



International Chamber of Commerce

*The world business organization*

## **Priority Areas of Concern for Business**

### **for Interregional Negotiating Group, 18-21 September 2010 Montreal**

The International Chamber of Commerce (ICC) supports creation of a practical, workable and cost effective International Regime (IR) on Access and Benefit Sharing (ABS) with a clearly defined scope that promotes national ABS regimes that are transparent and provide legal certainty. While supporting many elements in the most recent draft Protocol text (Montreal Draft Protocol Text), we have concerns that other proposals will create an IR that hinders, rather than promotes, innovation and creation of benefits from genetic resources.

#### **Key Points:**

##### **1) The IR should be a prospective system with no retroactive effect.**

- The IR should only apply to genetic resources acquired or accessed from provider country after the entry into force of the IR and its ratification in that country.
- The IR should not apply to pre-IR transfers of genetic resources (GR) and should have no impact on existing (pre- or post-CBD) material transfer agreements.
- Temporal scope should not be defined by “utilization” which may lead to obligations on GR used after the Protocol, but accessed previously.
- “Country of origin” should be deleted throughout the text in favor of the provider country.
- The IR should not disturb the public domain; e.g., ABS obligations should not apply to traditional knowledge (TK) that has entered the public domain.
- Examples in the Montreal Draft Protocol Text:
  - Article 3 (Scope) should provide that the Protocol only applies to GR and TK associated with GR acquired after its entry into force for the provider country.

##### **2) The IR should recognize existing int’l instruments and instruments under negotiation and exclude GR that are the subject of ABS obligations in current and/or future agreements.**

- ABS for the use of plant GR for food and agriculture is already regulated under the FAO International Treaty for Plant GR for Food and Agriculture (IT PGRFA).
- ABS for the use of animal GR is under development under the FAO Global Plan of Action on Animal Genetic Resources
- The Multilateral System under the IT PGRFA creates a level playing field for all users, public and private, in developing and developed countries.
- Examples in the Montreal Draft Protocol Text
  - Article 3, 3bis: Should exclude GR that are the subject of ABS obligations included in current and/or future agreements in other fora.

##### **3) New disclosure or checkpoint requirements for patents and other IP, as well as marketing approval, should be deleted from the IR.**

- Mandatory patent, IP and/or marketing approval disclosure requirements will not counteract “bio-piracy”.
- Mandatory patent, IP and/or marketing approval disclosure requirements will create significant uncertainty and reduce investment in use of GR for innovative products, including those needed to address threats to biodiversity, such as climate change.
- WIPO has a mandate for text-based negotiation on IP and genetic resources; therefore, any such proposals should be discussed in WIPO under that mandate.
- Examples in Montreal Draft Protocol Text:
  - Article 13(a) – Reference to intellectual property or marketing approval offices as “checkpoints” must be deleted.
  - Article 13bis – must be deleted.

**4) Any “certificate/permit” system should be voluntary, limited to compliance with national laws and consistent with legal certainty.**

- It is premature to legislate specific certificate content in the IR.
- A certificate, or equivalent, should be available, on a voluntary basis, as *prima facie* evidence demonstrating compliance with national laws.
- The lack of a certificate should not be considered evidence of non-compliance.
- Provision of certificates should not become a requirement in regulatory regimes, e.g., intellectual property or marketing approval systems.
- Examples in the Montreal Draft Protocol Text:
  - Articles 5(2)(d) and 13: Article 13(4) is premature and should be deleted.
  - COP should further consider content for any such certificates (Art. 13(5))

**5) The IR must not go beyond the scope of the CBD.**

- The ABS provisions of the CBD (e.g., Art. 15) are limited to GR. References to “derivatives” should be deleted.
- Benefit-sharing relating to “derivatives” should be handled in mutually agreed terms.
- Consistent with COP Decision II/11, the IR must not include human GR.
- Pathogens/pests which represent only a threat to biodiversity should be excluded. For all others, uses to detect pathogens/pests, prevent disease or cure damage caused by them to human, animal and plant health should be excluded.
- “Commodities” made freely available in commerce should be excluded regardless of how they are used.
- Examples in the Montreal Draft Protocol Text:
  - References to “derivatives” throughout the text should be deleted.
  - Article 3 should include appropriate exclusions, e.g., for “human genetic resources,” certain “pathogens” as noted above and “commodities in trade”.

**6) The IR should provide that GR will be accessed, and any benefits shared, on mutually agreed terms where required in publicly available national ABS laws.**

- ABS obligations should only arise where Parties have implemented requirements in publicly available national laws.
- If GR are accessed consistently with national laws, there is no “misappropriation”.
- Benefits are to be shared on mutually agreed terms. Governments should not impose on users/providers a mandatory “pre-negotiated” basket of benefits.
- Access regimes should treat foreign and domestic entities equally.
- Examples in Montreal Draft Protocol Text:
  - Articles 4 and 5 should provide that ABS obligations must be implemented in national laws and be based on mutually agreed terms made at the time of access.

**7) The IR should support national laws and enforcement structures.**

- Proposals that require officials and judges in one country to interpret and apply foreign laws introduces uncertainty and raises significant sovereignty issues.
- IR should avoid new international bureaucracy – instead, support for developing countries and ILCs may be provided through Capacity Building (e.g., Article 18).
- Examples in the Montreal Draft Protocol Text:
  - Articles 12(1-2) should not mandate liability in a Party based on application of foreign law but should instead be directed toward cross-border assistance to determine whether prior informed consent or mutually agreed terms were obtained; Article 14 already provides for enforcing mutually agreed terms across borders.
  - Article 14Bis – proposal for CBD “ombudsman” should be deleted.

**8) The IR should provide for protection of undisclosed information.**

- The IR should not undermine undisclosed information, including confidential business information (CBI), trade secrets and other proprietary information.
- Examples in the Montreal Draft Protocol Text:
  - The bracketed reference to CBI in Article 11(2) should be retained.

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*More details on business positions on these points can be found in ICC papers at <http://www.iccwbo.org/policy/ip/index.html?id=2480>.*