International Chamber of Commerce
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Department of Policy and Business Practices

Objective, scope, fair and equitable benefit sharing, access and compliance

Submission to the Secretariat of the Convention on Biological Diversity for the 7th Ad Hoc Open Ended Working Group on Access and Benefit Sharing, Paris, France, 2-8 April 2009

Introduction

The business delegation – coordinated under the umbrella of ICC - remains committed to contributing constructively on substantive discussions in the access and benefit sharing (ABS) negotiations. It has made submissions to and participated in the Technical Expert Groups on Concepts, Terms, Working Definitions and Sectoral Approaches[1], and on Compliance[2], and intends to do so with respect to the Technical Expert Group on Traditional Knowledge. Business looks forward to continuing to play an active and helpful role in the negotiations on an ABS International Regime (IR).

A diverse range of industries[3] utilize genetic resources in their everyday business, and access, use and create value from these resources in different ways. These industries - many of which consist in large part of small and medium-sized enterprises (SMEs) - play an essential role in creating social and economic benefits from genetic resources. As the Convention on Biological Diversity (CBD) negotiations struggle with the challenge of increasingly complex issues and a call to move toward a more practical discussion based on established common terms and definitions, business can assist in clarifying exactly how genetic resources are accessed, developed and commercialised and methods to best ensure the sharing of benefits.

All businesses are engaged in a continuous evaluation of **risk and return on investment**. A high risk environment will discourage investment and reduce opportunities for creating benefits.

[1] "Access and Benefit Sharing: Sectoral Approaches, Concepts, Terms and Working Definitions" - 17 October 2008, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/Sectoral%20approaches%20final.pdf
[2] "Priority Issues for the CBD/ABS Compliance TEG" - 28 November 2008, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/ICC%20Compliance%20TEG%20Paper%20final%2028%20Nov%2008.pdf
[3] Including, in alphabetical order: agricultural biotechnology, animal breeding, cosmetics, farming, flavours and fragrances, foods and drinks, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical and biopharmaceutical products, and plant breeding.

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Given the long time period and heavy investments required to commercialize inventions using genetic resources, businesses need national laws or guidelines which are transparent, practical, science-based, non-discriminatory, and provide legal certainty to justify their investments.

Business therefore supports the creation of a practical and workable IR which will facilitate the activities of the different sectors working with genetic resources today and take into account the future evolution of those activities.

This paper outlines **general principles** business believes to be **important to the success of an IR** and specifically provides input to the issues which the Ad Hoc Open-ended Working Group on Access and Benefit Sharing (AHOEWG) is mandated to negotiate at its 7th meeting: **objective, scope, fair and equitable benefit-sharing, access and compliance**.

General Principles

It is of critical importance that the IR should be a **precisely targeted, facilitative structure that promotes national ABS regimes that are transparent, non-discriminatory, predictable and coherent across borders**; national ABS regimes that are difficult to reconcile with each other should be avoided. The IR should not be a heavy regulatory framework that will stifle the creation of value from genetic resources, and their trade and sustainable uses. This approach will promote not only the efficient organization of access and benefit sharing, but also the other two pillars of the CBD: conservation and sustainable use of genetic resources. Lessons should be learnt from the experiences of national regimes which show that highly regulated and bureaucratic ABS systems have failed to generate social and economic benefits.

In order to ensure that the CBD's objectives are attained, business submits **that the IR should be based on the following principles**:

- An IR should include **clear definitions** consistent with the terms and jurisdictional limitations of the CBD itself.

- **Research, economic activity and freedom to innovate** using genetic resources should be encouraged rather than constrained. This will help promote the generation of benefits and will be the single most important basis for assessing the success of the Regime. Access conditions should respect the Article 15(2) directive to "facilitate access" to genetic resources. Benefit-sharing arrangements in relation to derivatives and downstream products should be determined through mutually agreed terms in the ABS contract between the providing and accessing parties, as provided for in Article 15(7)[4]. Concepts such as "derivatives" or "products", however they may be defined or understood, should be determined between contracting parties.

[4] Article 15(7) "….Such sharing shall be on mutually agreed terms."

- The IR should **not seek to restrict what can be mutually agreed** and should encourage the **systematic use of contracts**, in the form of Material Transfer Agreements (MTAs) or other forms of agreements, to the greatest extent possible. These agreements may include, as appropriate, in addition to the terms and conditions for access and benefit sharing, clauses addressing conditions for the use of the GR, commercial rights, transfer of the GR with or without traditional knowledge to third parties, short-term and long term non-commercial and commercial benefits, the agreed dispute settlement mechanism, choice of law, and/or conditions regulating the future termination of the agreement. **Contractual agreements**, common in the normal course of ethical international business, enforceable under the judicial systems of sovereign CBD member states, and respecting CBD standards (if implemented by the applicable national law), remain the best methods to manage ABS of genetic resources.
- The CBD specifies that national governments have sovereign rights over the regulation of genetic resources found in their territories. The IR should therefore leverage national law, enforcement, and regulatory structures rather than attempt to create new mechanisms and obligations that are yet to be proven effective in real world experience. The IR should therefore focus on the **further development and harmonization of national regimes** in the spirit of the **Bonn Guidelines**.
- Such national ABS regimes should identify a **national focal point** which is authorized to grant access and prior informed consent, and to facilitate the negotiation of mutually agreed terms – this is essential to provide legal certainty and transparency for all stakeholders. Any measures to ensure the participation and involvement of indigenous and local communities in mutually agreed terms, and the sharing of benefits with traditional knowledge holders, must be part of a transparent ABS regime.
- The IR should take a **sectoral approach** to address the unique aspects of how genetic resources are accessed and managed in the many business and science sectors using genetic resources. If the IR is to be effective in promoting business activities which support biodiversity, it should maintain and foster the diversity of uses of these resources as well as of the commercial arrangements through which they are acquired.
- The IR should draw a distinction according to the specialties of sectors rather than between **commercial/non-commercial uses**. In reality, it may prove extremely difficult if not impossible to differentiate between non-commercial and commercial research. Scientific research that starts out as non-commercial may ultimately contribute to the commercial development of a product, either by the same party or by others. Similarly, commercial research may be licensed for public research purposes, (as in the case of the development of Golden Rice which relied heavily on commercially funded research). It is important to recognize that very few collaborative bio-prospecting agreements result in successful products, even in the case

of multinational corporations. Business, especially SMEs[5], may be deterred by increases in expenses or bureaucratic red-tape as much as non-commercial research institutes. Complicated requirements for access and benefit-sharing may have the unintended effect of causing a significant decline in academic and commercial research alike.

- The IR should not promote ABS regimes characterized by the **stacking of multiple payments** for a single product. This should apply in cases where multiple countries have particular GRs in common as indigenous resources, but also in cases where a particular GR has multiple beneficial properties and/or becomes the subject of multiple research projects. The IR should provide for **mutual recognition** between countries of ABS agreements so that once a user has entered into an ABS agreement in good faith, no further demands will be made.
- When negotiating the IR, CBD Parties should consider the **implementation costs** of proposed elements for both countries providing genetic resources and users, as well as the bureaucratic challenges that could have significant negative impacts on SMEs and research, and on the generation of potential benefits. In particular, any lengthy processes or negotiations before the start of a research program should be avoided. Cost-benefit and regulatory impact assessments should be undertaken before introducing new untested mechanisms.
- The IR should be a **prospective** system with no retroactive effect. Provisions of the IR should only take effect after the entry into force of the IR and its ratification in the provider country consistent with the provisions of Article 36 of the CBD.

Objective

The objectives of the IR should be consistent with the terms of reference of the AHOEWG detailed by the Ninth Conference of the Parties (COP-9), Decision VII/19D, and with the terms of the CBD itself. The mandate of the AHOEWG is clear: "to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention."

The **objectives** of the International Regime should therefore be **limited to the said mandate**, namely:

(1) to protect the sovereignty of states over their natural resources;
(2) to facilitate access to Genetic Resources on the basis of mutually agreed terms and with the prior informed consent of the providing Party; and
(3) to ensure sharing of the results of research and other benefits arising from the use of genetic resources on the basis of mutually agreed terms.

[5] Many sectors working with genetic resources, such as biotechnology, plant and animal breeders, traditional medicines, etc - and businesses working in this area in developing countries - consist mainly of SMEs.

Furthermore, the IR must be consistent with the other defined objectives of the CBD – namely, conservation and sustainable use. Efforts to further broaden or otherwise modify these governing principles are **outside the scope** of the working group and should be rejected.

In the view of business, the most effective way of achieving these objectives would be for the IR to establish international benchmarks and guidelines that would assist CBD Members in developing **consistent, predictable, non-discriminatory, transparent and effective national ABS systems which provide legal certainty**.

The IR should develop Article 15(7) of the Convention, by identifying those "legislative, administrative or policy measures" which can, through implementation by the contracting parties, facilitate the activities of interested parties in the identification of sustainable uses, the agreement of mutually-agreed terms and the sharing of benefits.

Scope

The scope of the IR will be key in determining the approach to other issues under discussion, such as compliance measures. It is therefore essential that the scope of the IR be clearly defined.

Business suggests that the IR's scope be determined along the following lines:

- In order to ensure legal certainty, the IR should only apply to **acquisitions of genetic resources** which take place **after entry into force of the IR in the provider country**, and be without prejudice to prior acquisitions carried out in good faith. The IR will likely add additional requirements relating to ABS regimes. Any acquisitions prior to the entry into force of the IR in the provider country will have been made pursuant to national laws in force at that time, and access and benefit-sharing terms agreed accordingly. The IR should not provide the possibility of changing obligations relating to such acquisitions after they have been made.
- The IR should only regulate the relationship between the provider and party gaining access to genetic resources and **not seek to regulate downstream activities**. An IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement by governments and users alike. Broadening the scope of the IR to downstream products would bring under the IR common household items such as wine, bread and wood products. Benefit-sharing arrangements in relation to derivatives and downstream products should instead be determined through MAT in the ABS contract between the providing and accessing parties, as provided for in Article 15(7). Concepts such as "derivatives" or "products", should not be part of the IR itself, but instead. should be determined in the **MAT** between parties to the individual ABS agreement. ABS stakeholders already rely heavily on mechanisms based on written agreements which are proven and feasible methods to address ABS concerns.

- The scope of the IR should be **limited to only genetic resources** as defined in the CBD. Consistent with the terms of its mandate from Decision VII/19 D, the IR should be limited to effective implementation of Article 15, Article 8(j) and the three objectives of the Convention. As such, it should seek only to elaborate matters relating to access and benefit-sharing with respect to genetic resources, as defined in the Convention, based on MAT's between the acquirer and the provider (Article 15(4) and 15(7)).

  The inclusion of **biological resources** as defined in Article 2 of the CBD would bring under the IR biological resources that are currently traded by countries all over the world as commodities, such as ornamental and garden plants, timber, agricultural produce (like apples or rice), and even household pets. There are good reasons to draw clear lines between commodity trade in biological resources and the sustainable use of genetic resources. The IR will have to draw clear boundaries between what is included and what is excluded or it will risk inadvertently **stifling trade** in several areas.

- **Certain genetic resources should be excluded**. When defining which genetic resources should be covered by the IR, Parties should consider the following points:

  - The IR should exclude **human genetic resources**, consistent with COP Decision II/11 and the Bonn Guidelines.

  - 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) and the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO.

  - The IR should not include genetic resources that enter the **public domain** without any restriction by the provider country.

  - Genetic resources **not subject to the jurisdiction of any particular country** should be excluded from the scope of the IR. The CBD does not apply to such resources and only recognizes "the sovereign rights of States over their natural resources" (CBD Article 15.1).

  - The IR should not seek to regulate transactions involving **human, plant and animal pathogens**. Pathogens are arguably not included within the scope of the CBD itself. For example, such "resources" do not appear to fit within the CBD objectives of "conservation" and "sustainable use" in the sense used in the CBD. Since the objective of the IR refers to these CBD objectives, it is best to exclude pathogens from this framework.

- **Traditional knowledge** (TK) is a very difficult concept to define and is subject to different interpretations by different communities and peoples. To ensure legal certainty, it is essential that if TK associated with genetic resources is to be governed by the IR, it should be clearly defined based on a common understanding, and limited to "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for

the conservation and sustainable use of biological diversity." As with other ABS measures, measures regarding traditional knowledge associated with genetic resources must be transparent.

Fair and equitable benefit sharing

Business supports fair and equitable benefit-sharing which, under the terms of the CBD, should be on "**mutually agreed terms**" (Article 15(7)). Such terms will normally be embodied in an agreement between the provider and the recipient of the genetic resource. Transparency and internationally accepted contracting principles must apply to such agreements in order to maintain legal certainty for the provider and the recipient of genetic resources.

The development of **model clauses** or menus of clauses may be helpful to guide ABS negotiations. Alternatives, such as a database of sample clauses from successful ABS agreements or capacity building programs relating to "best practices" are preferable. If established, any such clauses should not be binding as the IR should permit flexibility in achieving MAT for material transfers. However, the Standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture is a good workable system for the plant breeding sector where many transfers of genetic resources are constantly being made.

There is a long history of benefit-sharing in many sectors using genetic resources. The manner in which benefits are currently shared should be considered in the development of the IR. **Existing systems** should not be unnecessarily disturbed and should, on the contrary, be recognized and carefully considered for the development of the IR.

Benefits from ABS transactions are not necessarily monetary in nature, (such as payments upfront or during the development process; funding for research or joint ventures), but can also include: the exchange of knowledge, skills, and technology; the sharing of research data, the free access to the use of protected varieties for further research and breeding, and networks; and the collection and conservation of genetic resources through financing or specific support activities. ABS transactions also indirectly benefit society as a whole as they can lead to improved productivity of agricultural crops, the development of new health, food and other products, and the creation of new employment opportunities resulting from the economic stimulus of new innovative products. The **full range of benefit-sharing** should be taken into account on the negotiations on the IR.

The wide-spread availability of genetic resources has led to demands for **horizontal benefit-sharing among in-situ repository countries**. The resolution of such questions and any disputes that arise from them should lie outside the IR and above all should not prevent acquirers of genetic resources from holding clear title to acquired resources. Claims of third countries not party to an ABS agreement would add great uncertainties to the process and should not be permitted. However, in cases where multiple countries hold resources in common, agreements

between such countries could be arranged so that benefits received by one member in a group of countries or indigenous communities that holds a particular resource in common would share the benefits received with others from that group. Any such agreement would be between potential providers of the genetic resource in question, and therefore should not have any effect on the liabilities or obligations of the user under an ABS agreement. It should be noted, however, that attempting to negotiate such an agreement would likely be highly complex and resource intensive.

CBD Parties should address with caution certain IR instruments currently under discussion, such as **certificates**, which could engender bureaucratic approaches to ABS that preclude benefit generation. Burdensome measures introduce significant costs for governments, users and local communities, and may deter larger companies and price innovative small and medium-sized enterprises, and research institutions out of the market entirely.

Access

Business supports the concepts of access to genetic resources being linked to fair and equitable sharing of benefits on the basis of mutually agreed terms, as envisioned in the CBD. The IR should **facilitate responsible access** and **prevent illegal access** to genetic resources. Business therefore supports **access standards** consistent with the CBD requirement to "facilitate" access in Article 15(2), such as those that would help ensure transparency and clarity, including the identification of clear authorities and points of contact to improve reliability in agreed terms of access. All concerns should be handled at the point of access through ABS agreements in order to reduce any uncertainties as to the status of genetic resources and benefits arising from their use.

Certainty, clarity and transparency of access rules depend fundamentally on the identification of **national focal points**. Business strongly supports the identification of a national focal point - one single authority that is authorized to grant access and grant prior informed consent. This is an essential part of developing an access regime that is consistent with the principles of legal certainty and transparency and is thereby a crucial element of a workable IR.

Any national laws governing the terms of access, e.g. in national ABS regimes, should be **non-discriminatory** and should thereby treat domestic and foreign researchers on similar terms. It should be realized that all countries are interdependent in terms of genetic resources and that most countries, including developing countries with extensive biodiversity, depend heavily on genetic resources accessed from other countries. Non-discriminatory treatment would therefore be beneficial for all CBD parties.

All researchers, regardless of their national origin or their countries' standing in the CBD , should be permitted to access resources under the facilitative mechanisms of the ABS regime, but also

be subject to the benefit-sharing requirements implemented by national laws in provider countries; this will help maximize potential benefits consistent with the goals of the CBD.

Negotiations on the IR also need to move toward a much more informed discussion of the **realities of access to genetic resources today**, and specifically a better understanding of access to genetic resources through **ex-situ** collections. The model upon which CBD obligations were based was one of a linear flow of genetic resources beginning with "bioprospecting" of genetic resources from their in-situ state, negotiation of mutually agreed terms with the sovereign state, and consultation with the concerned indigenous and local communities. This model is not an accurate reflection of how genetic resources are accessed, utilized, or shared today. Many genetic resources have long since been extracted from their original natural environment. Many have become commodities or staple commercial products in the trading system. Ex-situ collections exist in many countries for different types of genetic resources and range from zoos and aquariums to herbaria, such as the various botanical gardens and the Consultative Group on International Agricultural Research (CGIAR) system. Although the in-situ case is more conceptually clear and manageable than ex-situ cases, access of genetic resources through ex-situ collections is considerably more common in today's context.

Compliance

When discussing compliance issues, it is helpful to distinguish between regulatory compliance (i.e. compliance with laws and regulations set by governments relating to ABS); and compliance with contractual provisions (i.e. compliance with terms in an agreement mutually agreed between two parties such as Material Transfer Agreements).

Mechanisms for enforcing compliance will differ according to the type of compliance that is being addressed. In both cases, business submits that any compliance system set up by the IR should build on **existing enforcement systems**.

Regulatory Compliance

- Business believes that that the great majority of users of genetic resources make their best efforts to comply with ABS requirements. Nevertheless business does recognize that many CBD Parties have serious concerns relating to **misuse and/or misappropriation of GR**, with or without related TK. As there is currently little empirical data on the scope or the significance of such misuse and/or misappropriation, business supports more research on this topic to provide a solid factual basis for the AHOEWG's efforts to address this issue. This would greatly assist in identification, where applicable, of any appropriate and proportionate measures, and contribute to the likelihood of success of the IR overall.

- Business recognizes the importance that a number of CBD Members place on mutual recognition of and enforcement of **judgments across borders** to enforce domestic national ABS laws in cases involving allegations of misuse or misappropriation of GR with or without related TK. At the same time, business notes the historic reluctance of states to enter into multilateral obligations requiring mutual recognition. Business looks forward to a discussion of possible approaches to address this difficult issue.

- Any further consideration of "**disclosure requirements**"[6] should be made dependent on the outcome of discussions in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in WIPO which, because of its collective intellectual property (IP) expertise, as illustrated by its discussions and detailed documentation, is the appropriate body for the consideration of matters relating to the relationship between IP and CBD related issues.

- Business remains greatly concerned about the possible **introduction of new instruments** without proven effectiveness in real life[7]. It therefore strongly recommends that the further elaboration of an "internationally recognized certificate" should not begin before a feasibility study is first undertaken and carefully analysed. Business firmly believes that if many of the issues still outstanding are not addressed in detail, the feasibility of establishing such a certificate system will be called into question (see report of the Technical Experts Group in UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007)). To date, discussions in the negotiations concerning certificates have failed so far to clarify fundamental concepts.

  Key matters that remain unresolved are:
  - what would the system certify (compliance with the CBD or national laws)?
  - who would certify?
  - who would use the certification and why?
  - what would be the impact of not having a certificate?
  - when does a certificate have to be produced?
  - what would be the cost and benefit of such a system?

- Business believes that **raising awareness** among stakeholders about ABS requirements will play a key role in improving compliance with ABS regimes. CBD Parties should make positive efforts to educate stakeholders about ABS laws and to make these more transparent. Business is willing to support governments in these efforts with respect to its own constituency.

  In this respect, several sectors have put into place **voluntary guidelines** and "**best practices**" to help companies in those industries to understand and comply with ABS

[6] See ICC paper on "Access and benefit-sharing: special disclosure requirements in patent applications" - 25 May 2005 : http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/ABS_%20Special%20Disclosure.pdf

[7] See ICC paper on "Issues for consideration by the CBD Group of Technical Experts concerning a Certificate relating to genetic resources" 15 September 2006 at http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/CertificationSubmission_to_CBD.pdf

requirements. Among those are Biotechnology Industry Organization (BIO) Guidelines for BIO Members Engaging in Bioprospecting[8], the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guidelines for IFPMA Members on ABS, and the BIO Model Material Transfer Agreement (MMTA)[9], EuropaBio Principles for Accessing Genetic Resources[10], International Standard for Wild Collection of Medicinal and Aromatic Plants[11].

Business believes that such voluntary guidelines contribute significantly to promoting awareness of, and compliance with, ABS regimes among the users of genetic resources, and should be taken into account by CBD Parties when considering a sectoral approach to the IR.

Contractual Compliance

- Private international law offers many opportunities that are currently used to enforce agreements relating to international business transactions around the world (see for example the paper by the delegation of Canada submitted to the sixth ABS WG meeting (UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). No special "measures to ensure access to justice" need to be developed that are peculiar to the CBD context. Instead, **existing tools** such as negotiation, mediation, arbitration and legal instruments for the enforcement of foreign judgments should be further explored.
- Negotiation, mediation, arbitration and conciliation mechanisms are common in business and provide a concrete basis for discussions on **the resolution of disputes arising from ABS contracts**. An example of a dispute resolution process referenced in an international instrument is found in 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. This article provides that if the dispute has not been settled by negotiation or mediation, any party to the sMTA can submit the dispute to arbitration using the rules of an international body agreed by the parties or, failing such agreement, the Rules of Arbitration of the International Chamber of Commerce's International Court of Arbitration. Although arbitration procedures are unlikely always to be appropriate for all relationships or sectors, a potential advantage of them is that they allow ABS stakeholders to gain cost effective legally-binding judgments. that are enforceable across borders in countries that adhere to the New York Convention on Recognition and Enforcement of Foreign Arbitral Awards.

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[8] http://www.bio.org/ip/international/200507guide.asp
[9] http://www.ifpma.org/Issues/CBD and http://www.bio.org/ip/international/BIO_Model_MTA.pdf
[10] http://www.europabio.org/positions/Bioprospecting%20Principles_Final.pdf
[11] http://www.floraweb.de/proxy/floraweb/MAP-pro/Standard_Version1_0pdf