International Chamber of Commerce
The world business organization

Prepared by the ICC Task Force on
CBD/ Access and Benefit Sharing

Comments on the Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization in the Union (as amended by the European Parliament)

Highlights

- Retroactivity
- Material scope
- Due diligence requirements

Document No. 450/1082 – 29 October 2013

Introduction

ICC and its members are fully supportive of the aims of both the CBD and the Nagoya Protocol. However, the implementation of the CBD and the Nagoya Protocol will lead to additional burdens for authorities, industries and researchers in terms of compliance, documentation and auditing. It is important to keep this burden as low as possible. Otherwise both the use of genetic resources and the development of new products therefrom will be severely hampered. This would run counter the objectives of the CBD as well as the Nagoya Protocol.

ICC is concerned about the way the Nagoya Protocol may be implemented in the European Union. The draft EU Regulation to implement the Protocol, as amended by the European Parliament, comprises elements of retroactivity and goes beyond the scope of the Nagoya Protocol in terms of material scope and due diligence requirements.

Specific concerns

ICC calls upon the European Union to take account of the following aspects in the process of implementation of the Nagoya Protocol in EU legislation:

1. Retroactivity

The draft Regulation provides for retroactive effect. It thereby extends the scope of both the CBD and the Nagoya Protocol (NP) and leads to high legal uncertainty.

Recital 9

EP Text
(9) In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol should only apply to new acquisitions or new utilisations of genetic resources and traditional knowledge associated with genetic resources that take place or commence after the entry into force of the Nagoya Protocol for the Union

Position:
The inclusion of “new utilisations after the entry into force of the Nagoya Protocol” brings any new uses of resources legally collected before the entry into force of the NP in the EU under the scope of the Regulation. This is an evident case of retroactivity, infringing on the principle of legal certainty. Any retroactivity must be strictly avoided.

It is extremely important for legal certainty that the regulation applies prospectively, and not retroactively. Businesses are only able to undertake investments if the regulatory framework is clear, transparent and provides legal certainty. It can be expected that without legal certainty, access to and research and development

activities on genetic resources in Europe will be significantly deterred hence pre-empting any benefit-sharing in the end.

Proposal for new text:
(9) In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol should only apply to new acquisitions ***~~or new utilisations~~*** *of genetic resources and traditional knowledge associated with genetic resources that take place or commence after the entry into force of the Nagoya Protocol for the Union*

Article 3 (4) – Definition of "access"

EP Text:
"access" means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol in accordance with the applicable domestic access and benefit-sharing legislation or regulatory requirements of that Party.

Position:
The definition of "access" in Article 3 (4) refers to the acquisition of a genetic resource "in a Party to the Nagoya Protocol" and not to the acquisition "in the Party to the Nagoya Protocol" (exercising sovereign rights over that genetic resource; see Article 2, sentence 1). Not only would access after the entry into force of the NP to genetic resources in the country of origin be covered, but also any access to a genetic resource after the entry into force of the NP in any other country (for example, from a collection to which the genetic resource was brought from the country of origin before the NP or even the CBD entered into force). This would clearly entail retroactivity.

Proposal for new text:
"access" means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in ***~~a~~*** ***the*** *Party to the Nagoya Protocol,* ***which exercises sovereign rights over that genetic resource*** *in accordance with the applicable domestic access and benefit-sharing legislation or regulatory requirements of that Party.*

2. Material Scope

With respect to its material scope, the draft Regulation also goes beyond what is provided for by the CBD and the Nagoya Protocol. The instances of extended scope mentioned will significantly impact on the practicability of access and use of genetic resources. The resulting deterrent effect will negatively affect the intended benefit sharing.

Recital 22a (new)

Recital 22a (new) should be deleted because the need for a GMBSM has even not been addressed at the ICNP and COP 1. In addition, ICC believes that there is no

need for such a mechanism (see ICC position paper[1]) at least not before the provisions of the Protocol have been implemented into national law and experiences with its functioning have been collected for a reasonable period of time.

Article 2 – Scope

Position:
It should be clarified that the Regulation does not relate to those genetic resources which have only pathogenic and no beneficial properties. "Pathogens" were not intended to be included within the scope of the CBD and the Nagoya Protocol - under Article 8(c) of the CBD, members are obliged to control or eradicate alien species which threaten ecosystems, habitats or species.

Proposal for new Text:
"This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by a specialised international instrument to which the Union is a Party; to genetic resources which are available as commodities in the normal channels of trade; to genetic resources which are pathogens of humans or domestic animals. This Regulation does not restrict or impose requirements on the exchange and use of other pathogens for diagnostic purposes".

Article 3 (3) – Definition of "genetic resources"

EP Text:
*(3) "genetic resources" means genetic material of actual or potential value**,** or derivatives thereof;*

Position:
The adding of "***, or derivatives thereof"*** is not in accordance with the definition of "genetic resource" as provided for by both the CBD and the NP. This addition extends the scope of the draft Regulation to any naturally occurring biochemical compound resulting from the genetic expression or metabolism of genetic resources, i.e. any chemical substance. It is not possible to identify in practice, whether such substance is resulting from the genetic expression or metabolism of genetic resources. This causes tremendous legal uncertainty and will put the functionality of due diligence obligations in Art 4 of the draft Regulation - its core piece - at risk. In addition, the definition of genetic resources resulted from a compromise during the negotiations of the Nagoya Protocol by which parties agreed that derivatives would be included in the concept of "utilisation", through the definition of biotechnology. The draft Regulation should therefore align with the position adopted by the Nagoya Protocol, as supported by the EU during its negotiations.

[1] "Business views on a Global Multilateral Benefit-Sharing Mechanism (Article 10, Nagoya Protocol)" at www.iccwbo.org/Advocacy-Codes-and-Rules/Document-centre/2011/Business-views-on-a-Global-Multilateral-Benefit-Sharing-Mechanism-(Article-10_-Nagoya-Protocol)/

Proposal for new text:
*(3) "genetic resources" means genetic material of actual or potential value**~~, or derivatives thereof~~**;*

Article 3 (5) – Definition of "user"

EP Text:
(5) "user" means a natural or legal person utilising genetic resources or traditional knowledge associated with genetic resources or who subsequently commercialises genetic resources or products based on genetic resources or traditional knowledge associated with genetic resources;

Position:
The addition of "person[s]…"who subsequently commercialize[s] genetic resources or products based on [these]" to the definition of "user" is not in accordance with the CBD and the NP. Indeed neither the CBD nor the NP provide for a definition of "user". However, the NP provides for a definition of "utilization". This definition includes research and development, but not commercialization. The definition of "user" cannot go beyond the definition of use. The definition of "user" in the draft Regulation has therefore to be limited to research and development. Otherwise the definitions of "user" and "utilization" in the draft Regulation would be conflicting. This conflict cannot be overcome by adapting the definition of "utilization" to the definition of "use" (including commercialization), since such extension of the definition of "utilization" to commercialization would be in conflict with the NP.

Proposal for new text:
*(5) "user" means a natural or legal person utilising genetic resources or traditional knowledge associated with genetic resources **~~or who subsequently commercialises genetic resources or products based on genetic resources or traditional knowledge associated with genetic resources~~**;*

3. Due Diligence Requirements

Some of the due diligence requirements established by the draft Regulation are burdensome and provide a source of legal uncertainty. They will have deterrent effect to the access to as well as to the use of genetic resources and will thereby run counter the objectives of the CBD and the Nagoya Protocol.

Recitals 3a (new), 17 and Art. 7, (2c) and Art. 12 (2a) (new) – Patent disclosure

Any obligation to disclose origin in patent applications should be avoided. This issue is dealt with in other fora, in particular in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Since there is no consensus in the WIPO IGC about the inclusion of a disclosure obligation, the EU should not include any binding regulation on this, which would contradict and pre-empt the current status of negotiations.

The filing of a patent application does not constitute an appropriate check point. Including IP offices in the compliance system related to ABS would interfere with the IP system and create confusion and legal uncertainty. In addition, there is no evidence that such a requirement would contribute to meeting the objectives of the Nagoya Protocol.

Article 3 (11) - Definition of "internationally recognised certificate of compliance"

EP Text:
(11) "internationally recognised certificate of compliance" means an access permit or its equivalent issued by a competent national authority in accordance with Article 6(3)(e) of the Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing-House;

Position:
The sMTA developed under the International Treaty on Plant Genetic Resources for Food and Agriculture (IT) fulfils the requirements of PIC and MAT.

In cases where material (plant genetic resources for food and agriculture (PGRFA)) is accessed under the terms and conditions of an sMTA according to the IT, that sMTA should be accepted as an internationally recognised certificate of compliance and no further information or evidence whatsoever should be needed.

Proposal for new text:
(11) "internationally recognised certificate of compliance" means an access permit or its equivalent issued by a competent national authority in accordance with Article 6(3)(e) of the Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing-House; ***a standard Material Transfer Agreement as established under the IT PGRFA shall be regarded as fulfilling the requirements of an internationally recognized certificate of compliance.***

Article 4 (2) (c)

Position:
Under this obligation a (subsequent) user – when discovering that the initial access was not in accordance with applicable ABS rules – has to do all he can in order to get PIC and MAT. However, to oblige a user who acted in full good faith and carried out all efforts to get the PIC and MAT to discontinue the use of the genetic resource after potentially several years of research is a disproportionate measure. For several sectors, discontinuing the use of a single genetic resource would effectively mean breaking down years of research.

Proposal for new text:
(c) obtain a proper access permit ***and*** *establish mutually agreed terms*~~*, or discontinue the use*~~ *where it appears that access was not in accordance with applicable access and benefit-sharing legislation or regulatory requirements.*

Article 4 (2) (a) and (3) – Subsequent users

EP Text:
(3) the source from which the resources or the knowledge were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with such resources

Position:
It has to be clarified in the text that information on subsequent users has to be given in the case where the genetic resources in question has been transferred to those subsequent users in an unaltered form. In other words: in cases where those subsequent users do not access the genetic resource directly from its country of origin but indirectly via another user which has accessed it directly. If this obligation is not limited to such cases, it will be impossible to comply with it, especially in the plant breeding sector as those genetic resources will be crossed into a breeding program to develop new plant varieties.

Proposal for new text:
(3) the source from which the resources or the knowledge were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with such resources ***in cases where the genetic resources are transferred to such subsequent users in an unaltered form****;*

Article 4 – (5 new)

Position:
According to Article 8 (c) of the Nagoya Protocol special consideration should be given by Parties to the importance of genetic resources for food and agriculture when implementing the Protocol in their legislation. In the plant breeding sector, hundreds of different genetic resources are combined into one single plant variety which in the end will be commercialized. Such commercially available newly bred plant varieties are freely available to everybody for research and further breeding and development. This is due to the specific compulsory exception under plant variety protection, referred to as the breeders' exemption. This free flow of plant genetic resources, characterised by the breeders' exemption, must not be jeopardized by any regulatory obligation. Therefore, in the case where a user (a breeder) is accessing a commercially available plant variety in which a genetic resource falling under the scope of the future EU regulation has been incorporated and for which due diligence has been exercised, the user should no longer be bound by any regulatory obligations in respect of that genetic resource. to be consistent with this, in such a scenario, the initial user of the genetic resource should not have an obligation to transfer information relevant for access and benefit-sharing to the user accessing the commercially available plant variety.

Proposal for new text:
5. In the case where a genetic resource, for which due diligence has been exercised, has been incorporated into a plant variety that is available on the

market, the obligations referred to in paragraphs (1) to (3) of this Article shall be deemed to have been complied with by users of that plant variety. In this case, the obligation of the initial user to transfer information relevant for access and benefit-sharing shall be waived.

Article 5 – Union trusted collections

EP Text:
This Article has been deleted by the EP.

Position:
The Article should be reintroduced as proposed by the European Commission (COM). Union trusted collections provide for an increased level of legal and economic certainty, especially for SMEs.

Article 7 (2) – Monitoring use compliance

EP Text:
2. Users shall declare to the competent authorities established under Article 6(1) that they have fulfilled the obligations

(a) establishing prior informed consent and mutually agreed terms;

(b) receiving research funding involving utilisation of genetic resources and traditional knowledge associated with genetic resources;

(c) applying for patents or for new plant variety rights at relevant national, regional or international institutions covering, inter alia, the accessed genetic resources, products, including derivatives, and processes derived from the use of biotechnology, or traditional knowledge associated with the genetic resources;

(d) requesting market approval for a product developed on the basis of genetic resources or traditional knowledge associated with such resources, or

(e) at the time of commercialisation where a market approval is not required.

Position
The Text as proposed by the COM is preferred. Due diligence can only be exercised, but not really be “fulfilled”. It lies within the nature of a risk assessment – which is what due diligence is about – that through no one’s fault, certain aspects may not be seen because they are not visible at the time the due diligence is carried out.

In order to create a level playing field, ensure fair competition and avoid risks of market distortions or disproportionate compliance costs for products that require a marketing authorization versus those that do not require a marketing authorization, the time of commercialization of a product should be the trigger for a declaration of compliance to a competent authority. Innovative and research-based small and

medium-sized enterprises will especially be profoundly affected by an increase in the complexity of a regulatory system arising from the link between a compliance declaration regarding the Nagoya Protocol and market authorization of a product.

We agree with the European Commission that small and medium-sized enterprises form the backbone of the European economy, contributing significantly to innovation, growth and job creation. SMEs can thrive best in a business environment in which regulation respects the specific needs of SMEs. Since the adoption of the Small Business Act for Europe (SBA), cutting red tape and listening to the voice of SMEs have been firmly embedded in the Commission's work.

Similarly, the filing of a patent application is not considered as an appropriate check point, as explained above. Finally, the review of patent applications or of marketing authorisation applications are complex and technical regulatory processes, which should not be affected by considerations outside their remit.

Proposal for new text:
2. Users shall declare to the competent authorities established under Article 6(1) that they exercised due diligence in accordance with Article 4 at the time of commercialisation.

Article 7 (3) – Monitoring use compliance

EP Text:
Competent authorities shall verify the information provided under points (b) to (e) of paragraph 2 and transmit to the Access and Benefit Sharing Clearing House Mechanism, to the Commission and if appropriate to the competent authorities of the State concerned within three months the information received pursuant to this Article. The Commission shall within three months summarise the information received and make it public in an easily accessible, open, internet-based format

Position:
The Text as proposed by the COM is preferred. Due diligence can only be exercised, but not really be “fulfilled”. It lies within the nature of a risk assessment – that is what due diligence is – that through no one’s fault, certain aspects are not seen because they are not visible at the time the due diligence is carried out.

Proposal for new text:
“Competent authorities shall transmit to the Commission every two years the information received on the basis of paragraphs 1 and 2. The Commission shall summarise the information received and make it available to the Access and Benefit-sharing Clearing House.”

The reference in Art 9 (7) of the draft Regulation as amended by the EP to Art 7 (2) has to be deleted accordingly.

Article 8 – Best practices

EP Text:
This Article has been deleted by the EP.

Position:
The Article should be reintroduced as proposed by the European Commission (COM). Best practices are considered to be an important element of due diligence, easing and fostering compliance by users, and providing for a better level of legal and economic certainty.

Article 9 – Entry into Force

EP Text:
Article 4 (1) to (4), Article 7, and Article 9 shall apply one year after the date of entry into force of this Regulation.

Position:
The requirements set by the draft Regulation regarding due diligence are very high. It will take significantly more time than one year to have all the necessary tools and processes developed and implemented. Four years are needed.

Proposal for new text:
Article 4(1) to (4), Article 7, and Article 9 shall apply ~~one~~ ***four*** *year**s** after the date of entry into force of this Regulation.*

Article 16a

The reference to criminal law should be deleted. This is not in line with a due diligence system based upon users' best practices.

The International Chamber of Commerce

ICC is the world business organization, a representative body that speaks with authority on behalf of enterprises from all sectors in every part of the world.

The fundamental mission of ICC is to promote open international trade and investment and help business meet the challenges and opportunities of globalization. Its conviction that trade is a powerful force for peace and prosperity dates from the organization's origins early in the 20th century. The small group of far-sighted business leaders who founded ICC called themselves "the merchants of peace".

ICC has three main activities: rule setting, dispute resolution, and policy advocacy. Because its member companies and associations are themselves engaged in international business, ICC has unrivalled authority in making rules that govern the conduct of business across borders. Although these rules are voluntary, they are observed in countless thousands of transactions every day and have become part of the fabric of international trade.

ICC also provides essential services, foremost among them the ICC International Court of Arbitration, the world's leading arbitral institution. Another service is the World Chambers Federation, ICC's worldwide network of chambers of commerce, fostering interaction and exchange of chamber best practice. ICC also offers specialized training and seminars and is an industry-leading publisher of practical and educational reference tools for international business, banking and arbitration.

Business leaders and experts drawn from the ICC membership establish the business stance on broad issues of trade and investment policy as well as on vital technical and sectoral subjects. These include anti-corruption, banking, the digital economy, telecommunications, marketing ethics, environment and energy, competition policy and intellectual property, among others.

ICC works closely with the United Nations, the World Trade Organization and other intergovernmental forums, including the G20.

ICC was founded in 1919. Today it groups hundreds of thousands of member companies and associations from over 120 countries. National committees work with ICC members in their countries to address their concerns and convey to their governments the business views formulated by ICC.

.

International Chamber of Commerce
The world business organization
Policy and Business Practices
38 Cours Albert 1er, 75008 Paris, France
Tel +33 (0)1 49 53 28 28 Fax +33 (0)1 49 53 28 59
E-mail icc@iccwbo.org Website www.iccwbo.org