International Chamber of Commerce
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Access and Benefit Sharing: Sectoral approaches, Concepts, Terms, Working Definitions

Submission to the Technical Experts Group on Concepts, Terms, Working Definitions and Sectoral Approaches

Industry supports the creation of a practical and workable International Regime (IR) on Access and Benefit Sharing adapted to the different sectors working with genetic resources. As reflected by record levels of attendance at the Ninth Conference of the Parties, the business community remains engaged and focused on substantive discussions in the access and benefit sharing (ABS) negotiations, including on the objectives, scope and main components of an IR (the Regime). In this paper, business seeks to provide information as requested in the Terms of Reference for the upcoming Technical Experts Group (TEG) on Concepts, Terms, Working Definitions and Sectoral Approaches.

The business community has been an active participant in negotiations concerning access to and the sharing of benefits from genetic resources even before the entry into force of the Convention on Biological Diversity (CBD) in 1993. The business delegation, coordinated by the International Chamber of Commerce (ICC), today represents various business sectors with diverse interests in genetic resources and their sustainable commercial uses. Many of these consist in large part of small and medium-sized enterprises (SMEs) and include, in alphabetical order: agricultural biotechnology, animal breeding, cosmetics, farming, flavours and fragrances, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical products, and plant breeding. All these industries may access, use and create value from resources covered by the CBD in different ways[1].

If the IR is to be effective in promoting economic activity, it should maintain and foster the diversity of uses of these resources as well as of the commercial arrangements through which they are acquired. ICC believes that it is of key importance that the IR should be a transparent, non-discriminatory, predictable, and facilitative structure that is narrowly targeted. It should not be a heavy regulatory framework that will stifle the creation of value from genetic resources, trade and sustainable uses. This will promote not only the efficient organization of access and benefit sharing, but also the conservation and sustainable use of genetic resources.

[1] See EFPIA (European Federation of Pharmaceutical Industries and Associations) brochure "Good business practice and case studies on biodiversity" http://www.efpia.eu/content/default.asp?PageID=559&DocID=3787

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Biological resources, genetic resources, derivatives and products

The terms of reference for this TEG seek clarification on the implications of different ways of understanding biological resources, genetic resources, derivatives and products. Clear definitions of these terms are essential for defining the scope and other key elements of the IR.

The IR should only cover genetic resources

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 be limited to "genetic resources," as defined in the Convention and should seek only to elaborate matters relating to access and benefit-sharing with respect to such genetic resources, based on "mutually agreed terms" (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.

The IR should not regulate downstream products or activities

The IR should also only regulate the relationship between the provider and party gaining access to genetic resources and not seek to regulate downstream activities and/or derivatives or products being developed from them. Based on its experience of working with genetic resources, it is clear to business that any IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement. Broadening the scope of the IR to downstream products would bring under the IR common household items such as wine, bread and wood products – it would be extremely difficult to know where to draw the line.

Benefit sharing arrangements in relation to derivatives and downstream products should instead be determined through mutually agreed terms in the ABS contract between the providing and accessing parties, as provided for in Article 15(7)[2]. Concepts such as "derivatives" or "products", however they may be defined, should not be part of the IR itself, but instead should be determined between contracting parties.

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

Certain genetic resources should be excluded

When defining which genetic resources should be covered by the IR, Parties should consider the following:

- Consistent with Decision II/11, the IR should exclude human genetic resources.

- 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 were already made publicly available without any restriction by the provider country.

- 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. Therefore it is best to exclude pathogens from this framework.

Issues to be considered for a sectoral approach

The terms of reference also seek specific information on how different sectors use genetic resources and possible differences in access and benefit sharing arrangements used by various sectors. It should be noted that genetic resources may be used in different ways in the same sector and that, conversely, different sectors may have similar methods of using genetic resources. This paper therefore sets out below the different variables affecting how businesses access, use, and create value (and thus benefits) from genetic resources, instead of describing the different practices of various sectors, which may change with time.

Some of the issues should be explicitly dealt with in the IR, while others should be decided upon by users and providers. For the sake of completeness, the latter issues are also reiterated below.

Availability of genetic resources: widely distributed versus rarely present/ *in situ* versus *ex situ*

- Genetic resources might be available in *in situ* conditions in one or multiple countries. If species are widely distributed, different users may be able to obtain the same material from different places under different conditions. This may cause confusion and uncertainty with respect to Prior Informed Consent requirements and the accessing party's rights to use the genetic resource. On the other hand some resources may only be present in *in situ* conditions in one or few countries.

- Materials may be still existent *in situ* in countr(y)(ies) of origin, but could also be available *ex situ* in one or more public and/or private collections. *Ex situ* collections are wide-spread and range from gene banks, zoos and aquariums to herbaria, botanical gardens as well as other public and private collections. Getting access from *ex situ* collections may be easier and more practical in some cases. In other cases, access to genetic resources in their natural surroundings may be more relevant.

- The vast majority of genetic resources is accessed by businesses from *ex situ* collections and through intermediaries – *in situ* bio-prospecting is relatively rare and, when undertaken, is usually carried out by businesses through local institutions.

The distribution of genetic resources should be considered in Access and Benefit Sharing arrangements. Furthermore, it should be realized that access can be obtained both *in situ* and from *ex situ* collections, according to what is most appropriate. The route chosen may have an impact on the access and benefit sharing arrangements used.

Use: direct versus indirect; in full versus in part; relationship to final product

Genetic resources are utilized in many different ways:

- They are not always present in a final product. Rather, the genetic resource may be a step in a process, a research tool or catalyst, a part of a raw material, or an inactive component of a vaccine or herbal medicine;

- They may be used in their original form, a modified form, or simply as a source of information (e.g. as a digital gene sequence) or be completely substituted by synthetic models;

- They may be used as a fully functional organism or only as a sub-unit of an individual gene;

- They may be consumed in an end-market sale or may be reusable;

- The relationship between the accessed genetic resource and final products may be one-to-one, one-to-many, many to one or many to many.

These multiple types of uses should be considered in the development of the IR.

Use: common versus new

- Many genetic resources have long since been extracted from their original natural environment (examples include vectors, plasmids, and cell lines). Many have become commodities or staple commercial products in the trading system. They are also used for education and research by academic and public research institutes around the globe.

- The value of, and specific information on, the genetic resource may already be known, while in other cases, research has to be undertaken to discover new innovative uses of the resource.

- Only in some cases are rare/new (previously unknown or unappreciated) genetic resources used.

The "commonness" of many genetic resources, and/or of the ways in which they are used should be taken into account in the IR.

Relevance of genetic resource for end product: structural versus marginal

- The genetic resources obtained may contribute structurally and add value to the end products.

- Alternatively, genetic resources may be used, but do not contribute to the added value of the end product. In plant breeding, for example, a cross may be made with a certain genetic resource which has been obtained. It could be that no relevant genes from the genetic resources obtained are actually introduced in the end product that is finally developed after many more years of research, crossing and selection.

- Genetic resources that are used to test another product should be considered as biological resources which, as stated above, should not fall within the scope of the IR.

- Gene recombination including genetic resources should not automatically lead to benefit sharing. If neither a structural amount of genes from the genetic resource nor a relevant characteristic of the genetic resource is involved, then benefit sharing should not be obligatory.

The contribution of the genetic resource to the ultimate commercial product should have an influence on the level of benefit sharing; however these specific arrangements should be made between the acquirer and provider. Some genetic resources may be very relevant for the process, but are used as biological resources. As indicated before, biological resources should not be encompassed within the scope of the IR.

Research and investment: No previous knowledge versus knowledge of specific characteristics or information/product development risks

- The value of, or specific information about, the genetic resources obtained may sometimes be known. However, in most cases a considerable amount of research and further product development is required before there can be commercialization arising from use of the genetic resources.

- Product development out of genetic resources involves long-term risk and investments:

    - The duration of a product development cycle may take decades;

- The success rate of new product development may vary, but often is very low;

- Even when the success rate is high, margins may be low.

Parties should realize and take into account the varying degrees and types of information available in relation to different genetic resources. The investment in time and money that is required for research and product development should also be considered.

Complexity in movements of genetic resources

- The number of intermediate sales and purchases of genetic resources between access and end-market sale may vary from one to dozens;

- Every day, there are millions of common transactions (sales and uses) of genetic resources and of items in some way derived from or using genetic resources.

- Genetic resources move within as well as between countries. Moreover, they move between and among both developed and developing countries[3].

It is important for the Parties to consider the frequency and interdependency of movements of genetic resources, as well as their implications on costs of enforcement for governments and costs of compliance for users.

Size of the sectors

- The total size of the various industry sectors dealing with genetic resources varies tremendously;

- The proportion of small, medium-sized and large companies varies from sector to sector - however, many sectors using genetic resources consist mainly of small and medium-sized companies;

- Small and medium-sized companies probably depend more on access to genetic resources.

One important issue to consider in this context is that it is smaller companies that are likely to undertake *in situ* bioprospecting; these companies face margins and economic realities more akin to those encountered by non-commercial researchers than by larger firms. Accordingly, a regime that draws a line between commercial and non-commercial use may erect barriers that preclude activities by the important SME segment. Similarly, this is where it is critical that the IR

[3] See "Plant Genetic Resources for Food and Agriculture: A Common Heritage of Mankind?" presentation by Radha Ranganathan at ICC Panel Discussion " Making Intellectual Property Work for Development", WIPO, 26 April 2007 at http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/pages/R_Ranganathan26April07.pdf

not discriminate between foreign and domestic users, as smaller local companies often rely on foreign companies for funding of commercial research.

Benefit sharing systems currently used

There is a long history of successful agreements relating to both access and benefit sharing. Benefit sharing can be either direct or indirect.

- Direct benefits can include:
    - Payments upfront or during the development process;
    - Exchange of knowledge and skills which can be valuable for both the providing country and the user;
    - The collection and conservation of genetic resources through financing or specific support activities, thereby helping conserve and enhance biodiversity.
- Even more important are indirect forms of benefit-sharing like:
    - Improved productivity of agricultural crops;
    - The development of new health, food and other products;
    - The immediate availability of improved products for further research and breeding without any consent, through the breeders' exemption in the plant breeding sector. As much cumbersome work had already been carried out to develop these varieties, any subsequent users can save resources, and society obtains faster access to further R&D results;
    - The positive impact on economies since these new products are often the motor for further development, creation of new employment opportunities and improvement of education, infrastructure, etc.

The manner in which benefits are currently shared should be considered in the development of the IR. Existing systems should not be unnecessarily disturbed. Moreover, current systems should be recognized and appreciated.

Standard/Model contract versus individual contract

- To avoid long, expensive and complex negotiations, some sectors would find simple standard contracts for access and benefit sharing of genetic resources more appropriate for their businesses.
- Other sectors would find individually-negotiated contracts based on specific uses more relevant to the manner in which they access and use genetic resources.

- In some cases, certain sectors would find it appropriate to use contracts pertaining to the different phases of product development.

The IR should provide sufficient flexibility to accommodate different sectoral needs, possibly with standard/model contracts, depending on the need of certain sectors.

Other internationally recognized Access and Benefit Sharing systems

There are existing access and benefit sharing mechanisms through other treaties and conventions that affect particular sectors. For example, part of the plant breeding sector is already working with the Standard Material Transfer Agreement of the FAO international Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). This system recognizes that the freedom to use products for further research and development should be recognized as a benefit in its own right, as this allows future research to benefit from past work.

Another example of such international access and benefit sharing mechanisms is the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO.

Rules and agreements of other relevant international conventions should be carefully considered for the development of the IR when applicable in the same sector. The IR should not contradict other international agreements. An example is the breeders' exemption under Plant Variety Protection (PVP) law governed by the International Union for the Protection of New Varieties of Plants (UPOV). The freedom to use developed varieties that are protected solely by PVP for further breeding without the consent of the breeder, should be recognized and maintained.

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