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Objectives, Scope, Compliance, Fair and Equitable Sharing of Benefits, and Access in the ABS International Regime

Members of the Access and Benefit Sharing Alliance (ABSA) appreciate the opportunity to submit our views in response to Convention on Biological Diversity (CBD) Notification Ref: SCBD/SEL/VN/GD/64971 requesting proposals in advance of the 7th meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (ABS WG-7). This submission provides ABSA perspectives on issues under consideration by ABS WG-7 for drafting operational text in the areas of: **Objectives, Scope, Compliance, Fair and Equitable Sharing of Benefits and Access.**

Before reaching these issues, it may be helpful to recall the ABSA's ABS Negotiating Principles (attached as Annex 1). ABSA member companies support the development of an ABS International regime (IR) that provides an enabling environment needed to generate social and economic benefits and promotes equity, transparency, predictability, fairness and national treatment for all participants in the ABS IR.

By taking into account real-world needs of innovators the world over, CBD members now have an opportunity to deliver on promises to all ABS stakeholders, including small and medium enterprises (SMEs) and local and indigenous communities with the most to gain from the sustainable commercialization of Genetic Resources (GR), with or without traditional knowledge (TK). Highly bureaucratic ABS regimes in developing countries have failed to generate social and economic benefits in Africa, Asia and Latin America. Imposition of a similarly heavy regulatory framework through the ABS IR would represent a tragic lost opportunity. SMEs in developed and developing countries alike would be most likely to gain through transparent, predictable and nondiscriminatory rules facilitating access and thus the possibilities to generate sharable benefits. Of equal importance, developing countries may be adversely affected by a resource intensive, highly proscriptive ABS IR, particularly in times of increasing economic insecurity, and would stand to benefit more from a targeted, cost-effective ABS IR.

As outlined below, **Objectives** and **Scope** for the ABS IR should remain consistent with the definitions, terms and jurisdictional limitations of the Convention itself as interpreted by subsequent decisions of CBD Ministers, including the *Bonn Guidelines*, the only international ABS instrument with consensus support of CBD members.¹

¹ The *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, were adopted by COP Decision VI/24) to assist countries in the implementation of CBD ABS provisions, including Articles 8(j), 10(c), 15, 16 and 19, and are available online at www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf.

Objectives

The objectives of the ABS IR should harken back to the words of the CBD Treaty itself, and accordingly should encompass the following:

1. Protect “the sovereign rights of States”² over the *in situ* “genetic resources being provided by a Contracting Party”³ and “only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.”⁴
2. Identify mechanisms for ABS stakeholders to ensure “[a]ccess, where granted, shall be on mutually agreed terms,”⁵ and “shall be subject to prior informed consent of the Party providing such resources, unless otherwise determined by that Party,”⁶ and, finally, to establish terms of benefit sharing “upon mutually agreed terms.”⁷
3. “Encourage the equitable sharing of the benefits arising from the utilization of” traditional “knowledge, innovations and practices.”⁸
4. Endeavor “to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.”⁹

Scope

Consistent with the **Objectives** proposed above and with the terms of its mandate from Decision VII/19 D, the ABS IR should be limited to effective implementation of the relevant provisions in Article 15, Article 8(j) and the three objectives of the Convention.¹⁰

Based on the clear language of the CBD Treaty, CBD members should limit the scope of the ABS IR to “genetic resources being provided by a Contracting Party”¹¹ and “only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with

² Convention on Biological Diversity, Article 15.1.

³ Convention on Biological Diversity, Article 15.3.

⁴ Ibid.

⁵ Convention on Biological Diversity, Article 15.4.

⁶ Convention on Biological Diversity, Article 15.5.

⁷ Convention on Biological Diversity, Article 15.7.

⁸ Convention on Biological Diversity, Article 8(j) (order of phrasing reversed).

⁹ Convention on Biological Diversity, Article 15.2.

¹⁰ Ideas such as “derivatives” or “products” have no mention in the CBD. Nonetheless, they should be addressed under the ABS IR via individual ABS agreements. For more discussion of derivatives and other downstream products in the ABS IR, see **Fair and Equitable Benefit Sharing**, pp.5 - 6.

¹¹ Convention on Biological Diversity, Article 15.3.

this Convention.”¹², based on “mutually agreed terms” (MAT’s) between the acquirer and the provider, and Prior Informed Consent, “unless otherwise determined by that Party,”¹³

In this context, CBD Parties should agree to exclude “biological resources” as defined in Article 2 of the CBD that would otherwise would bring under the IR all natural resources and other commodities currently traded by countries all over the world, such as ornamental and garden plants, timber, agricultural produce (like apples or rice), and even household pets.

In addition, the IR should exclude human genetic resources consistent with Article 2 of the CBD, subsequent decisions taken by CBD Ministers, and the *Bonn Guidelines*. Article 2 of the Convention, for example, first defines “Genetic Material” as “any material of plant, animal, microbial or other origin containing functional units of heredity”, and subsequently defines “genetic resources” as “any material of plant, animal, microbial or other origin containing functional units of heredity.” Further, as adopted by CBD Ministers at the 2nd Conference of the Parties, Decision II/11: Access to Genetic Resources, “Reaffirms that human genetic resources are not included within the framework of the Convention”¹⁴ The intention to exclude human genetic resources is confirmed explicitly in defined scope of the *Bonn Guidelines*: “All genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, *with the exclusion of human genetic resources.*” (emphasis added)¹⁵

The IR should recognize existing international instruments and also exclude resources that are already the subject of agreements or negotiations in other fora such as the FAO International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA), the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO, and human, plant and animal pathogens currently the subject of unrelated benefit sharing negotiations in the World Health Organization (WHO).

The IR should apply to *in situ* GR with or without TK acquired after entry into force of the ABS IR in the provider country, and should form a prospective system with no retroactive effect.¹⁶

Compliance

ABSA members joins CBD Parties, research institutes, indigenous groups and local communities in seeking the development of an enforcement system in the ABS IR that

¹² Ibid.

¹³ Convention on Biological Diversity, Article 15.5.

¹⁴ Decision II/11: Access to Genetic Resources, UNEP/CBD/COP/2/19, p. 22.

¹⁵ See *Bonn Guidelines*, “C. Scope 9, p.7.

¹⁶ The CBD does not apply to genetic resources beyond those “that are provided by Contracting Parties that are countries of origin of such resources.” CBD Article 15.3. In that light, these resources should be excluded from the scope of the IR.

provides effective and proportionate redress for all parties in cases of illegal or inappropriate activities related to the IR. While there is currently no agreement on the appropriate mechanism to enforce the ABS IR, ABSA members believe that an existing mechanism or, more likely, a combination of mechanisms, can be identified to serve as a deterrent to illegal or inappropriate activities and to address the question of enforcement across borders that would ensure durable and meaningful benefits for CBD members and indigenous peoples without undermining the incentives that industry needs to undertake bio-prospecting.

ABSA members have long believed that mechanisms considered for inclusion in the ABS IR be measured against real world experience. In this context, all compliance mechanisms under consideration for inclusion in the ABS IR should be subject to two key tests:

1. Examination of real-world experience at the national level to see if they have been effective in domestic ABS regimes; and,
2. Benefit-cost analysis to ensure that their potential value to ABS stakeholders would not be outweighed by the cost either at the national level (particularly the cost to developing countries) and/or at the international level.

ABSA members also seek the legal certainty, consistency and equity, which would benefit all CBD stakeholders, through the inclusion of a requirement to provide Mutually Agreed Terms (MAT) in each ABS Agreement – the detailed, written terms and conditions required for legitimate bio-prospecting in those agreements governed by the ABS IR.

Japan's highly-regarded ABS regime does just that. Japan's domestic ABS regime is currently the single most effective national ABS system with proven benefit-generation, and operates through written agreements, i.e., contracts. One way to promote greater inclusion of MATs in written ABS agreements would be through development of model Material Transfer Agreements (MTAs) as in the International Treaty on Plant Genetic Resources (ITPGR).¹⁷ Development of model MTAs also could help to avoid later disputes by promoting transparency and greater understanding on both sides.

There is also increasing awareness that the ABS IR should balance compliance mechanisms with incentives. CBD members understand the need to encourage responsible *in situ* bio-prospecting and to contribute to the increased conservation of *in situ* GR. Development of an ABS IR that encourages environmentally sustainable levels of *in situ* bio-prospecting, is needed both to identify promising areas of research for scientific and commercial development that will generate benefits for CBD members, as well as to provide a greater awareness of the resources found in CBD members. These incentives should encourage the continued cataloguing of the genetic inventory of the planet – a process that has not even approached a fifth of the genetic resources

¹⁷ “UNU-IAS Report, Certificates of Clarity or Confusion: The search for a practical, feasible, and cost effective system for certifying compliance with PIC and MAT” (2008), where authors Brendan Tobin, Geoff Burton and Jose Carlos Fernandez-Ugalde note that MTAs may be helpful to address the absence of national ABS regimes. p. 8.

remaining *in situ* in CBD members. These goals are related, in that increased taxonomy and related bio-prospecting activities may provide greater incentives for conservation.

Compliance mechanisms that would create only a right to litigate in the national judicial system should be avoided. The current situation facing CBD members and indigenous peoples will not improve through the adoption of enforcement mechanisms that rely on far-flung civil litigation. Established forms of alternative dispute resolution include negotiation, mediation and arbitration based on previously agreed written agreements. Alternative dispute resolution may provide a cost-effective alternative to cross-border civil litigation given the international scope of arbitral decisions. For example, Article 8(4)(C) of the Food and Agriculture Organization (FAO) International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPFGRA) Standard MTA provides for recourse to negotiation, mediation and binding arbitration under the auspices of the International Chamber of Commerce' International court of Arbitration.

Some of the international instruments currently under discussion in the area of compliance, such as certificates of origin, still lack clarity in their basic terms and concepts. While ABSA members conceptually understand the potential value of an international certificate as formal documentation of PIC and/or MAT, we have seen very little documentation relating to successful real-world experience with international certificates,¹⁸ and so are not able to make informed decisions on the merits of various certificates proposals. Further, there has been little discussion at the expert level of the actual need for the various certificate systems, as balanced against their cost at the national and international level. As noted, this benefit-cost analysis is essential to the development of a successful ABS IR.

Finally, the ABS IR providing legally binding provisions requiring CBD member governments to provide focal points and transparency in decision-making regarding penalties, to avoid any adverse impact that subsequent changes in government policy may have on companies that had sought and received the appropriate permits in the ordinary course of business.

Fair and Equitable Benefit-Sharing

ABSA members understand the economic value and importance of derivatives and/or downstream products relating to GR with or without TK, and the concern of many developing country CBD members of their importance to **Fair and Equitable Benefit-Sharing**. However, to date it has proven impossible for the ABS WG to agree even upon workable definitions, and/or their inclusion in the ABS IR. Again, the *Bonn Guidelines* provide valuable guidance, and specifies that the parties should address this important issue through negotiation of Mutually Agreed Terms (MAT) in ABS

¹⁸ ABSA members would appreciate an opportunity to review information on national experiences by commercial and noncommercial researchers certification systems implemented at the national level.

agreements.¹⁹ ABSA supports this approach for use in the ABS IR so that the parties to individual ABS agreements can address the issue of derivatives and/or downstream products on a case by case basis, as appropriate given the specific issues raised by research that may differ from sector to sector.

Overall, ABSA members believe that Fair and Equitable Benefit Sharing can best be ensured through an ABS IR that stresses transparency, predictability, legal certainty, equity and provides national treatment to all ABS stakeholders. As noted in the ABSA ABS Principles, ABSA members remain committed to “respect the sovereign rights of CBD members over their *in situ* genetic resources (GR) and to the equitable sharing of the commercialization of GR and any related relevant traditional knowledge (TK) derived from indigenous and local communities, assuming a clear, internationally accepted definition of TK.”²⁰

Access

As noted by the Indian Minister for Environment and Forestry at the High-level Segment of the 9th Conference of the Parties (COP 9) at Bonn in May 2008: “So far, even after 16 years of adoption of CBD, only 18 countries have come up with legislation on Access and Benefit Sharing. A benefit sharing arrangement needs to be put in place with utmost speed to prevent provider countries from losing interest and diverting the scarce resources for their development needs.”²¹ Industry agrees with India’s assessment that the issue of national regimes is an area in urgent need of assistance. It is a truism that without effective ABS regimes at the national level to facilitate access to GR and provide clean title to GR, businesses will remain reluctant to engage in high-risk commercial activities in developing countries.

An ABS IR should encourage adoption of national access provisions flexible enough to provide for the timely decision-making on ABS applications made by scientific and commercial researchers in different sectors. Procedures established to regulate bio-prospecting in a number of CBD members, including in Brazil and in India, have failed to provide for timely decisions, thus frustrating commercial and scientific activities. In addition, there should not be any discrimination between domestic and foreign bio-prospecting applications. There is evidence that the promulgation of restrictive laws in the Philippines and in a number of Latin American countries has chilled bio-prospecting and has not advanced CBD goals.

¹⁹ “(b) In the implementation of mutually agreed terms, users should . . . (v) Ensure that uses of genetic resources other than those for which they were acquired, only take place after new prior informed consent and mutually agreed terms are given;” and, further, “2. Indicative list of mutually agreed terms 44. (i) Provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products.” *Bonn Guidelines*, p. 6 and p.13.

²⁰ ABSA ABS Negotiating Principles, attached at Annex 1, and available online at: <http://www.abs-alliance.org/version02/html/issue.html>.

²¹ Statement by Honorable Minister of State (Environment), India for the High-level Segment of the Ninth Conference of the Parties (COP-9) to the Convention on Biological Diversity (CBD), 28-30th May 2008, Bonn, Germany.

It is well understood that complicated requirements may drive academic scientists underground or result in worse documentation of research activities; in fact this could affect commercial bio-prospecting even more negatively. Few bio-prospecting agreements lead to commercialized discoveries, but nonetheless contribute to the goals of the Convention and the science-base of CBD members.²² Non-commercial research ultimately may contribute to the commercial development of a product and commercial research may be licensed for public research purposes. The development of Golden Rice, for example, relied heavily on private-sector research. Given the need for research to move back and forth between non-commercial and commercial purposes, ABSA members fail to understand how different rules or standards for commercial versus noncommercial uses of GR, with or without TK, would be workable in real world conditions.

Fortunately, the clear text of the CBD Treaty recognizes the need for creation of “conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the Convention.”²³ The ABS IR should encourage the further development and harmonization of national regimes in the spirit of the *Bonn Guidelines*, including establishment of national focal points and possible model provisions for access and benefit sharing critical to its successful implementation at the national level.

Conclusion

ABSA members hope that the foregoing is helpful to CBD members and other ABS stakeholders at the upcoming 7th Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit Sharing to develop operational text to address the above areas. By focusing on areas of previous consensus found in the text of the CBD Treaty, prior Ministerial Decisions on ABS and the *Bonn Guidelines*, CBD members have the greatest likelihood of finding common ground on a combination of voluntary and legally binding provisions needed for an effective ABS IR.

Annex I: ABSA ABS Negotiating Principles

²² Merck, a founding member of the ABSA, did not successfully commercialize any of the discoveries found during its multiyear collaborative bio-prospecting agreement with INBIO.

²³ Convention on Biological Diversity, Article 15.2.



ABS NEGOTIATING PRINCIPLES

INTRODUCTION:

As a core stakeholder in development of any International Regime (IR) relating to Access and Benefit Sharing (ABS), members of the Access and Benefit Sharing Alliance (ABSA) are committed to identifying practical ABS approaches with demonstrated real-world benefits at the Convention on Biological Diversity's (CBD) Ninth meeting of the Conference of the Parties (COP 9) in Bonn, Germany.

In this practical approach, we note that a number of prior ABS approaches have fallen short of expected benefits, including policies relating to mandatory disclosure of source, origin and proof of benefit sharing. Equally important, negotiation of the ABS IR should be based on organizational principles that ensure a transparent, equitable, consistent and predictable ABS negotiating process and outcomes.

In that spirit, ABSA members provide the following principles.

PREAMBLE:

ABSA members:

- Reaffirm their commitment to respect the sovereign rights of CBD members over their *in situ* genetic resources (GR) and to the equitable sharing of the commercialization of GR and any related relevant traditional knowledge (TK) derived from indigenous and local communities, assuming a clear, internationally accepted definition of TK.
- Underscore industry's established track record of compliance with the Bonn Guidelines, including Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and equitable benefit sharing.
- Support development of comprehensive digital libraries or registries to help identify holders of GR; capacity building to promote best practices for IP management; and the use of model Material Transfer Agreements (MTAs) to ensure effective compliance with PIC and MAT and to provide front-loaded benefits and clarity and fairness in the disposition or sharing of intellectual property rights.
- Believe that there is an increasing recognition among the parties, indigenous communities and NGOs of industry's critical role as a key stakeholder and generator of commercial benefits from biological diversity.

PRINCIPLES:

- An ABS International Regime (ABS IR) should include measures that ensure equitable and non-discriminatory terms for access to GR, demonstrably generate benefits, and provide positive incentives to encourage mutually beneficial and environmentally sustainable commercialization of genetic resources.
- An ABS IR should be based on reality and the actual experiences of stakeholders either at the local, regional or state level, including the actual experiences of countries, indigenous communities, NGOs, and industry.
- An ABS IR should recognize the ground realities by which businesses operate so that appropriate incentives are balanced against necessary enforcement provisions for the benefit of all stakeholders.
- To ensure a workable system, all stakeholders (countries, indigenous communities, NGOs and industry) should participate broadly in the elaboration of an ABS IR.
- NGO and industry groups should be encouraged to participate in the elaboration of an ABS IR, regardless of whether their national governments are currently CBD members.
- Development of ABS elements should reflect the individual needs and experiences of CBD members at various stages of economic development, which suggests a bottom-up, “cafeteria-style” approach rather than a “top down” one-size-fits-all regime based on a single legally binding instrument.
- An ABS IR should be amenable to simple and expeditious implementation, taking into account the individual needs and experiences of CBD members.
- An ABS IR should include national regulation and enforcement mechanisms. The Parties, with the participation of stakeholders, should also consider issues of extra-territorial enforcement.
- An ABS IR should ensure transparency, predictability, consistency, durability and non-discriminatory treatment with respect to both access and compliance through the inclusion of clear definitions consistent with the terms and jurisdictional limitations of the CBD itself.
- The CBD ABS WG should continue to rely on such other international organizations as the FAO, WIPO, WTO, as appropriate, for technical input during the 2007-2010 period.
- Supporting work by other international organizations, while essential to the work of the ABS WG, should respect the CBD’s unique mandate and remit for

comprehensive ABS negotiations and not prejudge the outcomes of the deliberations of the ABS WG. In this respect, the CBD should continue to rely upon the unique expertise and mandate of WIPO with regard to the harmonization of intellectual property standards.

AREAS OF CONTINUING DISAGREEMENT

- **New Additional Mandatory Disclosure Obligations**

Patent disclosure obligations enacted by CBD members have had a documented chilling effect on bioprospecting and GR commercialization. By making patent protection for GR commercialization contingent on an *ex post* examination of the sufficiency of the disclosure, mandatory patent disclosure regimes place at risk the very basis for the recoument of investment. [Patent disclosure obligations do not create ABS benefits, are polarizing and drive stakeholders further apart].

- **Certificates of Source, Origin and Legal Provenance**

ABSA members do not support the development of a certificate system that would create an additional formality or condition of patentability for biotechnology inventions. They also do not view the CBD Experts Group on Certificates as fully representing the broad spectrum of views found in the biotechnology sector. The group, if reconvened in the future for additional work, should be broadened to reflect the diverse needs and experiences of industry. The CBD Experts Group on Technology Transfer may provide a model for inclusion of more than one industry representative allowing representation of different segments of the biotechnology sector.

- **Areas Beyond the Jurisdiction of the Convention**

Difficult issues for the ABSA include suggested coverage of both *in situ* and *ex situ* resources; pre-CBD vs. post 1994 GR bioprospecting; human vs. plant and animal GR; and products vs. derivatives of GR. Boundary lines should be drawn consistent with the obligations and explicit legal boundaries of the CBD Treaty, as exemplified by the Bonn Guidelines.

All stakeholders require clear boundaries to commit resources to participation in an ABS IR Without a precise understanding of important terms such as "genetic resources, products and/or derivatives," it is impossible for any private company to enter into an agreement with indigenous communities or other holders of traditional knowledge.

- **Lack of Clarity Over the Definition of Traditional Knowledge (TK)**

A precise understanding of this important term is also needed before private companies are able to enter into agreements with indigenous communities or other holders of TK. Moreover, if more than one indigenous community (within a country or

otherwise) states a claim to the same TK, there needs to be a clear approach to TK rights that does not threaten a private company that has acted in good faith and is working on the basis of PIC and MAT with one of these communities (or with a focal point of a CBD member that has entered into good faith PIC and MAT with a community). Unless and until further international consensus is reached on the issue of TK, the ABS IR should follow the precedent established by the Bonn Guidelines.