International Chamber of Commerce
The world business organization

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

Comments on Draft EU Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

Highlights

- Positive elements of the EU Proposal
- Points requiring clarification

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Introduction

ICC welcomes the general approach taken in the draft Regulation to implement the Nagoya Protocol in the EU.

As the proposal recognizes, genetic resources play a significant and growing role in many economic sectors and involve a broad range of players, including but not limited to industry. Each sector may access, use and create value from resources covered by the CBD in different ways.

To translate raw genetic resources into commercially viable products that can contribute to economic growth and consumer choice, business actors engage in lengthy research and development processes that require significant investments with uncertain outcomes.

Businesses are only able to undertake such investments if the regulatory framework is clear and provides legal certainty, and if operating and transaction costs are proportionate to the commercial potential. Administrative requirements should therefore not be overly burdensome or costly, and should be easily implemented in normal business operations.

Positive elements of the EU proposal

ICC believes that the approach taken by the draft Regulation is generally helpful in meeting the above criteria, subject to clarifications on certain points. We support in particular the following elements:

- **Non-retroactive application of the Regulation**: It is extremely important for legal certainty that that the Regulation applies prospectively, and not retroactively. ICC therefore greatly welcomes the clear position that the Regulation applies only to genetic resources that are acquired after the entry into force of the Protocol in the European Union.

- **Due diligence based on best practices**: ICC supports the approach taken in the draft EU Regulation to establish a system of due diligence based on approved best practices as this provides a framework which helps ensure that users respect rules on ABS while providing them with flexibility to do this in the specific context of their different sectors.

- This **flexible approach** is an effective way to encourage compliance by business users as it will engage businesses in developing best practices to ensure implementation of ABS rules in their everyday operations. Any kind of rules need to be easily manageable and, preferably, based on existing regulations which can be fulfilled even by small and medium-sized enterprises without extra administrative workload in their day-to-day activities.

- **Exclusion of genetic resources governed by specific international ABS instruments and in international territories**: ICC welcomes the explicit exclusion from the Regulation of the genetic resources for which ABS is governed by a specialised international instrument to which the EU is a party, although it should be clarified that this exclusion relates to all plant genetic resources covered by the FAO International Treaty in relation to ABS. ICC also welcomes the implied exclusion of GRs in international territories.

- **EU focal point**: ICC finds the centralization of information on national competent authorities by the commission and the designation of a focal point at EU level very useful.

- **Union trusted collections**: ICC supports the concept of Union trusted collections in principle (see Article 5 below). The presumption that due diligence will have been exercised by a user if the user acquires a GR from a Union trusted collection will help provide legal certainty and lower the administrative burden.

- **Exclusion of human genetic resources:** The reference in paragraph 12 of the Preamble to the CBD decisions to reaffirm the exclusion of human genetic resources from the framework of the Convention is welcome.

- **Traditional knowledge defined in MATs**: ICC welcomes the approach that traditional knowledge referenced in the Regulation should be that defined in mutually agreed terms, given that there is no internationally agreed definition of traditional knowledge.

However, there are still several areas of the draft regulation which require clarification and may cause undesired effects.

Business users will make the efforts necessary to comply with the requirements of the final Regulation, but need to have clarity and legal certainty to be able to implement the provisions in practice.

Implementing regulations will play an important role in clarifying many of the points and making the Regulation operational. Business users look forward to working with the EU, member states institutions and other stakeholders in developing these.

Points requiring clarification

General

- The definition of the scope of the Regulation will be fundamental in determining whether its provisions can be implemented in practice. Commodities as well as genetic material which is subsequently advanced through the development process up to commercialisation should be excluded from the Regulation's scope to avoid the situation where implementation by users will be extremely difficult or unworkable in practice (see Article 2 below) The feasibility of the legislation hinges on the scope being clear and appropriate. We urge that a workshop with industry representatives be organized where this issue of appropriate limits can be discussed, and informed decisions can be made as to what constitutes an appropriate scope.

- Use of the term "illegal": The draft Regulation does not clearly set out the meaning of the term "illegal" (Explanatory Memo: section 2, last paragraph; section 3, third and last paragraph; Preamble: Paragraphs 8, 19 and 28; Articles 9 and 11). While our understanding is that it refers to actions in contradiction with existing ABS laws, it must be noted that such actions can sometimes be undertaken in good faith, while the term "illegal" carries a connotation of bad faith. We would be grateful for a clarification from the Commission in this regard.

- Procedural due process safeguards, such as for example rights of appeal, rights to have notice, etc., should be put into place. For example, in case of a seizure (Article 9(7)) there seems to be no provision for appeal against the seizure or to obtain a fast remedy in the event the seizure is inappropriate or unfounded.

- Reference to "sovereign rights" and respect for property rights, In paragraph 3, General Context, of the Explanatory Memorandum and paragraph 5 of the Preamble, the statement is made that the "*Convention recognizes that states have sovereign rights over natural resources found within their jurisdiction and the authority to determine access to their genetic resources*." ICC would like it to be clear that this statement in no way exhausts the rights associated with private ownership of genetic resources. There should be no confusion that "sovereign" could mean "absolute". As such, in the context used in the draft Regulation, the term "sovereign" should either be deleted or placed in an appropriate context.

- A harmonized approach among Member States in implementing Articles 9 and 11 with respect to user compliance controls and sanctions will be important so that companies have some predictability and a level playing field throughout the EU.

Specific provisions

Explanatory memorandum

- Paragraph 9: "*Parties to the Protocol will need to make further choices on the temporal application of implementing measures, on the respect of existing specialised ABS instruments*". This statement implies that a retroactive application of the Protocol could be justified. We believe that the EU should take a clear position on the non-retroactive nature of the Nagoya Protocol as the draft Regulation is a pioneering piece of legislation which will be watched closely in many other countries.

  This statement also implies that Parties can choose not to respect existing specialized ABS instruments. This does not correctly reflect Article 4 of the Protocol which clearly states that "*The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, [ ].*", implying that Parties have an obligation to respect existing specialized instruments, "*except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity*."

Draft Regulation

Preamble

- Paragraph 10: We support the citation of the International Treaty on Plant Genetic Resources, but would like clarification that this exclusion relates to all plant genetic resources covered by the FAO International Treaty in relation to ABS. We believe that an explicit reference to the WHO Pandemic Influenza Preparedness Framework should also be made.

- Paragraph 20: It would be important to state that other legally acceptable forms of documentation evidencing compliance would also be considered sufficient proof/evidence that MATs and PIC have been established/obtained, in the event an internationally recognised certificate is not available**.**

Article 2 – Scope

The following points relating to scope require clarification:

- The status of commodities, when used for R&D, is not clear. ICC would welcome a clear exclusion of commodities from the scope of the Regulation. Not only would it be extremely difficult to apply ABS rules to commodities in practice, because of the practical difficulties in tracing their source, but applying ABS rules to commodity trade in biological resources will also not help achieve the Protocol's aim to encourage the sustainable use of genetic resources. It will be very difficult for companies in many sectors to have certainty as to what materials are covered by the Regulation for their sector if this exclusion is not explicit.

- The scope of 'accessed material' should be limited and exclude material which is subsequently used through the development process up to commercialisation. Expanding the scope to materials subsequently advanced through development would be essentially unworkable, at least very cumbersome, since it would necessitate a functional traceability system throughout the development process and the user chain.

- ICC would also welcome an explicit exclusion of pathogens which have no beneficial properties. Pathogens were not intended to be included within the scope of the CBD and accordingly also the Nagoya Protocol – under Article 8(h) of the CBD, members are obliged to control or eradicate alien species which threaten ecosystems, habitats or species.

Article 3 – Definitions

- (11) "*internationally recognized certificate of compliance*" – as users have no control over whether an access permit or its equivalent is made available to the Access and Benefit Sharing Clearing House (ABSCH), an access permit or its equivalent which has not been made available on the ABSCH should also constitute evidence of compliance.

Article 4 – Obligations of users

- Any kind of rules need to be easily manageable and, preferably, based on existing regulations which can be fulfilled even by small and medium-sized enterprises without extra administrative workload in their day-to-day activities.

ICC therefore suggests including a new Article 4(5) as follows:

Article 4(5): This due diligence obligation should apply to all users, but a user's size, sophistication and experience with these regulations are relevant and important considerations in evaluating whether its due diligence system complies with this regulation.

- A clear understanding of what is meant by "use" is fundamental for users to understand how to implement their obligations in the Regulation, and in this article in particular. While the definition in Article 3 provides some guidance, there are still many outstanding questions. For example:

    - Does the term "use" mean the use of the genetic resource in the form received, or does "use" also apply to use of the GR in a modified form, as GRs will often be transformed in the R&D process? As stated above under Article 2, the scope of the Regulation should exclude material which is subsequently used through the development process up to commercialisation.

- How can the end of the period of use under Article 4(3) be defined? Does "use" in this article only apply to use by the user in question? If a genetic resource is used more than once, would the twenty year period begin again with respect to each "use"? For example, a concrete cases where it may be difficult to determine the end of the period of use is when a genetic resource is used to identify a gene to produce a new medication, and the relevant gene is then used in genetically altered microorganisms to produce the medication. Does the use period end when the gene is taken and transferred into another organism, the last time that the created organisms are used to produce the medication, or at time of the market approval or commercialization?

The following elements would also benefit from clarification:

- (1 and 2) How should the obligations to transfer information to the next user in the chain be fulfilled? Currently, Article 4(2) requires only that "*users shall: (a) seek, keep and transfer to subsequent users information on....*" A "user" in the EU regulation is a defined entity, limited to those "*using genetic resources or traditional knowledge associated with genetic resources*." "Using" is itself defined as conducting research and development.

  However, the supply chains in most industries are not limited only to "users". They also include intermediaries who do not conduct research and development; these intermediaries' sole interaction with the genetic resource is to pass it along the supply chain to the next entity that may or may not be a user. If these intermediaries are not required to "*seek, keep and transfer*" information then how are users further down the supply chain reasonably expected to obtain the information required to meet their obligations under Article 4(2)?

  The draft article does not apply neatly to cases where a genetic resource passes from one user conducting R&D through several entities which are not users, before again being subject to additional R&D by a downstream user. What are the obligations under Article 4(2) for users for whom the immediate downstream entity is not a user? Are they required to pass the same amount of information along to all subsequent parties? Similarly, what are the obligations of a downstream user if they do not receive sufficient documentation from the upstream supplier who was not a user and was not therefore obliged by the Regulation to disseminate information about the genetic resource? The subsequent user will not have sufficient documentation for it to comply with the Regulation, but will not have a direct relationship with the upstream user from which it could acquire that information.

- In addition, it is essential for users to know the cut-off point in the chain for these obligations. Do the obligations to transfer obligations end at the moment of commercialization? The obligations to transmit information will be practically impossible to implement after commercialization. If there is no clear cut-off point, the implication is that the chain of information transmission has to continue ad infinitum which is surely unrealistic.

- (2)(a)(3) It should be made clear that 2(a)(3) does not imply that a later user is under the obligation to trace back and verify the whole provider chain down to the first access, but that "*the source from which the resources or the knowledge were directly obtained*" means the provider from which the user had obtained the resources or knowledge.

- (2)(a)(4) It would be useful to clarify the meaning of the wording "*presence or absence of rights and obligations related to ABS*".

- (b) Given the uncertainties concerning the legality of access in many countries, this provision is particularly difficult to apply and creates legal uncertainty. Clarification as to what "*additional information*" means would be useful.

- (2 c) What degree of certainty is required for it to "*appear*" that access was not in accordance with applicable ABS rules or regulatory requirements?

Article 5 – Union Trusted Collections

- ICC supports the principle of trusted collections but would like explicit clarification as to certain details concerning the Union "register of trusted collections" to be established including: application of this register to privately owned collections, administrative and other costs associated with becoming registered; and the potential for prejudice and bias against users acquiring genetic resources from collections that are not registered at the time a transfer takes place or loses accreditation after a transfer has occurred.

- We also seek clarification as to whether the following could be considered Union trusted collections:

    - Private collections: Explicit acknowledgement that private collections are not within the jurisdiction of a state under the Regulation would also be helpful.

    - Collections in a non-EU-country

- Implementing regulations should clarify how long records should be kept by collections under Article 3(c).

Article 7 – Monitoring user compliance

Several points need to be clarified to provide more certainty for users:

- Declaration upon commercialization:; (2) It would be helpful to make this concept more precise, by specifying:

    - whether the obligation to declare also applies to commercialization outside the EU market;

    - whether a declaration is necessary each time a product is commercialized in a new market or only the first time it is commercialized anywhere; and

    - to which competent authorities the declaration should be made – should this be in country where user is based or in the countries where the product is commercialized, or at EU level if commercialization is in the EU?

- Separate declaration requirement for regulated products at the time of seeking market approval ((2) and Preamble, para. 17*):* In this article, a declaration that due diligence has been respected has to be made when applying for marketing approval in the case of regulated products, but only at the time of commercialization with respect to other products developed on the basis of genetic resources or traditional knowledge associated with genetic resources. It is unclear why a special early burden should apply to regulated products, as it seems that the same standard could be applied to all products that are commercialized – i.e., declaration to competent authorities at the time of commercialization.

- Definition of product subject to declaration: The term "*a product developed on the basis of a genetic resources or traditional knowledge associated with a genetic resource*" should be replaced by "*a product developed by use of a genetic resource or traditional knowledge associated with such a genetic resource*" to make it consistent with the definition of "use of genetic resources" under Article 3.

- Protection of confidential information: 7 (3) provides that information to be transmitted should be made available on the ABS Clearing House. It is essential that the need to protect confidential information be taken into account and that a procedure be put into place to ensure that such information is not transmitted to the ABS Clearing House.

Article 9 – Checks on user compliance

An overarching concern is that this article gives competent authorities potentially wide-ranging powers to make compliance checks and take interim measures, like seizures, at their own discretion without any due process safeguards for users, such as the right to appeal the decision, to be given notice or to obtain a fast remedy in the event the seizure is inappropriate or unfounded. It is essential that safeguards and processes to protect the rights of those who are being controlled are put into place.

- (3) ICC urges that only substantiated concerns of Parties to the Nagoya Protocol and CBD should be taken into account to avoid abuse of the process.

- (4) When carrying out checks, competent authorities should take care to ensure that the costs and burdens involved for the companies do not outweigh the benefits obtained from such checks.

Article 10 – Records of checks

The current draft provides that competent authorities shall keep records of checks and that such records shall be kept for at least five years.

For the purposes of legal predictability, users need to know the opposability period of these records and the starting point of such period. ICC therefore suggests that there should be a maximum or fixed time period, rather than a minimum time period.

Article 12 – Cooperation

It would be useful to have some clarification on the role of third countries in this system.

Article 13 – Union platform on access

Although it will be useful to have a Union platform to help coordinate and streamline access regimes in the Union, more specificity on its remit and terms of reference would be helpful. A possible additional role for the platform could be to review the impact of the Regulation on trade and conservation.

Article 17 – Entry into force and application

As this Regulation introduces new concepts and practices which will have to be communicated to and understood by a wide range of stakeholders, and will require both governments and users to put into place new mechanisms, processes, and tools, ICC suggest that a transition period of at least two years would be more realistic than the one year currently proposed.

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.

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