#### Submission of views in preparation for the Expert Meeting on the need for and modalities of a Global Multilateral Benefit-sharing Mechanism of the Nagoya Protocol

Collective submission of

the IUCN Joint SSC-WCEL Global Specialist Group on ABS, Genetic Resources and Related Issues (ABSSG)

[Contributors: Klaus Angerer, Lisa Benjamin, Evanson Chege Kamau, Graham Dutfield, Christopher H. C. Lyal, Estelle Mawal, Sonia Peña Moreno, Manuel Ruiz Mueller, Than Thi Huong Trang, Joseph H. Vogel, and Tomme R. Young. Collation of views by Tomme Young and Annie Minnis.]

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This report provides expert input to the discussion of the Expert Meeting on the need for and modalities of a global multilateral benefit-sharing mechanism (GMBSM.) It synthesizes the substantive contribution of various members<sup>1</sup> of the IUCN Joint SSC-WCEL Global Specialist Group on ABS, Genetic Resources and Related Issues (also known as the "ABS Specialist Group" or "ABSSG"), an international group of experts in ABS law and policy, which includes in its membership, lawyers, policy experts scientists from the spheres of government, diplomacy, academia, activism and civil society. This submission is intended to reflect all issues raised in expert exchange of views, showing both areas of disagreement and areas of shared belief and agreement. Where members have so requested, their complete submissions have been annexed as appendices to this submission

This submission answers the point raised in Notification SCBD/ABS/VN/jh184620, in the order stated therein. It begins, however with a brief mention of some basic issues that were raised in nearly all responses submitted. To avoid needless repetition, those primary issues are discussed in the opening sections, and should be considered to be also incorporated in all responses to issues identified in the Notification.

#### I. Issues Relevant to All Questions

A globally functional legal/commercial regime can only function on the basis of clear and unambiguous international consensus on critical components. Legal principles can only apply if the parties, negotiators, arbitrators and courts are able to clearly determine whether or not a particular resource is included within

<sup>&</sup>lt;sup>1</sup> Members of the ABSSG are participating in their individual capacity, and should not be interpreted as presenting the views of their government or organization.

the ABS regime, and how the 'resource' in question is characterized – in this case as a chemical, a piece of encoded information, or as a hybrid embracing both aspects. The GMBSM illustrates this need for clear agreement on key concepts as a prerequisite to functionality. It is difficult to imagine how such a mechanism could function, if the Parties cannot know with certainty whether a given genetic resource or element of "traditional knowledge associated with genetic resources" (ATK) is governed by ABS as a first step in the determination of whether it should be addressed by the GMBSM. The members of the ABSSG identified two crosscutting areas, as matters of particular shared concern that must be addressed in order to consider any of the questions raised by the Notification.

#### A. Determining which Resources and Activities are Covered by the GMBSM

The basic GMBSM question – whether a genetic resource occurs in a "transboundary situation" – depends on how specifically one identifies each genetic resource.

Some genetic resources are unique to particular individuals, while others are shared at the level of a localized population of a subspecies/variety; still others at the level of an entire species and others by an entire genus or higher taxon.<sup>2</sup> For example, consider the ATP synthase, an enzyme found in all life forms (Doering et al, 1995) and compare this with epibatidine, which was found only in in a particular sampling of one population of *Epipedobates anthonyi*.<sup>3</sup> Between the two extremes the compound paclitaxel (the principal agent in the block-buster chemotherapeutic *TAXOL*) is found in both a "new world" species (Taxus brevifolia)<sup>4</sup> and an "old world" species (Taxus baccata)<sup>5</sup>.

In determining the coverage of the GMBSM, it is essential to agree on what type of resource we are talking about – whether "genetic resource" refers to the physical material only or the informational content of that material or a combination of the two. The contributors to this submission included some who favored the first option, and some who favored the second.<sup>6</sup> Virtually all, including those who expressed no preference, noted emphatically that a final decision choosing one or the other, or some clear combination of both is necessary in order to create a proper legal basis for the establishment of a GMBSM. Such a decision is also necessary if the COP/MOP wishes to properly justify a decision NOT to establish a GMBSM. *Either way, the experts agree that a final decision on this issue appears critically essential.* 

(As a result of the group's diverse views on this essential matter, the arguments presented below include some that are based on a "physical sample" approach and others that are based on a "genetic information" approach. Although the persons compiling this summary have tried, it is not always possible to identify the particular underlying approach underlying a particular comment, without unduly lengthening and complicating this discussion. The reader is encouraged, throughout this summary, to keep this key question in mind, in considering the various views expressed below.)

 $<sup>^{2}</sup>$  One contributor noted that it is always possible that a valuable genetic element found in a plant or microbe assumed to be specific to an endemic species may turn out later to have transboundary distribution.

<sup>&</sup>lt;sup>3</sup> Angerer, K. 2011. "Frog tales – on poison dart frogs, epibatidine, and the sharing of biodiversity." Innovation: The European Journal of Social Science Research. 24(3): 353–369. According to one commenter, "The [collected] toxin was ... cyrogenically preserved; when researchers returned to the same population in situ, they could not isolate the same compound"

<sup>&</sup>lt;sup>4</sup> Wani, M.C. Taylor, H.L. Wall, M.E. Coggon, P and McPhail, A.T. 1971 "Plant antitumor agents. VI. Isolation and structure of taxol, a novel antileukemic and antitumor agent from *Taxus brevifolia*" *J. Am. Chem. Soc.* 93(9):2325-2327.

<sup>&</sup>lt;sup>5</sup> Malik, S. Cusidó, R.M. Mirjalili, M.H. Moyano, E. Palazón, J. and Bonfill, M. 2011. "Production of the anticancer drug taxol in *Taxus baccata* suspension cultures: A review." *Process Biochemistry* 46(1):23-34.

<sup>&</sup>lt;sup>6</sup> The specific and detailed views of members of the ABSSG on the choice between these alternatives have not been included here, because they are outside the scope of the Notification. The ABSSG will be happy to provide a detailed analysis on this issue, upon request.

#### a) "Genetic Resource" as Physical Sample

If the term refers solely to the physical material (*i.e.*, if "genetic resource" only includes only physical samples) then the GMBSM would cover only the following:

- organisms or specimens whose provenance is unknown, and
- possibly (depending on other decisions), specimens collected outside national jurisdiction.

In any other situation, a specimen will have a specific source – either a specific country or an area outside of any national jurisdiction. Given the specificity and accessibility of GPS technology, it seems relatively unlikely that a particular sample will be harvested at a location that precisely straddles the border dividing two countries, and there are comparatively few examples of disputed border areas left in the world, even fewer of these being areas in which biological sample collection will be occurring.<sup>7</sup>

Numerous contributors noted that there is a real difference between "specimens whose provenance is unknown" and "specimens whose provenance is undisclosed" and that the GMBSM should not become a tool by which particular users or collectors can or would wish to evade national ABS requirements, simply by claiming that they do not know where the resources were collected. During the negotiations of the Bonn Guidelines, spokespersons for botanical collections, zoos, genebanks and herbaria stated unequivocally that *ex situ* collections of biological species and varieties keep a clear and well-maintained record of all species held in such collections.

Various contributors also raised the issue of misappropriation of genetic resources in this context, noting that baseline studies conducted in many developing countries from many regions indicate that genetic resources and ATK have previously been removed from their country of origin without PIC and with no agreement relating to ABS, but that these resources either have not been utilized to date, or were not utilized until after the "relevant date" for application of ABS principles. As a result of the lack of documentation regarding the origin of these genetic resources and ATK, their utilization appears to trigger a need to apply the GMBSM.

#### b) "Genetic Resource" as Genetic Information<sup>8</sup>

By contrast, if the term "genetic resource" refers to the genetic information carried by the specimen, then there are very few genetic resources that would *not* be considered to be "transboundary." Only narrow-range endemics, isolated populations, and situations in which the genetic resource in question is unique to a particular individual would appear to be outside of the GMBSM. Contributors to this submission were divided over their views of this approach. Some strongly supported it, taking the view that it will bring about an end to the "winner take all" approach of relying solely on the national law of the country in

<sup>&</sup>lt;sup>7</sup> The phrase "comparatively few" is not agreed by all contributors, but insisted upon by historical experts. Despite the decline in sheer volume of disputed area, however, examples of disputed areas of biodiversity concern do exist. Although the term "Peace Parks" is often used to refer to parks dedicated as memorials to peace, at least two "peace parks" have been declared as a way to achieve peace. (*See e.g.*, "From demilitarized zone to peace park". 02 April 2008. IUCN website at <u>http://www.iucn.org/about/union/secretariat/offices/asia/asia\_news/?719/From-demilitarized-zone-to-peace-park</u>.) In addition, a growing number of transboundary protected areas are being

developed to help park managers avoid the legal and practical problems that arise when protected area boundaries are on or near national frontiers.

In agreeing to form a peace park or transboundary protected area, governments have necessarily entered into detailed agreements regarding the various practical and sovereignty issues that appear likely to arise. If such an instrument does not include language on national rights vis-à-vis natural resources in the area – language that is sufficient in detail and concreteness to serve as a basis for resolving significant controversies regarding ABS, then the instrument either does not purport to alter the rights and enforcement capabilities/authorities of each country, or is poorly drafted indeed.

<sup>&</sup>lt;sup>8</sup> Contributors differed on terminology, with some referring to "natural information" where others prefer to use the term "genetic information" which is more commonly used in CBD discussions. Except where specifically noted, this summary uses both terms interchangeably, and assumes that they are identical in coverage, and particularly that "genetic information" includes any biochemical information incorporated into the concept through the NP's definition of "derivative."

which the physical sample was collected, while others cautioned against an approach that might potentially violate national sovereignty principles and implicitly discourages countries from making efforts to identify and characterize genetic resources that are likely to exist in other countries.

### **B.** Other Elements of Uncertainty Regarding Resources and Activities Included in the GMBSM

The coverage of the GMBSM is one of many aspects of the issue that depend on the development of a consensus interpretation of other critical elements of ABS terminology. Two of these are the "relevant date" for application of the NP, and the need for legal clarity regarding numerous key concepts.

#### a) "Relevant Date"

Of these the most frequently identified challenges that must be addressed in order to establish a functional GMBSM is the "trigger date" or "relevant date" for determining whether a particular genetic-resourcerelated or ATK-related action is governed by the NP. Many contributors to this submission chose not to specify which date should be the "relevant date," while others expressed specific support for one or another of the following options:

- Adoption of the CBD;
- Entry into force of the CBD;
- Adoption of the Nagoya Protocol;
- Entry into force of the Nagoya Protocol;
- Ratification or other accession to the CBD by the country of origin or country providing the genetic resources;
- Ratification or other accession to the Nagoya Protocol by the country of origin or country providing the genetic resources; or
- Adoption of ABS legislation by the country of origin or country providing the genetic resources.

Contributors also differed in their view of which actions should trigger the application of ABS principles, with many stating that ABS should apply to any new utilization of genetic resources or ATK after the relevant date, regardless of when those resources were collected; while others felt that ABS should only apply to such resources that were collected after the relevant date.<sup>9</sup>

Although disagreeing on these issues, they did appear to agree that the following points relevant to this issue are critical decisions that must be made as prerequisites of the establishment (or decision not to establish) a GMBSM:

- (1) that the list shown above is a finite list of options that can be identified as the "relevant date" (although there may be two different relevant dates one for genetic resource utilization and the other for the utilization of ATK);
- (2) that the "relevant date" should be tied to the decision regarding which actions trigger the coverage of ABS (whether that trigger is based on utilization, collection, access or some other objectively determinable event); and
- (3) that the specific identification of a relevant date, and specification of the particular actions or events after that date that trigger benefit-sharing is critical to the functionality of the ABS regime, and should be agreed at the international level, as a key element of the GMBSM and to resolve other concerns.

<sup>&</sup>lt;sup>9</sup> Here also, many contributors to this submission included detailed arguments in favor or against particular choices, which views are excluded here as being outside the scope of the Notification. The ABSSG would be more than happy, however, to provide a detailed analysis on this issue, upon request.

#### b) Other Definition and Clarification Issues

A number of other issues that need to be clarified, in addition to those directly related to the definition of the term "genetic resource" were also raised as potential challenges. These include the following:

- The Nagoya Protocol creates serious definitional questions by including the words "research and development on the ... biochemical composition of genetic resources" in the definition of utilization of genetic resources. While to some this definition may imply that the Protocol adopts the physical specimen meaning of "genetic resources," to most of the experts contributing to this submission it implies that the scope of "utilization of genetic resources" may be much broader than formerly believed. There is significant variation among national ABS frameworks on this point. This suggests that the specifications for inclusion of users and their activities within the coverage of the GMBSM may be difficult to concretize.
- Although specifically including provisions that address ATK, the Protocol does not define or provide detailed standards and provisions for how it shall be applied to ATK. Regardless of how the definition of genetic resources is interpreted (see I.A, *supra*), it is clear that ATK is quite different in nature from genetic resources, for purposes of how it can be accessed, utilized, regulated, monitored, overseen and enforced.
- Although specifically including provisions that address "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," the Protocol does not define or provide detailed standards and provisions for this special type of resources.

#### c) Overall Operation of the ABS Regime

A large number of participants raised questions regarding how the GMBSM will fit within the operation of the ABS regime, with particular emphasis on five points – (1) how the voluntary mechanism of Article 11 will be integrated with the GMBSM; (2) how the utilization of Article 4.2 (in the form of bi-lateral, trilateral, etc. agreements among countries involved in a particular proposed ABS relationship) would intersect with the GMBSM; (3) how the utilization of Article 4.2 (in the form of regional agreements regarding regionally-distribute genetic resources and ATK) would interact with the GMBSM; (4) how national ABS frameworks and sovereign rights (and the rights of providers and provider communities, with regard to PIC and MAT) are addressed and protected, and (5) more generally, how voluntary choice/compliance fits within the overall picture.

These questions are addressed below, in connection with specific questions from the notification, however, the contributors to this submission generally agree that the GMBSM is only one part of an overall regime with overall goals and mandates, and want to reassert here the importance of recognizing the fallacy of designing a single component of a regime without planning and clarifying the rest.

#### **II.** Issues Identified in the Notification

The following are our responses to the specific questions and points listed in the Notification.

# A. Situations and Factors indicating the Need for a GMBSM ("Situations which may support the need for a global multilateral benefit-sharing mechanism that are not covered under the bilateral approach")

The ABSSG members contributing to this submission identified a range of concerns relevant to this question. These concerns fall into four categories of concerns to be addressed – (a) abuses of the ABS regime; and (b) the importance of ensuring that the GMBSM operates to eliminate rather than exacerbate conflicts; (c) loopholes; and (d) the particular resources and situations to which the GMBSM could apply. Each of these concerns is separately addressed in the following sections:

#### a) Abuses

In general, the contributors view the need for a GMBSM as arising to avoid a kind of abuse of the genetic resources/ATK and the provider country's sovereign rights to regulate or engage in other oversight with regard to them. For example, a user may believe that he is not obliged to comply with ABS requirements - *i.e.*, to obtain PIC, MAT, an ABS contract, an ABS permit, etc.– with regard to a particular genetic resource or ATK element, because that resource is shared across national boundaries, rendering it difficult or impossible for the actual source country, community or individual to prove that it is the provider of the resource. In such cases, the (potential) user or user country could take (and in numerous cases has taken) it upon himself to come to its own conclusion as to whether the person he obtains genetic material from is entitled to provide the material, and on the basis of this unilateral decision, determine that he need not seek PIC.

Various contributors also raised the issue of historic abuses. They cited the prevalence of a potentially innocent type of misappropriation, noting that baseline studies conducted in many developing countries from many regions indicate that genetic resources and ATK have previously been removed from their country of origin without PIC and with no agreement relating to ABS, but that these resources either have not been utilized to date, or were not utilized until after the "relevant date" for application of ABS principles (as discussed in I.B.a, *supra.*) As a result, these resources lack documentation regarding their origin. Many contributors to this submission have stated that the utilization of such resources after the "relevant date" appears to trigger a need to apply the GMBSM.

#### b) Conflict Avoidance

In the context of the basic concerns over abuse of the providers legal and/or sovereign rights, as noted in our response to point II. C.k, *infra*, several of the experts have suggested that the issue of the distinction between Articles 10 and 11 is also relevant to this point. The underlying issue embodies a major difference in opinions among the experts. While some are emphasizing that there should be a clear, jurisdictional difference between "Article 10 situations" and "Article 11 situations," others have indicated that this is not mandated by the language of the two sections.

The latter group has stated that both articles should be read as applying to all situations in which the genetic resources and/or ATK are transboundary or are either "found in" or "shared" by more than one Party. Several have specifically interpreted Article 10 as asking the party to consider whether a mechanism is needed to address these situations, in the event that the Parties involved have been unable to achieve a mutually satisfactory solution by "endeavour[ing] to cooperate." This is similar to CBD article 27 (dispute settlement), which calls on Parties to attempt to settle their disputes by negotiation, but if unable to do so, authorizes recourse to formal mediation or other mechanisms set up under the CBD, for arbitration and conciliation, as formally established in Annex II to the Convention. The primary differences between CBD Article 27 and NP Articles 10 and 11 are as follows:

- (i) NP Article 10 is a call for possible future establishment of the GMBSM, where the CBD mechanisms are formally established; and
- (ii) given that ABS compliance involves formal commercial/legal commitments of a user and provider, supported by formal international commitments of user and provider countries to regulate, there is a possibility that, even if no GMBSM is ever established, the legal issues concerning the rights of providers and provider countries in transboundary situations of any type could be decided in national or international court actions or arbitrations anyway (by contrast, the CBD mechanism would not appear to apply to any "hard law" situation.)

Many contributors have indicated that, if there is no GMBSM, then direct legal action will be the only way for providers and provider countries to determine what their rights are. They suggest that the GMBSM will be a way to avoid the cost and acrimony of such an approach.

Taken together the above concerns and analyses have prompted some experts to stated that, "if Articles 10 and 11 cover different situations, and no GMBSM is to be established, providers and/or provider countries and communities should begin immediately to discuss filing joint legal action in

international courts for interpretation of their rights in situations involving 'the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.'" For many contributors, the desirability of avoiding such legal action is a major reason for supporting the creation of a GMBSM.

#### c) Avoiding the Creation of Loopholes and Perverse Incentives

Paralleling the above concerns regarding abuses and legal conflicts is the need to avoid the creation of loopholes that allow a user to evade ABS responsibilities. The overarching goals of ABS – equity and the provision of incentives for ecosystem protection – and the functionality of the entire ABS system depend on the assurance that the ABS system is loophole-free, so that any exceptions and special provisions can be carefully considered and appropriately limited.

Loopholes may lead to abuses, in particular when more than one country's law might apply or be claimed to apply to a particular ABS transaction. In such cases, a common type of loophole is any provision that enables "forum shopping" – by which a user avoids the obligation to pay benefit sharing by accessing a transboundary or shared resource in a country that does not require PIC and MAT, or that imposes fewer requirements than the other potential providers.

The GMBSM, itself, should not <u>unintentionally</u> become a path by which users can avoid compliance with national ABS law. If the GMBSM's requirements are significantly less demanding than applicable national ABS law, then it is important to ensure that the user cannot circumvent national ABS law by first removing the genetic resources and ATK without informing the country; and second announcing that his utilization activities will be governed by the GMBSM's less strict rules, because the origin of the resources is unknown and the resource occurs in more than one country. The effect of this situation is potentially a "forced waiver" of some or all of the rights and requirements of the country whose law is being circumvented. This problem is discussed in part II.D, *infra*.

Some of the ABSSG members submitting views did not oppose the idea of a single mechanism that *intentionally* supplants the country-by-country system, so long as this is done in a manner that all Parties accept. Others were strongly opposed to any GMBSM that "overshadows" the operation of national ABS mechanisms or undermines their efficacy.

All members caution against creating a mechanism that unintentionally and/or perversely encourages or motivates users to remove genetic resources or ATK without PIC, in order to take advantage of preference for the GMBSM. Unless all countries agree, the GMBSM should not become an alternative to national ABS legislation, which can be selected by the user without the consent of the provider country. In creating a secondary mechanism applicable where national ABS requirements cannot apply, the GMBSM should, if anything, provide an incentive for the user to comply with national requirements, and to all countries to adopt both provider-side ABS measures and user-side ABS measures.

In particular, this concern arises with regard to genetic resources that have been removed from their country of origin without PIC, prior to the "relevant date" as described above. While the ABSSG members submitting views are strongly desirous that benefit-sharing occur with regard to these resources, they are also concerned that the GMBSM should not operate as a reward to biopiracy and/or the misappropriation of genetic resources and ATK.

#### d) Particular Situations/Resources to be Included

A number of contributors identified particular categories of genetic resources and ATK that need to be addressed in some specific manner, in order for the ABS framework to function internationally without controversies and without loopholes. It was noted that, even if the resources in these categories are not included within a properly functioning GMBSM, it will still be necessary to come to some clear understanding as to how the Nagoya Protocol will be implemented with regard to them:

• genetic resources and ATK accessed before the "relevant date" (as discussed in Part I.B.a, *supra*;

- genetic resources and ATK in *ex-situ* collections or databanks, where the original country in which the collection occurred is not known or discoverable;
- genetic resources found in the territory of more than one country, over which PIC cannot be obtained from all persons and communities authorized to grant it in all relevant countries, due to inconsistencies in legal requirements among the countries involved;
- ATK that is shared among indigenous communities of similar or identical ethnic/traditional orientation, where such communities are located in more than one country;<sup>10</sup>
- Genetic resources that are shared widely among both countries that require PIC and those that have waived it;<sup>11</sup>
- Plant genetic resources is taken from the MLS under the SMTA, but used for non-food or non-feed purposes (*i.e.*, beyond the scope of the ITPGRFA's role as a component of the international ABS regime);
- The genetic resources of biological resources or samples that have been granted or gifted to a country or person, without specific discussion of the ABS implications of that grant;
- Microorganisms and other compounds.<sup>12</sup>

Several contributors raised the question of genetic resources and ATK for which PIC cannot be obtained. Their various positions on this category are discussed in this submission under heading II.A.c, *supra*.

In this context, too, the question of the relationship between Articles 10 and 11 arose as a related issue. (See discussions in II.A.b, *supra*, and II.C.k, *infra*.) In addition, this response again raised the critical situation in which genetic resources covered by Article 10 or 11 are found in multiple countries, one of which has waived PIC and/or determined that MAT are either not required or generic. See II.D, *infra*.

#### **B.** Possible Modalities for a Global Multilateral Benefit-sharing Mechanism as well as Information Regarding the Implications of Different Scenarios on These Modalities

#### a) Proposal of a Global Modality

While all contributors either agreed that a specific modality is needed or expected, most did not propose one, citing the various issues described in part I.A and I.B, *supra*, as prerequisites, without final agreement on which it is not possible to design a system. Several contributors pooled their efforts to provide the following proposal<sup>13</sup> (based apparently on the "genetic information" approach to the definition of "genetic resource," as set forth above), which they believe can be the appropriate modality and which provided a basis for many points made below regarding the potential benefits of and obstacles

<sup>&</sup>lt;sup>10</sup> One example offered is that of the H'mong ethnic minority group, which includes communities in many countries, which all possess shared ATK regarding, for example, medicine.

<sup>&</sup>lt;sup>11</sup> One contributor offered the example of the dandelion (*Taraxacum officinale*) and the possibility that it may have value in the treatment of cancer.

<sup>&</sup>lt;sup>12</sup> The contributors discussing this item noted that it is difficult or impossible to determine the geographic distribution of many microorganisms (such as digestive enzymes, etc.). *See* Fritze, D. and Oumard, A. (2015) "*Ex situ* collections of microbes and how they adjust to ABS conditions", in: Kamau, E.C., Winter G. and Stoll, P-T. *Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol*, London: Routledge, pp 226–244; *see also* an opinion stated in one of the CBD's online discussion groups at https://bch.cbd.int/abs/art10\_groups/?threadid=5280#5338.

<sup>&</sup>lt;sup>13</sup> The proponents of this proposal offer it as an example of the application of the economic concept of "bounded openness," which they believe can be the appropriate modality to achieve efficiency and equity. Their full proposal, and its more detailed explanation of this concept is attached to this submission as Annex A. It is included in the form received, and has not been commented on or revised or recommended by the members of the ABSSG.

to implementation of this modality. While the majority of contributors to this submission do not share the views expressed in this modality, all agree that the way to move forward is to begin the process. Hence, the ABSSG includes this proposal in our submission, as a potential "rough draft" on the basis of which the parties may begin to move forward

Their proposal can be reduced to ten steps which have appeared in the academic literature, under various expressions by different authors, since 1992:

- (1) A negotiation of royalty rates between User and Provider countries based on a matrix of relevant characteristics of utilization;
- (2) Establishment of a global fund to hold royalties in escrow;
- (3) Disclosure of utilization in the transmittal of applications for intellectual property;
- (4) Recognition of need to address the redundancy of natural information<sup>14</sup> at different taxa as an empirical question;
- (5) Determination of the diffusion of natural information across taxa, and recognition of the costs of that determination as a transaction cost that is subject to change and that will decrease as the technology and information resources involved develop;
- (6) Determination of the geographic distribution of the information dispersed across taxa and recognition of the costs of that determination as a transaction cost that is subject to change and that will decrease as the technology and information resources involved develop;
- (7) Monitoring and tracking of patents which have disclosed natural information and their commercialization;
- (8) Collection of revenues by the global fund;
- (9) Allocation to appropriate accounts, reimbursement of the infrastructure costs required in order to perform steps (5) through (8), to be distributed when the patents involved have expired;
- (10) Dispersal of royalties to the identified countries of origin, proportional to their relative holdings of the natural information, when the revenues collected under step (8) exceed the costs allocated under step (9).<sup>15</sup>

#### i. Key Facts and Observations Regarding The Proposed Global Modality

The proponents offer the following as key facts and observations regarding the manner in which this process would work:

<u>Key Fact/Observation A</u>: Cadastral systems vary from country to country as do the legal principles, on the basis of which land can be owned or alienated.<sup>16</sup> At present, however, various national approaches

<sup>&</sup>lt;sup>14</sup> See footnote 27, *supra*. The term "natural information," as used in this context, is not agreed by many contributors, but insisted upon by the proponents of the global modality proposal set out in this section. In opposition to the proponents' use of this terminology, one expert noted, "The question of what is natural and what is not is hardly clear cut. Is cDNA sequence data unnatural and gDNA natural? Or are both natural?" Another commented, "Given the above-recognized need to come to a clearcut understanding of the terms "genetic resources," "derivative," etc., it seems hardly progress to introduce another vague and ambiguous term to further muddy the waters." A number of commenters noted that even though the pre-existing terminology problems still stymie the ABS discussions at times, it is possible to track the intent of the persons using these terms to some extent. With regard to the current proposal, they could not confidently analyze it, because the terminology, in addition to being vague, was non-standard.

<sup>&</sup>lt;sup>15</sup> Vogel, J. H. 2015. "Foreword: On the Silver Jubilee of 'Intellectual Property and Information Markets: Preliminaries to a New Conservation Policy" in Ruiz Miller, M. Genetic Resources as Natural Information: Implications for the Convention on Biological Diversity and Nagoya Protocol. (New York: Routledge.)

specify particular ABS-related rights for individual landowners or communities. This factor adds another step to the determinations under step 5, in order to enable the alignment of the GMBSM's distribution of royalty revenue among the various persons and communities that are authorized providers within the countries that are the Provider Countries with regard to a particular species:

o Determination of the geographic diffusion of the natural information among landowners in each country of origin of the species in question and other relevant practical and legal question relating to the authorization of individual and community providers, to enable rational dispersal of such royalties as become available under step 10.<sup>17</sup>

<u>Key Fact/Observation B</u>: As viewed by this modality's proponents, upon expiration of an IPR related to natural information, future activities that use that same information, should not incur an ABS obligation. A key concern with regard to ABS is that it creates a disincentive for users, because many negotiations imply that the users' benefit-sharing obligation with regard to each specific utilization is unending. Virtually every other input into the R&D process of a commercial product has a predictable term and cost. Even if that cost is paid over time, as under a patent, there is a clear end-date, by which the obligation is concluded.<sup>18</sup>

<u>Key Fact/Observation C:</u> Those who access and utilize genetic resources and/or TK often ignore the existing body of understandings and research regarding the ABS processes and responsibilities as set out in the CBD and the NP.<sup>19</sup> From the outset, the GMBSM will need to be designed in a way that ensures that users will find it beneficial to comply with national ABS obligations, where possible, and that in cases to which the GMBSM applies, the provider country will find the application of the GMBSM more

<sup>16</sup> Andreasson, K. 2006. "Legal Coordinated Cadastres – Theoretical Concepts and the Case of Singapore", TS 69 – Land Administration Concepts, Legal Coordinated Cadastres, Theoretical Concepts and the Case of Singapore, Shaping the Change XXIII FIG Congress Munich, Germany, October 8-13, 2006. http://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=1024806&fileOId=1027725

<sup>19</sup> Examples of the primary analysis of these responsibilities include the following:

Oldham, P. 2009. "Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology", ESRC Centre for Economic and Social Aspects of Genomics (Cesagen). UNEP/CBD/WG-ABS/3/INF/4.

Hammond, E. 2014. "Patent Claims on Genetic Resources of Secret Origin" TWN Third World Network. Online at http://www.twn.my/title2/biotk/misc/budapest\_final\_21%20Feb2014.pdf.

Davis, K. Smit, M.F. Kidd, M. Sharrock, S. and Allenstein, P. 2015. "An access and benefit-sharing awareness survey for botanic gardens: Are they prepared for the Nagoya Protocol?" *South African Journal of Botany* 98: 148–156. Online at http://dx.doi.org/10.1016/j.sajb.2015.01.015

Watanabe, M. E. 2015. "The Nagoya Protocol on Access and Benefit Sharing International treaty poses challenges for biological collections." *Bioscience*, 65(6): 543-550.

Vogel, J.H. Álvarez-Berríos, N. Quiñones-Vilche, N. Medina-Muñiz, J.L. Pérez-Montes, D. Arocho-Montes, A.I. Vale-Merniz, N. Fuentes-Ramirez, R. Marrero-Girona, G. Valcárcel Mercado, E. and Santiago-Rios, J. 2011. "The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access and Benefit Sharing" Law Environment and Development (LEAD) Journal, 7/1:51-65. Online at http://www.lead-journal.org/content/11052.pdf.

Vogel, J.H. Fuentes-Rivera, C. Hocking, B.A. Oduardo-Sierra, O, and Zubiaurre, A. "Human Pathogens as Capstone Application of the Economics of Information to Convention on Biological Diversity." *International Journal of Biology*, 5(2): 121-134. Online at http://www.ccsenet.org/journal/index.php/ijb/article/view/22760.

<sup>&</sup>lt;sup>17</sup> Vogel, J. H. 1994. Genes for Sale. New York: Oxford University Press. And *Ibid*.

<sup>&</sup>lt;sup>18</sup> See e.g. Kamau, E.C., Winter, G. and Stoll, P-T. 2015. *Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol*, (London: Routledge) at pp.18 and p. 325, where it is suggested that where it's suggested that that a formula could be developed which determines a point of time in the valorization chain of R&D when providers' rights of benefit sharing expire (become exhausted /disappear).

beneficial than insisting that users instead comply with national ABS legislation. Proponents of the above modality believe that it accommodates such design, reducing transaction costs for public science to zero and for the commercial user to almost zero, when compared with the costs of the patent processes they already undertake. The system also accommodates the need for confidentiality of research streams. Disclosure only comes into play when the patent is commercially successful, at which point the GMBSM will query the User regarding the species and location of collection, proceeding through steps (4) to (10), as set forth above.

<u>Key Fact/Observation D</u>: Significant genetic resources were collected (bioprospecting) under Material Transfer Agreements before the ratification of the CBD.<sup>20</sup> Under the above modality's "bounded openness" approach (described in more detail in Annex I to this submission), ABS contracts covering such resources would binding only for the natural information that is endemic to the contracting Party. Where a particular resource is diffused across taxa and jurisdictions, the user would have to remit royalties to the proposed global fund according to the suggested modality of the GMBSM.<sup>21</sup>

#### ii. Key Challenges and Criticisms of the Proposed Global Modality

With regard to this proposal, other members of the ABSSG, although generally agreeing with its approach, noted several concerns, which would need to be addressed through the international process for development and adoption of a GMBSM along the above lines:

**<u>Practical Issues</u>**: In the view of some contributors, the above modality relies on the existence of technical capabilities that are dubious or nonexistent. In particular, these contributors suggest that modern taxonomy is not capable of addressing the issues relevant to steps 4, 5, 6, 9 and 10 (and "Key Fact/Observation A) at the scale implied. For example, step 10's call for "(10) Dispersal of royalties to the identified countries of origin, proportional to their relative holdings of the natural information" neglects to consider the interim step of calculating this proportion, or to recognize that, in addition to requiring a massive global-grassroots effort for every species, this figure is constantly changing, in light of the rapid loss of biodiversity. Calculation of this figure, and the costs of the process required will not be a negligible amount – indeed one contributor suggests that these costs will entirely consume any benefit-share that will be derived.

The proponents of the modality counter by noting that "proportionality" is an approximation and that any loss of habitat in a participant country would reduce that country's proportional share, indicating that this modality would align the GMBSM with the CBD's overall mandate to promote incentives for conservation. Moreover, in their modality the effort to come to reliable estimates of proportionality would only be undertaken if the expected cost of that effort is significantly less than the benefit to be shared; otherwise the funds would be used to address "global taxonomic needs." (The proponents' full unedited proposal is annexed to this for the benefit of readers who need a more detailed and technical explanation of its provisions and justifications.)

Other contributors to this summary, whether supporting the proposed modality or not, have raised and struck down the technological deficiency issue as a straw-man, noting that legal and administrative mechanisms are regularly developed using calculations and data derived under the "best current method"

<sup>&</sup>lt;sup>20</sup> See, e.g., Reid, W.V. Laird, S.A. Meyer, C.A. Gámez, R. Sittenfeld, A. Janzen, D.H. Gollin, M.A. and Juma, C. 1993. *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*. Washington, DC: World Resources Institute.

<sup>&</sup>lt;sup>21</sup> The proponents who originally submitted the proposed modality outlined section II.B.a)i, *supra*, offered a fifth key observation regarding a specific situation involving the efforts of the government of Puerto Rico, and its "colonial" relationship to the United States. Others who have contributed to the ABSSG submission do not share in the ability to present this specialized and not previously publicized description of a political situation as their own. Accordingly, Annex A to this submission provides the views of the original proponent group of ABSSG members, as submitted to the ASSG, in their entirety.

or "best available technology" for determining/estimating particular costs or thresholds. As the GMBSM develops, the technological and computational methods will continue to evolve.

**Functionality and Motivation Issues:** In depth discussion of the proposed modality identifies several other factors that may impact its desirability. First, it is predicated on the view that no benefit distribution to individual countries or providers will happen unless the benefits shared with regard to a particular species/ATK that is accessed through the GMBSM as envisioned in this modality cover significantly more than the cost of scientific analysis to determine the distribution of the species or ATK. There will be no analysis of distribution until it is after the particular species or ATK has been patented, and that patent has produced significant (financial/cash) benefit-shares. At that point, an investigation will be conducted to identify the best means of determining the species distribution and the shares of the various countries. This will be followed by a cost-benefit analysis : whether the cost of determining distribution and shares will be cost-effective in comparison with the benefit received. If so, the GMBSM will have the remainder of the life of the patent to conduct the needed analysis of the distribution and shares. At the end of the patent, the remaining funds will be distributed among the countries. If the cost-benefit analysis finds that the it is not cost effective to determine the distribution and shares of the various potential providers, then the benefits will be used for conservation purposes.

Critics of the proposed modality note several concerns related to this process. First most of its determinations will be "expert analyses" and thus outside of the control or ratification of the providers. This places a lot of control in the hands of the GMBSM staff. Experience with the ITPGRFA indicates that benefits received on a per-species basis will initially be small, and that the mechanism will become a means from taking those benefits that might have gone to one or more particular countries, and putting them in the hands of individuals to distribute for other purposes.

Moreover, even if the benefit-sharing amounts are relatively large, it would be rather easy, based on the need to undertake some level of multi-country or even worldwide analytical process, to determine that the costs of such analysis are too great and to decide to retain the benefits for other uses to be decided by the persons or entities that make up the institution/secretariat that operates the GMBSM. Such persons' continued employment and stature will depend on the goodwill and continued budgetary growth of their institution.

Finally, the decision to hold "significant funds" for a period of many years after they have been shared as benefits, without even any clear decision as to whether they will ever be distributed as benefit-sharing will operate as a significant disincentive for providers and provider countries to participate in the mechanism. The mechanism will need to address motivation/incentive issues, if it is to be useful as a tool for making ABS work.

All of the above factors can potentially be addressed through careful design. Alterations of the basic plan to address these challenges should be the work of an expert team.

**<u>Patent/IPR focus</u>**: The above modality is apparently based on the assumption that meaningful benefits to be shared arise only where the utilization of a particular genetic resource is patented, and that activities/innovations not protected by intellectual property rights (IPRs) are, by definition not producing benefits to be shared. Concerns expressed in this connection include the following:

- Some of the most important aspects of benefit-sharing relate to non-monetary benefits, including obligations to share research results and technology, as well as capacity-building. For the GMBSM to functionally support ABS, the modality selected must encompass these obligations as well.
- With regard to genetic-resource and ATK patents, recent experience indicates a multi-level process. Researchers and commercial users initially file a very general patent, with the aim of protecting whatever future use they might discover. They may later patent the develop of an "interim product" an ingredient or component that can be used in a particular type of product or process. Then they may patent that product or process. It is essential for any

patent-based element of the GMBSM to consider this "patent hierarchy," which is not adequately considered in the proposed modality.  $\$ 

- In addition, the same genetic resource or ATK may lead to different uses. For example, IPR may have been developed on the use of a protein derived from a given gene for use as a medical treatment. Irrespective of the success of this, subsequent research may develops a marketable product in cosmetics from the same 'natural information' an activity that should incur ABS obligations;
- The proposed modality does not take into account the problems of post-access transfer of the genetic resource and/or ATK, and the uncertainties regarding what activities and transfers would be considered derivatives.<sup>22</sup>
- The above modality, as described, specifically and intentionally creates potential loopholes for public and other uses not protected by patents or other IPRs, which produce interim products and information transferred to other users free of ABS obligations.<sup>23</sup>

#### b) Multi-level Modality: Including Regional or Sub-regional Mechanisms

Another suggested approach views the overall coverage of the GMBSM more narrowly, noting that it should apply primarily to resources from areas outside of the national ABS systems, determined on the basis of the resource's regional distribution. Contributors suggested that most transboundary genetic resources or ATK could be addressed through regional co-ordination. For example, one contributor noted that the new Caribbean Biodiversity Fund could become a regional mechanism used for regional benefit-sharing, leaving to the GMBSM only those shared resources that do not come within the ambit of such a regional mechanism, or those to which more than one such mechanism would apply.<sup>24</sup>

In this connection, another contributor noted the importance of using existing experience in consideration of the global nature of the GMBSM, including the experience to date with the mechanisms established under the International Treaty on Plant Genetic Resources for Food and Agriculture and the International Seabed Authority.

#### c) Other Opinions on Modality Issues

Although many of these were not agreed by all contributors, a range of other points were made, suggesting particular characteristics that one or more contributors felt should be found in whatever modality is used. These points include the following:

<sup>&</sup>lt;sup>22</sup> The proponents respond by stating that, in their view, the modality directly addresses the problem of post-access transfer by declaring the checkpoint to be the application for a monopoly intellectual property right.

 $<sup>^{23}</sup>$  The proponents responded to this point by stating their view that "the degree of benefits is greatest where government sanctioned monopolies lie, *viz.*, intellectual property rights, and [that] the capture of other benefits may not justify the associated transaction costs."

<sup>&</sup>lt;sup>24</sup> A variety of contributors have noted the long existence of proposals for the establishment of various types of "joint provider" arrangements, couched in every format from a "cartel" (Vogel, J.H. (2009) "Reflecting Financial and Other Incentives of the TMOIFGR: The Biodiversity Cartel" in Ruiz Mueller, M. and Lapeña, I., *A Moving Target: Genetic Resources and Options for Tracking Their International Flow*. IUCN Environmental Policy and Law Paper Series, ABS series No. 067-3) to a bilateral or other collective agreement pursuant to NP Art. 4.2 among provider countries that share particular genetic resources or ATK of interest, to offer such resources jointly (Young, T. "An International Cooperation Perspective on Implementation of the Nagoya Protocol", in Morgera, E. Buck, M. and Tsioumani, E., eds, *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective* (Leiden/Boston: Martinus Nijhoff, 2013) at pp.451–505.) In a recent case study of the East African Community, Kamau also argues that existing mechanisms of the Community suffice for the establishment of a regional common pool of genetic resources and notes that the Community is already heading towards such an approach. *See* Kamau, E,C. and Winter, G., *Common pools of genetic resources. Equity and innovation in international biodiversity law* (London: Routledge, 2013) at pp.343-398.

First, contributors agreed that where the GMBSM applies, participation (including reporting and benefit-sharing) should be mandatory. With regard to genetic resources from areas beyond national jurisdiction (variously described as including one or more of the following the oceans beyond EEZs, oceans beyond territorial seas, seafloor beyond national OCSs, Arctic ice, and Antarctica) contributors were divided with some feeling strongly that some such areas should be included in the GMBSM, and others identifying other processes that should be authorized or established to address them, and one flatly calling for their exclusion from the GMBSM at this time. Based on these responses, there appears to be one area of consensus – that the Nagoya Protocol COP/MOP should come to a specific decision on inclusion/exclusion of each such area.

Second, more controversial was the statement that, where benefit-sharing is required, it should be converted to financial value for purposes of benefit sharing, and that all benefit-sharing should be monetary and/or financial in nature. Some contributors strongly disagreed, noting that the benefit to be shared may be information or technology, and the user in question may be a non-commercial researcher or other entity that is happy to share information or to help build capacity to utilize it, but unable to share any money or other financial benefit.<sup>25</sup> In this connection, several contributors noted that other existing multilateral benefit-sharing mechanisms (*e.g.*, those established under the International Treaty on Plant Genetic Resources for Food and Agriculture and the International Seabed Authority) have shown that monetary benefits may not materialise for a very long time and may not be sufficient anyway, whereas non-monetary benefits can be shared quite quickly and with great positive impact.<sup>26</sup>

Third, also controversial: Some contributors stated that monetary benefits shared should be used first for purposes of conservation and promoting the sustainability of genetic resources and ATK, and second to directly benefit the communities in areas in which the resource is distributed. This statement was contradicted by those who felt that national legislation in each country should be the determinant of how benefit-sharing payments are used and/or distributed, and others who felt that benefits should be paid directly to indigenous communities, which should have the power to determine how they are used and/or distributed.

### C. Areas Requiring Further Consideration, as Identified in Paragraph 23 of the Report of the Expert Meeting on Article 10 of the Nagoya Protocol.

Regarding the need for further consideration of the areas listed under item C, the members of the ABSSG offer a number of comments.

Initially, many members expressed the opinion that the creation of a functional mechanism should be an expert-driven process. One or more teams of experts with experience in commercial mechanism/legislation development processes should be tasked to develop proposals and flesh them out into comprehensive draft mechanisms. Those mechanisms should in turn be submitted to general analysis and comment – a process that refines any new concept, increasing its chance of success. In the course of such development, the Parties will be provided with the expert input, arising from their practical experience in creating a legally and practically functional GMBSM mechanism, on the basis of which they can more rationally and knowledgeably answer these questions. Conversely, as noted by one scientist, "[in addition to these experts], a pragmatic approach must involve experts in biodiversity also,

<sup>&</sup>lt;sup>25</sup> As noted by one contributor, "the choice of the term 'mechanism' in [the negotiation of] Article 10 was specifically made to limit discussion to the establishment of a 'fund'." She also pointed out, "[w]henever 'benefit-sharing' is used in international law, it is always with respect to both monetary and non-monetary... so it may be dangerous to establish a different precedent under Article 10."

<sup>&</sup>lt;sup>26</sup> See discussions in Morgera, E. (2015) "An International Legal Concept of Fair and Equitable Benefit-Sharing," Edinburgh School of Law Research Paper No. 20; BENELEX Working Paper No. 6, online at <u>http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2633939</u>; and Tsioumani, E. (2014) "Exploring Benefit-Sharing from the Lab to the Land (Part I): Agricultural Research and Development in the Context of Conservation and Sustainable Use," Edinburgh School of Law Research Paper No. 2014/44; BENELEX Working Paper No.4. online at <u>http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2524337</u>.

otherwise processes will be developed which rely for their success on information which is simply not available"

Beyond this general comment, the following sections provide additional individual answers to the inquiries identified in paragraph 23 of the report of the Expert Meeting on Article 10 of the Nagoya Protocol (document TJNEP/CBD/ICNP/3/5.)

#### a) Whether or Not There is a Need for a GMBSM

While generally agreeing that there is a need for a GMBSM, the members of the ABSSG offered a range of responses to this question. Some noted, and all agreed that the need is more properly described as the need for a practical means of addressing the loophole in ABS regarding trans-boundary genetic resources and ATK. They note that the disparity in national and regional implementation efforts between countries and regional integration organizations that view themselves as primarily providers, and those that are perceived to have most users under their jurisdiction. This continuing disparity suggests that it is unlikely that the transboundary resource loophole can be resolved by relying only on comprehensive national implementation of the Nagoya Protocol.

Some contributors consider the existence of Article 10 to be prima facie evidence of a strongly perceived need for a GMBSM, while others note that Article 10 does not mandate creation of such a mechanism, but only calls on Parties to consider the need therefor. Both groups agree that a significant percentage of Parties feel that a GMBSM or some other mechanism is needed in order to address the above-mentioned loophole.

In addition, many have noted that although the need for and modalities of such a mechanism are separate questions, the responses are closely interlinked. If no modality can be designed that will operate legally across all countries, then it is not meaningful to discuss the need for such a mechanism or the fact that the transboundary loophole may be preventing functional ABS implementation. To a large extent, the process of designing modalities/options to address the loophole will provide the key information on the nature, requirements and costs of possible solutions – and it is clear that the need for a system can best be evaluated when one knows how much it will cost.

Many contributors noted particularly that, by requiring further detailed discussion of "the need for a GMBSM" before knowing what a GMBSM would require, the COP would unduly delay the efforts needed to design the new modality.

#### b) Whether There Is Sufficient Experience with Implementation of the Protocol to Determine Whether Such a Need Exists

There have been twenty-five years – one human generation – since countries started attempting, unsuccessfully to implement ABS.<sup>27</sup> It is unequivocally agreed that loopholes in international coverage of functional ABS legislation and other problems relating to regulation and enforcement have prevented full implementation of the concept. To the contributors to this submission, this appears to constitute sufficient experience on which to determine the need for a GMBSM. They generally agree in predicting that the Nagoya Protocol COP-MOP will delay action on this mechanism, using this question as a basis on which to pursue futile attempts to address these deficiencies through national and bilateral approaches, which are doomed to failure while the system continues to harbor problems such as the transboundary resources loophole.

In this connection, experts in the development of legislative and administrative frameworks have noted that, when designing a framework to address a new problem, it is not necessary to spend years trying to implement a framework that does not exist, in order to recognize the need to create new mechanisms to achieve certain of the sub-results necessary to building a functional framework.

<sup>&</sup>lt;sup>27</sup> Drahos, P. 2014. "Paying Peanuts for Biodiversity." Chapter 8 in *Intellectual Property, Indigenous People and their Knowledge*. Cambridge University Press.

#### c) Whether the Utilization of Genetic Resources Without PIC Would Entail Benefit-sharing Obligations that Could Be Met Through a GMBSM

The proponents of the modality described under II.B, *supra*, state that if ABS were to use this modality no other PIC would be necessary,<sup>28</sup> thus greatly reducing the transaction costs of "fair and equitable benefit sharing". They believe that the royalties are standardized across Parties according to a negotiated matrix of utilizations.

Numerous other contributors have indicated strong opposition to this apparent dismissal of the PIC concept, suggesting that it is absolutely necessary that any mechanism adopted must enable public comment from affected countries/communities or some other means of ensuring that the needs addressed by the PIC concept are not omitted under the GMBSM.

#### d) Whether a Party's Decision Not to Require PIC (e.g. under Art. 6(1)) or To Waive PIC (e.g. under Art. 8) Can Constitute Situations For Which It Is Not Possible to Grant Or Obtain PIC in the Context of Article 10

The response to this point reflects responses under points II.C.a and II.C.c, *supra*. Certainly, any functional, loophole free mechanism would have to address these situations.

#### e) Whether Benefit-sharing Requirements are Waived When a Party Has Decided Not to Require PIC or has Waived PIC

All ABSSG experts providing input on this question agree that, where a sovereign right is involved, no person, State or mechanism should be permitted to assume that any aspect of that right is waived by a particular State, unless the proper authority of the State in question has specifically waived it in writing. Moreover, the legal decree or other instrument waiving PIC may be adopted for other reasons, so that the adopting authority might have no intention of waiving benefit-sharing.

Thus, in general, the question of whether a Party has waived PIC should be decided on a countryby-country basis, by examining the text of the particular Party's waiver or decision, which should be reflected in a formal legislative or other authorized decree. Beyond this, see the response to point C.d above.

#### f) Whether There Is No Requirement for Benefit-sharing When Mutually Agreed Terms Are Not Required or Have Not Been Established

The ABSSG members submitting views have similarly agreed that the failure to establish mutually agreed terms may arise out of many factors that bear no relation to a national intention to waive benefit-sharing. Members have noticed, based on their personal experience with ABS in many countries, that "particularly in small countries, capacity to agree/establish MAT can be challenging." All contributors submitting views on this point agree that, even when achievement of MAT is difficult, benefit-sharing can never be waived without specific waiver in writing by the appropriate nationally authorized person or authority.

Under the existing interpretation in many countries which assume that "genetic resources" refers to physical samples, a decision to eliminate the benefit-sharing obligation "when mutually agreed terms are not required or have not been established" almost guarantees that "mutually agreed terms" will never be achieved. Such a framework would give users a strong incentive never to agree. This is not consistent with the goal of a functional ABS regime.

Situations may exist in which the parties to an ABS transaction have, with appropriate authorization, agreed that mutually agreed terms are not required, or have intentionally, decided not to establish them. To date however, where genetic resources and/or ATK are accessed without the establishment of mutually agreed terms, this usually means that the user is attempting to acquire and utilize genetic resources or ATK without being noticed by the provider country or community.

<sup>&</sup>lt;sup>28</sup> They have expressed the view that by their countries' agreement to adopt the modality, all prior informed consent requirements would have been met. As noted, this view is not shared by most other contributors.

Accordingly, it appears counterproductive to find that there is no requirement for benefit-sharing when mutually agreed terms are not required or have not been established.

g) Whether the absence of ABS legislation or regulatory requirements in a Party due to lack of capacity or lack of governance means that PIC for access to genetic resources is not required and there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC

All ABSSG experts providing input on this question agree that, where a sovereign right is involved, no person, State or mechanism should be permitted to assume that any aspect of that right is waived by a particular State, unless the proper authority of the State in question has specifically waived it in writing.<sup>29</sup> It is legally inappropriate to allow any person to assume that a country has decided to give up those rights solely on the basis of the fact that it has not been able or felt it necessary to adopt specific legislation saying that it "accepts" that particular sovereign right. Allowing this type of reasoning might set a very unfortunate precedent, that could apply to other sovereign rights and resources as well.

Members submitting views have noted the level of difficulty encountered by all countries in adopting national ABS legislation, and the fact that many of the countries that have already done so have identified many problems with their legislation after it entered into force, and are in process of revision. All countries are thus forced to address the ABS issue independently "from scratch" – a process that takes significant time and effort, owing to many challenges, including fragmentation of national authorities and development of national implementation capacity. Accordingly, the delay in adopting legislation should not put them in danger of irrevocably losing their rights to genetic resources and ATK and should not become a justification for legitimizing biopiracy.

 h) Whether the absence of measures in a Party to implement Article 7 means that PIC for access to traditional knowledge associated with genetic resources is not required and there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC;

Similar arguments to those set forth in II.C.f, II.C.g, and footnote 40 apply to this question. In addition, it is assumed that countries relationships with their indigenous and local communities must be individually addressed and that this process, too, is difficult and time consuming. Moreover, members who have worked in small and archipelagic countries note the added challenge of public education of local and traditional communities sufficient to enable them to provide PIC. Here also, allowing a user to obtain and utilize ATK without PIC because that user has unilaterally decided that it was "impossible to grant or obtain PIC" in a particular country would, in essence be a means of giving users permission to engage in biopiracy.

i) Whether a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if a genetic resource is found in more than one Party and it is possible to identify the source

<sup>&</sup>lt;sup>29</sup> This indicates a critical priority for all countries to eliminate any doubt by promptly adopting, at minimum, an initial piece of ABS legislation – one that specifically states that the country, in exercise of its sovereign rights over its genetic resources, declares that PIC and MAT are or are not required for any access to or use of genetic resources derived from the country's biological resources. Where PIC is required, if the country is not yet ready to adopt its full formal ABS framework, it should designate a national focal point or competent authority who should be contacted prior to any ABS-related access, collection or negotiation.

### of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable

The response to this point is essentially identical to the response given under I.A and B., above. The manner of addressing this question in the GMBSM will depend on the Parties' willingness and ability to agree at last on definitional issues left open in both the CBD and Nagoya Protocol.

Two contributors stated their belief that a GMBSM would be difficult to adopt, and more difficult to apply in a fair and equitable way. One of these based his views on scientific factors that prevent the achievement of a clear and complete record of the distribution of any species. Another took this position on the basis of the difficulty involved in obtaining agreement among countries sharing a resource, regarding the common use of that resource. She postulated that it would be better that each country manage the resources on its territory as physical samples. Both of these contributors took the position that the issue should be governed by the users choice of country in which he wishes to collect the resource. This latter sentence was opposed by most of the contributors, who claimed it would be unfair and inequitable.

The contributors to this submission were divided regarding the impact of Nagoya Protocol Article 11 on this question. Several contributors noted the importance of integrating several articles, in responding to this question, which turns on many points made above and below in this submission. To a large extent, responses were directly tied to the authors' views on the definition of "genetic resource." Some of those who adopted the "physical sample" definition (who viewed the GMBSM as having little potential scope), took the position that the specific place of collection/access should govern all ABS activities, except in situations where the collection happened near an international boundary or outside of national jurisdiction.

Others, took a variety of positions regarding situations where it is possible to identify multiple provider countries of a specific resource. Among these were the views that:

- the GMBSM should address this situation, so that when Parties come to a satisfactory solution by applying Article 11, then the ABS transaction involved would be removed from the coverage of the GMBSM.
- those countries should consider adoption of a "collaborative providers" agreement among themselves (applying NP Article 4.2), eliminating or preempting the need to apply Article 10 with regard to future ABS arrangements as to that resource.<sup>30</sup>
- as further detailed in part II.C.K, *infra*, in those situations Article 10 should not apply, because Article 11 provides a more expeditious result.
  - j) Whether traditional knowledge associated with a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if traditional knowledge associated with a genetic resource is found in more than one Party and it is possible to identify the source of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable;

Given the lack of definitions in relating to ATK, the response to this point is an even more emphatic statement of the response to point II.C.i, *supra*. The need for definitions and interpretative decisions regarding how ATK should be included in the Protocol and the differences between genetic resources and ATK in this regard is urgent and essential. Significant discussion and analysis of this issue is needed, once those other points have been resolved. Here also, the possibility of an Article 11 solution was raised, with the same division of views as is described in our response in II.C.i.

<sup>&</sup>lt;sup>30</sup> See footnote 35, supra.

### k) Whether Article 11 is Sufficient to Respond to Transboundary Situations

Given that extensive infrastructure, in the form of databases and capacity-building (including at the community level) is a prerequisite for a fair and equitable distribution of benefits of traditional knowledge, and in light of the previous history of implementation of CBD Article 15, reliance on generic provisions that require Parties to "endeavour to cooperate, as appropriate," to address differences in perspectives on the application of ABS and their respective rights therein appear to be manifestly insufficient. As noted above, although the contributors to this submission agree that the GMBSM should have a clear legal relationship to Article 11, there was some disagreement on what that relationship should be. Significant discussion and analysis of this issue is needed, once those other points have been resolved.

In this context, throughout their responses to all items above, several of the experts have emphasized the need to make a clear distinction between the coverage of Article 10, which calls for consideration of the need for a mechanism to address instances in which ABS applies to "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" and that of Article 11, which calls for cooperation, in the situations "where the same genetic resources are found in situ within the territory of more than one Party" and/or "where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties". This issue has raised a major difference in opinions among the experts in the section.

These contributors have found this discussion a bit vague in failing to clarify whether it is seeking information on resources included under Article 11 only or resources under either Article 10 or 11 or both. In this connection one contributor stated that, if only Article 11 resources are covered, then "it is obviously clear, in my view (and limiting my comment to GR), that it is not sufficient as it covers transboundary cooperation in regard to: 1) in situ GR and 2) found in parties' territories. So this excludes ex situ GR and GR of unknown origin."

The primary basis of this view is that "[g]enetic resources and ATK requiring transboundary cooperation under Article 11 cannot simply or automatically be thrown into the same pot with those referred to under Article 10... because the sovereignty of States and the power to invoke that right in order to subject them to PIC and MAT and benefit-sharing requirements is not taken away and is implied by 'genetic resources are found *in situ* within the territory of more than one Party' and ATK shared by one or more ILCs 'in several Parties'."<sup>31</sup>

On the other hand, several experts have questioned the validity of finely focused interpretative efforts, in regard to such a vague, ambiguous and poorly drafted instrument as the NP, particularly at an early stage when virtually no formal application has occurred. They question whether it is reasonable to claim that the NP provides any legal basis on which anyone could reasonably distinguish situations involving "genetic resources that occur in transboundary situations" from those involving "genetic resources ... found *in situ* in more than one country." They opine that there is no indication in the

<sup>&</sup>lt;sup>31</sup> Quoted from Kamau (2015) "Research and development under the Convention on Biological Diversity and the Nagoya Protocol" in: Kamau, E.C., Winter, G. and Stoll, P-T., *Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol*, London: Routledge, p.52. The quote continues, "These cannot be equated e.g. to genetic resources and ATK in *ex situ* collections of unknown origin, or genetic resources in ABNJ. States within the territory of which such genetic resources are found may decide to exercise that right corporately or opt to do so individually. To encroach on their right to do so would not only be derogatory to the principle of sovereign rights of states over their natural resources but also a departure from an important cornerstone of the CBD, the concept of bilateralism. Even the Nagoya Protocol is careful of what it can ask in its formulation of Article 11 and therefore only requires Parties to "endeavour to cooperate". What is probably novel in this regard is that the Protocol gives leeway for common pools endeavours at different points, including at a regional level."

language of the NP that either of these terms should be given any meaning other than its ordinary meaning, and claim that applying normal principles of English, the two are overlapping or identical in meaning.

With regard to the obligation of countries to cooperate, contributors have noted that Article 11 is only a suggestion, calling on Parties to "endeavor to cooperate." Once again, many contributors suggested the value of provider countries acting together with regard to identified shared or transboundary resources, as a means of, in essence, removing those resources from the operation of the GMBSM.

### I) Whether a GMBSM Should Address the Sharing of Benefits Arising from the Utilization of:

## i. Genetic resources in ex situ collections in relation to transboundary situations or for which it is not possible to grant or obtain PIC

The ABSSG members submitting responses on this issue generally made the same comments as expressed in point II.C.d, above. Proponents of the proposed modality described under B, above also stated that their proposal would eliminate and simplify this issue, while recognizing and upholding the basic premise that access to and utilization of any specimens held ex situ are subject to ABS obligations to the countries of origin. Experts who opposed elements of the proposed modality, however, noted the need to ensure that national ABS legislation is "the first port of call" in this process, and to avoid the loss of the benefits that the PIC concept is intended to provide. Some of this later group reiterated that the issue of the "relevant date" for application of ABS principles (as discussed in I.B.a, *supra*) is of critical importance to this point. At least one of these noted that there may be a need for a different "relevant date" for genetic resources held in *ex situ* collections, than for other genetic resource categories.

#### ii. Genetic resources in ex situ collections used for purposes for which PIC was not granted and for which it is not possible to grant or obtain PIC

Responses to this point are essentially identical to those given for point II.C.l.i, supra.

#### iii. Genetic resources in areas beyond national jurisdiction or whether this issue falls within the competence of the United Nations General Assembly

Responses to this point are essentially identical to those given for point II.C.l.i, *supra*. In addition, on the general topic of "genetic resources from areas beyond national jurisdiction" (variously described as including one or more of the following the oceans beyond EEZs, oceans beyond territorial seas, seafloor beyond national OCSs, Arctic ice, and Antarctica) contributors were divided. Some stated strongly that certain such areas should be included in the GMBSM. Others called for them to be addressed under other processes. One expert specifically noted that "ABNJ negotiations should be structured in coordination with the emerging treaty," and another who suggested that the UN should legally validate the authority of those negotiations to address the utilization of genetic resources from areas beyond national jurisdiction, and especially to determine the sharing of benefits with regard to these areas. Many experts have questioned how and to what extent the ABNJ process will apply to countries and users under their jurisdiction, particularly if some countries do not ratify or accede to whatever agreement or other document might eventually arise from that process.

Here also, their appeared to be consensus that the Nagoya Protocol COP/MOP should come to a specific decision one way or the other, regarding the inclusion/exclusion of each such area, apart from one expert, who flatly called for exclusion of these areas from the Mechanism entirely. He noted that "Once

the UNCLOS and UNGA have reached a decision we can implement something, rather than confuse the system by attempting to bring it under Nagoya."

#### iv. Genetic resources in the Antarctic Treaty area;

Responses to this point are essentially identical to those given for points II.C.l(i) through II.C.l(iii), above.

#### v. Traditional knowledge associated with genetic resources that is publicly available and where the holders of such traditional knowledge cannot be identified or for which it is not possible to grant or obtain PIC.

Although the ABSSG members are in general agreement that this point raises a thorny empirical question, they are widely divided on how it should be addressed. Currently, the extent to which traditional knowledge is protected under national law, and the nature of that protection is unaddressed by the Nagoya Protocol, and national legislation and legislative discussions in countries around the world are using an extraordinarily broad range of legislative approaches and legal theories to address it. As expressed under points C.g and C.j, while the need for agreement on this point among the Parties remains unmet, it appears necessary that the modality should include a means of addressing this point and the variety in national legislative treatment.

## III. Additional Concern: National Inconsistency Causing "Forced Waiver" of PIC

The ABSSG's discussion of this submission has also raised a concern not mentioned in the Notification: The possibility that the GMBSM or particular States or users might use their own interpretation of ABS to "force a country to surrender its right for PIC just because another country possessing the same genetic resource has waived its own." Many contributors to this submission specifically stated that, in designing the GMBSM, the NP COP/MOP must constantly be on the lookout against the possibility that its provisions or processes might indirectly or directly have this effect or otherwise undermine sovereign rights.

The IUCN Joint SSC-WCEL Global Specialist Group on ABS, Genetic Resources and Related Issues currently consists of 50 members, from 23 countries.<sup>32</sup> It includes a range of experts in law, policy, economics, scientific research and other key professional domains, each with particular interest in and experience with ABS, genetic resources, and related issues. The ABSSG stands ready to undertake a more in-depth analysis of this or any of the particular legal, economic, scientific and/or policy issues regarding ABS, genetic resources, ATK, biosafety and related matters. Requests and proposals should be submitted to ABSSG Chair, Tomme Rosanne Young at tomme.young@gmail.com.

ABS Experts interested in applying for membership in the ABSSG, should contact its Chair, Tomme Rosanne Young, in care of her assistant, Annie Minnis, at <u>Annie\_Ominous@hotmail.com</u>.

<sup>&</sup>lt;sup>32</sup> Vietnam, USA, UK, Switzerland, Spain, South Africa, Peru, Kenya, Italy, India, Greece, Germany, Ecuador, Costa Rica, Colombia, China, Canada, Cameroon, Bangladesh, Bahamas, Australia, and Argentina.

#### **Contributors:**

- Klaus Angerer is a Lecturer at the Institute for the History of Medicine, Justus-Liebig-University Giessen; currently pursuing a PhD project on the investigation and the uses of biological materials for the purpose of drug discovery, with fieldwork undertaken in a natural product company and other institutions. In additional research projects, he has focused on human-animal-relations (particularly with regard to poison frogs) and on the regulation of ABS under the CBD.
- Lisa Benjamin is Assistant Professor, The College of The Bahamas LL.B. Programme, where she teaches, among other subjects, international environmental law, Caribbean environmental law and intellectual property law. She is a consultant on the GEF 'Strengthening Access and Benefit Sharing in The Bahamas' project, and is a Director of the Bahamas Protected Areas Fund.
- **Dr. Evanson Chege Kamau** is senior researcher in law at the Research Centre for European Environmental Law (FEU), University of Bremen, Germany. His research has focused on access to genetic resources and benefit sharing issues for approximately the last 10 years. He has done several legal consultancies in the subject, including for IUCN and the African Union and has widely published in the area.
- Graham Dutfield is Professor of International Governance, School of Law, University of Leeds, UK.
- **Christopher H. C. Lyal** is Researcher, Natural History Museum, London. Leads for NHM on ABS and other CBD issues, including GTI. Member of IAC for ABS Clearing House, and Chair of IAC for ABSCH Pilot Phase. Leading Role with Consortium of European Taxonomic Facilities and Global Genome Biodiversity Network in developing Best Practices for ABS and tools to aid implementation.
- MAWAL A MBASSA Estelle is Jurist Environmentalist, Assistant researcher at the Legal Department of the Ministry of Environment, Protection of Nature and Sustainable development
- **Sonia Peña Moreno** is the Senior Policy Officer- Biodiversity at IUCN's Global Policy Unit. She coordinates the Union's inputs into the Convention on Biological Diversity including its participation at the Convention's various processes. She co-led the development of the IUCN Explanatory Guide to the Nagoya Protocol on ABS (2012) and has been actively following ABS related issues for many years.
- Manuel Ruiz Muller is Director of the Program of International Affairs and Biodiversity at the Peruvian Society for Environmental Law (SPDA), which won the 2014 Danielle Mitterrand Environmental Prize for its work on biopiracy. He teaches international law at the Catholic University and has participated in ABS discussions since 1992. He has been a consultant on ABS for UNCTAD, IUCN, ICTSD, WRI, IDB, IDRC, QUNO, among others. He has published Genetic Resources as Natural Information, by Routledge.

Than Thi Huong Trang is a Vietnamese independent research consultant, currently based in Paris, France.

- Joseph H. Vogel is Professor, Department of Economics, University of Puerto Rico-Río Piedras, USA. He has lectured and published widely on the application of economics to the UN Convention on Biological Diversity, Nagoya Protocol and the Framework Convention on Climate Change since the inception of both conventions. He has served as technical advisor on the Ecuadorian delegation at the COPs and worked on consultancies sponsored by the World Bank, InterAmerican Development Bank, USAID, UNDP and several NGOs
- **Tomme R. Young** is Chair, ABSSG; Legal Advisor, International Research Institute for Sustainability (IRIS). She has been consultant to over 100 governments on national legislation on ABS, biosafety, natural resources and protected areas and legal advisor to the negotiation of more than 50 international contracts, including 15 ABS-related contracts and over 30 international contracts on natural resources, energy, protected areas and EEZ fisheries. She would also like to thank Elisa Morgera for contributing comments on this document.