers, developing countries insisted on changing the expression ‘*genetic material*’ to ‘*genetic resources*’. This was accepted. The provision now reads as follows:

‘Utilisation of genetic resources’ means to conduct research and development on the genetic and/or biochemical composition of genetic resources, ...’

Earlier in the negotiations on the definition of this expression, developed countries led by the EU and Canada had summarily rejected an amendment to their proposal of the definition. Developing countries had suggested that the underlined expression in their proposed definition:

Utilisation of genetic resources’ means to conduct research and development on the functional units of heredity as well as on the naturally occurring biochemical compounds resulting from the gene

expression contained in genetic material accessed under

be changed to

... means to conduct research and development on the genetic material and biochemical compounds derived from genetic resources,

Whether developed countries accept that this change now includes derivatives within the scope may remain a bone of contention that may well impede the implementation of the Protocol. It bears reiteration that developing countries have been unequivocal in insisting that the exclusion of derivatives will render the Protocol meaningless. The overwhelming number of bioprospecting cases are based on the use of biochemical components resulting from metabolism; a considerably smaller number use biochemical components resulting from gene expression. Thus without the inclusion of such derivatives, the majority of typical uses would be excluded.

The expression '*utilisation of genetic resources*' (and its grammatical variations) appears in the articles in the Protocol relating to: scope, benefit sharing, access, and compliance. This implies that these provisions will apply not only to genetic resources but, as well, to derivatives. The expression as it appears in the benefit sharing article includes benefits arising from, as well, 'subsequent applications and commercialisation'. This would include the use of genetic material (including derivatives) by improving or using it for other purposes. So for example, benefits will have to be shared if the resource is used to make products such as chips or a vitamin.

(b) Pathogens

Very early on in the negotiations, at the resumed 9th Working Group meeting in Montreal in July 2010, the European Union (EU) sprung a surprise by introducing 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.

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 industry which makes vaccines, patents them and supplies them 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 fora 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 agreed. 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 is in these terms:

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, without addressing the question of patents over these vaccines, it is difficult to see how this expeditious benefit sharing may be secured. Further, the question of technology transfer remains unaddressed.

However, and as noted earlier, another article on relationship with international agreements and instruments 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 was a relationship clause with other international instruments. Hence the reference to international organisations appeared inappropriate as these were not of the same status as international instruments. Secondly, it is also inappropriate to refer to any ongoing work and 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 saving clause, and the permissive nature of the obligation (*should*), what the developed countries lost in the earlier article dealing specifically with pathogens has been reinserted surreptitiously by this provision.

(c) 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. Developing countries proposed their inclusion

while developed 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? This again creates legal uncertainty.

The CBD makes it mandatory for access to be based on PIC, unless a Party otherwise determines: Article 15.5. Parties must also take measures to ensure benefit sharing arising from the utilisation of the genetic resources: Article 15.7. 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 2 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.

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 benefits to be shared 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 implement the Protocol by enacting 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 will apply without violating the retroactivity rule in international law.

The final question is will the rules for access apply when access is not possible as the resource has been accessed long before the entry into force of the Protocol? Or will only the benefit sharing requirements apply? Where the access is not possible, then it is logical to suggest that only the benefit sharing rules will apply. How will this be practically effected? It is difficult to see how this provision can be tracked, let alone enforced, whether with regard to access or benefit sharing. For this reason, perhaps, Norway and Peru proposed the following:

'Parties should encourage users of genetic resources to take all reasonable measures to share benefits for genetic resources acquired before the entry into force of this Protocol in situations where no access and benefit sharing agreements have been established in accordance with the Convention with the countries of origin of such genetic resources.'

This however relies upon industry players doing the right thing - and can hardly help in cases of biopiracy.

There is a proposal in the Protocol 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.'* Whether, how and when, this provision will be realised is entirely unpredictable.

2.4 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 do no more than 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'*. As discussed earlier, the italicised phrase is defined in the Protocol to include derivatives. This perhaps is the only added value of the Protocol. Although this term also appears in the CBD it was a matter of constant dispute between developed and developing countries whether this meant that derivatives were included. The Protocol also states that the benefits include those arising from subsequent applications and commercialisation. This is implicit in Article 15.7 of the CBD.

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. This would condone biopiracy and 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.

However, could it 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 of a genetic resource or a biochemical compound, 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. This argument may be used to reinforce the view of some developed countries that no PIC is required for derivatives. Only benefit sharing is required. However this argument would violate the general tenor of the CBD and the Protocol. The spirit and thrust of these two instruments are to provide for benefit sharing that ensues upon the grant of access. Hence legal access under these two instruments are 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.

2.5 TRADITIONAL KNOWLEDGE (TK)

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

(a) PIC

The Protocol provides for two distinct situations where Parties must take measures in relation to ILCs and resources and/or TK. The first relates to access to genetic resources. The second relates to access to TK of ILCs associated to genetic resources.

In the first case, it is only where ILCs have an established right to grant access that the provision applies. It may be assumed that the right must be established by the Party, or at least recognised by it. There is, however, no obligation on a Party to establish or recognise such a right. This provision may thus grant an illusory right. However, it may be possible to assert that the right may 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 indigenous peoples had been established by, or was fast becoming part of, international customary law. 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.

In both situations, Parties are required to take

measures with *the aim of ensuring* that the genetic resource and/ or the TK of ILCs is accessed with their PIC. For access to TK, the measure must also aim to ensure that MATs have been established. In both situations the PIC of the ILCs must be obtained OR their prior approval and involvement obtained. This strengthens the provision in the CBD - Article 8j - which only requires the promotion of the TK with the approval and involvement of ILCs.

However, the requirement is to be in '*accordance with domestic law*' and the measures to be taken by each Party '*as appropriate*'. The cumulative effect of these two phrases renders the implementation of this PIC requirement to the absolute discretion of a Party. An alternative reading of these phrases could be that the Party is obliged through its national law to take such measures as it deems appropriate. This latter view is unlikely to prevail as there is no obligation to enact any domestic law - in contrast with other articles which stipulate this requirement.

(b) Publicly available TK

There were intense and prolonged negotiations with regard to publicly available TK. Developing countries, led by China and India, argued that such knowledge was not freely accessible and the PIC and MAT requirements should also apply; and further, where the knowledge was diffused throughout the country, 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 ILCs. The upshot, argued the developing countries, was that then the TK would be accessed for free! 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 shows the existence of prior art to defeat claims of innovation in patent applications. Secondly, it could not be relied upon to defeat the obligations in the CBD relating to access and benefit sharing of TK.

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 it was TK 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 a 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. This easily constituted the most blatant form of imposition by developed countries - and complete disrespect of the concerns of key developing countries in these negotiations. 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.

(c) Benefit sharing

Parties are also required to take 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. Again the obligation is ‘*in accordance with domestic law*’ regarding the ‘*established rights*’ (see earlier comments on these phrases). 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 - a CBD plus.

(d) Compliance

The compliance measures referred to earlier as ‘user country measures’ also apply to compliance with the domestic law in respect of ABS for TK associated with genetic resources. They are in fact a mirror image of those provisions. 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 resources but make no reference to the associated TK.

(e) 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*'.

- ii. Parties must also establish mechanisms to inform users of the TK associated with genetic resources their obligations for ABS from its utilisation. These measures must be posted on the Clearing House.
- iii. Parties must also endeavour to support the development by ILCs of
 - Community Protocols relating to ABS of TK;
 - Minimum requirements for MATs to secure fair and equitable sharing of benefits;
 - Model benefit sharing contractual clauses.
- iv. Parties are required not to restrict the customary use and exchange of genetic resources and associated TK within and amongst ILCs. This is '*as far as possible*' and in accordance with the objectives of the CBD. This again 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*' where the same genetic resources are located across boundaries.
- vi. This also applies where the same associated TK is shared by one or more ILCs in several Parties.

These are weak and ineffectual provisions.

2.6 TRANSFER OF TECHNOLOGY

The CBD requires Parties to provide or facilitate access and transfer of relevant technologies to provider countries. This must be under fair and most favourable terms, including 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.

Developing countries in these negotiations proposed early on - 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 final provision in the Protocol has excised the underlined words and reduced the obligation of developed countries to merely undertake to promote and encourage. This clearly subtracts from the existing provisions of the CBD. In common parlance, it is a clear CBD minus provision.

2.7 NON COMMERCIAL RESEARCH

The Protocol requires Parties to provide in their national law on ABS for simplified access for non-commercial research purposes. This is to promote research that contributes to the conservation and sustainable use of biological diversity. There is also expressed a need to provide for any change in the intent of use from non-commercial to commercial research. These are generalized and vague provisions lacking in specificity. 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. This requires more than a generalized provision in the Protocol.

2.8 NON-PARTIES

A rather short article deals with non-Parties. 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. The earlier proposal - which paraphrases 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. It allows transactions that could undermine the Protocol. It sets up a dual standard for transactions related to genetic resources, TK and derivatives. It would also not prevent non-Parties from developing 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. The obligation is imposed on the Party to the treaty to ensure this consistency.

2.9 GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

The Protocol also requires future work for Parties to consider the need for and modalities of a global multilateral benefit sharing mechanism. 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. The benefits are to be used to support the conservation and sustainable use of biodiversity globally. Two transboundary situations are described in the Protocol:

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

- 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 Africa Group since Working Group 5 in Montreal in 2007. The Protocol merely calls for future work to assess the need for such a mechanism. If such a need is established then the modalities of the mechanism will have to be negotiated. A similarly worded provision appears in the CBD (Article 19.3) calling upon Parties to consider the need for and modalities of a protocol that 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. In short it will be a long and arduous negotiation process before any such global multilateral mechanism may come to fruition, if at all.

3. A SUMMARY

The Protocol was expected to be balanced, provide for legal clarity and add value to the existing provisions of the CBD on ABS and related provisions. Save for provisions on access from the point of view of user countries, it hardly satisfies any of these expectations.

Legal clarity

Already alternative interpretations have begun to emerge on whether the scope of the Protocol covers derivatives; and if so, the extent of this coverage. There is also uncertainty expressed by some as to the temporal scope of the Protocol - whether it covers genetic resources and associated TK accessed before the coming into force of the Protocol; and if so, the extent of the coverage. The compliance measures are also generalised and lacking in specificity. There is also no provision on how publicly available TK should be addressed. Nor TK that is diffused and has no identifiable holder. Further, the provisions on transboundary TK or genetic resources are generalised and ineffective.

Balanced

Nowhere is the imbalance in the Protocol more pronounced than in the comparison between the access and the compliance provisions. The former is detailed and imposes clear obligations on provider countries. The latter is vague and incoherent. The obligations it seemingly imposes leave the implementation to the absolute discretion of countries with users in their jurisdiction. No compliance mechanisms have been established to ensure user measures are effectively applied, if at all.

Adding value to CBD, CBD minus

There are several provisions that do no more than repeat the existing provisions of the CBD. They

add no value to the Protocol. Notorious among these are the provisions on benefit sharing.

Some provisions actually detract from the CBD's requirements. They impose obligations where none existed before under the CBD. These include the elaborate obligations on access, the requirements for national law to create a special regime for pathogens, and for simplified access without adequate safeguards when the intent changes, and finally the carve out from the Protocol of resources which are the subject of ongoing work or practices of other international organizations.

A balance sheet on what developing countries secured through the Protocol vis a vis developed countries in respect of some key issues may be drawn up as follows:

Proposals of developed countries	Developing country proposals	Protocol accepts proposals of ...
Derivatives for benefit sharing only	Derivatives for access, benefit sharing and compliance	Subject to interpretation
Special considerations for pathogens	No special consideration for pathogens	Developed country
Relationship with other international organizations and their ongoing work and practices	No provision	Developed country
Detailed provisions on access	Agreed based on agreement on compliance	Developed country
Non-arbitrary access	No provision	Developed country
General provisions on compliance	Specific measures on compliance	Developed country
No designated or indicative list of checkpoints, including patent offices	Designated or indicative list of checkpoints, including patent offices	Developed country
No specific sanctions for non-compliance	Specific sanctions for non-compliance	Developed country
No mandatory disclosure	Mandatory disclosure	Ambiguous
Exclude confidential information on non compliance	No exclusion	Developed country

4. THE WAY FORWARD

a) To ratify or not

A Party needs to assess whether its interest is best served by being a Party to the Protocol. An

assessment needs to be made whether the benefits outweigh the burdens imposed by the Protocol or vice versa. What complicates this assessment is that many provisions remain unclear. Clarity may only be achieved at some future point of time

when the COP/MOP of the Protocol discusses some of these provisions; or Parties implement their law and take the necessary measures. Or when Parties carry out the routine review of the effectiveness of the Protocol. Key amongst these provisions is that on compliance. The monitoring checkpoints are left to Parties to identify based on a very general criteria. Unless effective checkpoint(s) is/are identified, the compliance provisions may well remain largely illusory. Compliance, with its assurance of preventing the misappropriation of a provider country's genetic resources, is the only significant reason for developing countries negotiating a protocol. Even if only for this reason, provider countries may wish to wait for user countries to establish their compliance measures before they can make a considered assessment of their effectiveness and the pros and cons of ratifying the Protocol.

b) To advance a beneficial interpretation

The other alternative is for a Party to ratify the Protocol and promote its implementation in a manner that is conducive to its national or developing country interest. There is sufficient scope for that. However it must also be noted that several provisions need no Protocol for the inclusion of those aspects in national law. For example, Parties always retain the prerogative to include whichever resources (such as derivatives) in their national law for users to abide by. However the national law will have no extra-territorial effect. Any non-compliance will need to be dealt with by international law - in this case the Protocol. If the Protocol is lacking effective compliance measures - as has been indicated in this article, then the reason for the Protocol, and being a Party to it, fails. For then a provider Party cannot deal effectively with cases of misappropriation of genetic resources, derivatives and associated TK once they leave its territory.

The areas where developing countries may seek to get COP/MOP decisions to further the interpretations that developing countries lost out

in terms of legal clarity and balance in the Protocol include the following: inclusion of derivatives in all provisions relating to access, benefit sharing and compliance; clarifying the ambit of temporal scope to cover new and continuing uses of materials accessed before the entry into force of the Protocol, repudiating the extension of access decisions to trade related criteria; establishing criteria for what constitutes effective compliance measures; establishing effective monitoring measures and checkpoints; establishing clear mandatory disclosure requirements at these checkpoints; sanctions for failure to disclose; and establishing rules governing publicly available TK.

However these are precisely the areas where developed countries dug in to secure the present provisions in the Protocol. It is therefore unlikely that they would readily agree to go down that pathway and agree to interpretations that they have secured in their favour in the first place. In any event it will take considerable time and energy for developing countries to secure any beneficial outcome.

5. CONCLUSION

Developing countries started the negotiations with high expectations. They held the high moral ground. It was to end biopiracy. It was to fulfil the critical unfulfilled objective of the CBD of benefit sharing. This would complete the circle - benefit sharing would provide the wherewithal and generate profits and transfer of technology that would then make possible the conservation and sustainable use of biodiversity. The CBD would come into full bloom with all the objectives functioning in harmony. Little did developing countries realise the impact that power relations would have in bringing to fruition a completely perverse outcome. For sure it all began to unfold when an important developing country leading a critical developing country negotiating group began a liaison with a leading developed country. The outcome is a salutary lesson in realpolitik which may well have seared the cause of multilateralism from a developing country perspective.



ANNEX I

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

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The Parties to this Protocol,

1. *Being* Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,
2. *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 the Protocol pursues the implementation of this objective within the Convention,
3. *Reaffirming* the sovereign rights of States over their natural resources and according to the provisions of the Convention,
4. *Recalling further* Article 15 of the Convention,
5. *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,
6. *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,
7. *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,
8. *Acknowledging* the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,
9. *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,
10. *Further recognizing* the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,
11. *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,
12. *Determined* to further support the effective implementation of the access and benefit-sharing provisions of the Convention,
- 12 *bis*. *Recognizing* that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilisation 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,
13. *Recognizing* the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation and adaptation to climate change,
14. *Recognizing* the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,
15. *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,
16. *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,
17. *Acknowledging* ongoing work in other international fora relating to access and benefit-sharing,
18. *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,

19. *Recognizing* that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,
 20. *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,
 21. *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,
 22. *Recognizing* the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,
 23. *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,
 24. *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,
 25. *Noting* the United Nations Declaration on the Rights of Indigenous Peoples, and
 26. *Affirming* that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,
- ave 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***

1. 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 3 *bis****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 specialised 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 specialised 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 specialised instrument in respect of the specific genetic resource covered by and for the purpose of the specialised instrument.

ARTICLE 4***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.
- 1 *bis*. 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.
2. To implement paragraph 1, each Party shall take legislative, administrative or policy measures, as appropriate.

3. Benefits may include monetary and non monetary benefits, including but not limited to those listed in the Annex.
4. 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 5

ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to its 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.
- 1 *bis*. 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.
2. 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;
 - (a *bis*) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
 - (b) Provide information on how to apply for prior informed consent;
 - (c) 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;
 - (d) 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;
 - (e) 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
 - (f) 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 5 *bis*

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 6***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 7***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 7 *bis****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 utilisation 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 8***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 9

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 10

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 available through the Access and Benefit-sharing Clearing-House.

ARTICLE 11

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(ies); 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 12

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.
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.

ARTICLE 12 *bis*

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.
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.

ARTICLE 13

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) Check points must be effective and should have functions relevant to implementation of this sub-paragraph (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 5, paragraph 2 (d) 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 *bis*) Confirmation that prior informed consent was obtained; and
 - (h) Commercial and/or non-commercial use.

ARTICLE 14

COMPLIANCE WITH MUTUALLY AGREED TERMS

- 1. In the implementation of Article 5, paragraph 2 (f) (i) and Article 5 *bis*, 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 25 of this Protocol.

ARTICLE 15

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 16

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 17

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 18

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 islands 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 18 bis

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, including the least developed 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 18 *ter****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 19***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 18 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 and the 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 and the 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 20***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 23 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 21

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 22

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 23

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 24

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 25

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 26

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 27***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 28***RESERVATIONS***

No reservations may be made to this Protocol.

ARTICLE 29***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 Depository.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depository, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 30***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.



ANNEX II

WORK PLAN FOR THE INTERGOVERNMENTAL COMMITTEE FOR THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING OUT OF THEIR UTILIZATION

A. Issues for consideration by the Intergovernmental Committee at its first meeting

1. The modalities of operation of the Access and Benefit-sharing Clearing-House, including reports on its activities; (Article 11, paragraph 4).
2. Measures to assist in the capacity-building, capacity development and strengthening of human resources and institutional capacities in developing countries, in particular the least developed countries and small island developing States amongst them, and Parties with economies in transition, taking into account the needs identified by the Parties concerned for the implementation of the Protocol; (Article 18).
3. Measures to raise awareness of the importance of genetic resources and associated traditional knowledge, and related access and benefit-sharing issues; (Article 17).
5. Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance, including procedures and mechanisms to offer advice or assistance, where appropriate; (Article 24).

B. Issues for consideration by the Intergovernmental Committee at its second meeting

6. Development of a programme budget for the biennium following the entry into force of the Protocol.
7. Elaboration of guidance for the financial mechanism (Article 19).
8. Elaboration of guidance for the resource mobilization for the implementation of the Protocol.
9. Consideration of rules of procedure Conference of the Parties serving as the meeting of the Parties to the Protocol; (Article 20, paragraph 5).
10. Elaboration of a draft provisional agenda for the first meeting of the Parties; (Article 20, paragraph 6).
11. The need for and modalities of a global multilateral benefit-sharing mechanism.
12. Continued consideration of items taken up at the first meeting of the Intergovernmental Committee, as needed.
