International Chamber of Commerce
Policy and Business Practices

EU ABS REGULATION - DRAFT GUIDANCE ON SCOPE AND CORE OBLIGATIONS

COMMENTS

Prepared by the ICC Commission on Intellectual Property (Task Force on ABS)

Summary and highlights

- Introduction
- Scope
- User obligations
- Due diligence

ICC INTERNATIONAL CHAMBER OF COMMERCE
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ICC appreciates the opportunity to comment on the draft horizontal guidance document. The document will be a key reference document for users of genetic resources within the EU and the participation of users in its development will help ensure its practical relevance, accuracy and value as a tool for users.

Below are some key comments endorsed by a wide range of businesses from different sectors.

Section 1. Introduction

Section 1.1. Overview of the legal framework

Provider country

The notion of "provider country" is key in the due diligence process, and it is essential for the user to understand its exact meaning to be able to fulfil his/her obligations. The guidance document should give sufficient direction to allow the user to determine which is the provider country in any particular situation. There should be only one provider country for each case.

Section 1.2. Definitions

Access

It is crucial for users to be able to determine the relevant date and place of access relevant for (i) ABS obligations and (ii) compliance obligations under the relevant EU regulations.

It would therefore be helpful if the guidance document explicitly stated that the term "access", for the purposes of the EU Regulation, refers to the act of obtaining the genetic resource from the provider country.

Use of "genetic material" and "genetic resource"

Under the definition in section 1.2, "genetic resources" are defined as "genetic material of actual or potential value" , i.e. a subset of all genetic material. Care should therefore be taken not to use the two terms interchangeably (e.g. page 14, 3rd paragraph) . The draft should be reviewed to ensure consistent use of these two terms throughout the guidance document.

Section 2. Scope of the Regulation

Section 2.1. Geographic scope

Section 2.1.2. Provider countries [...] access measures […]

We fully support the reference to the need for legal certainty and clarity from the part of provider countries and appreciate the confirmation that the "Regulation only applies to genetic resources over which the countries exercise sovereign rights and where access and benefit-sharing measures have been established by a Party ..":.

It would be helpful if the guidance document could clarify the notion of "access and benefit-sharing measures established by a Party" in that statement as follows:

- Do "established applicable access measures" mean only access laws or measures adopted as a result of, or to specifically implement, the Nagoya Protocol? Or are laws directly or indirectly regulating access to some or all genetic resources which were established before the Protocol's entry into force, or which do not implement the Protocol's provisions, also to be considered as such

"established applicable access measures"? If "established applicable access measures" refer only to access rules in conformity with the Nagoya Protocol, how would such conformity be determined?

- In some Nagoya Protocol parties, treaty provisions are directly applicable. However, it is impossible for users to obtain PIC and MAT without national implementing measures and structures. It would be helpful if it was clarified that direct application of the Protocol's provisions cannot be considered "established applicable access measures" for the purpose of the EU Regulation.
- Some countries have also taken the decision not to require PIC and MAT to access genetic resources under their sovereignty. It would similarly be helpful to have explicit confirmation that the EU Regulation does not apply in this case.

Section 2.2. Temporal scope

ICC appreciates the clarity provided in section 2.2 as to the temporal scope of the Regulation. We would suggest the following to make this even clearer:

- Clarify which obligations apply to genetic resources accessed between 12 October 2014 and 12 October 2015, given that Article 4 of the Regulation only applies as of 12 October 2015.
- The situation described in the third paragraph of section 2.2 is confusing and potentially inconsistent with the first paragraph and example, which clearly indicate that material which entered a collection before entry into force of the Regulation is out of its scope.

  For example, a genetic resource collected in a country and exported from that country prior to the entry into force of the Protocol would be out of the scope of the Regulation if accessed, after the entry into force of the Protocol, from a collection in the country to which it was exported. However, the same genetic resource deposited at the same time (i.e. prior to the entry into force of the Protocol) in the ex situ collection of the country where the resource was collected would fall within the scope of the Regulation.

  Different rules for collections which "hold material which originates from and exists in natural habitats in the country where the collection is established" as described in paragraph 3 of section 2.2 should be avoided. We suggest therefore that this paragraph should be deleted.

Section 2.3. Material Scope

Section 2.3.1. Genetic resources

As the term "functional units of heredity" is not defined in either the Convention or the Protocol, it is critical that it should be clarified for the purpose of the Regulation.

The text in the guidance document currently states that "Functional units of heredity are not defined in the Convention or the Protocol but are generally understood to include genes and DNA."

However, "DNA" may refer to both non-coding and coding DNA, neither of which is in itself a functional unit of heredity. From a scientific point of view, the term "Functional units of heredity" should be understood as "genes" only, and references to DNA should be deleted.

Information in the public domain

Scientific research is highly reliant on published information, which is an essential means of advancing scientific knowledge and of stimulating innovation. The current draft does not comment on the status of such information.

It is extremely important for users that the guidance document make it clear that information in the public domain (e.g. gene sequences or chemical structures published in journals or available in databases) is outside the scope of the Regulation.

Section 2.3.3. Utilisation

Utilisation is a key concept determining the scope of the Regulation, and clarity in its definition is crucially important. The determination of what constitutes "utilisation" should therefore not be left to users, who should not have to establish the meaning and scope of the Regulation, which is a matter for the courts.

The following suggestions could help the guidance note to more clearly explain how to interpret the term "utilisation", for the purposes of the application of the Regulation , while waiting for more specific guidance in the sectorial guidelines.

Research and development

It should be made clear that "utilisation" should encompass the intention to do both Research and Development. The term "utilisation" should not apply to activities that only have a Research component, with no *intention* to develop a product from the genetic resource.

The supposition in the 6th paragraph that "In principle, the further an activity is removed [remote] from accessing the genetic resources and the further it is situated "downstream" in the value chain, the greater the likelihood that this particular activity would fall within the scope of the Regulation" is not based on any evidence or rationale and is counter-intuitive. We therefore suggest its deletion.

Examples of activities falling (or not falling) under the Regulation's definition of "utilisation"

The list of examples of what does not constitute utilisation within the scope of the Regulation is useful. We suggest that this list be expanded to explicitly clarify that the following activities fall outside the scope of the Regulation.

- While we appreciate the confirmation that the use of GRs for testing and reference is excluded, it would be helpful to explicitly confirm the exclusion of the use of GRs as research tools in general. Examples of uses of GRs as research tools, other than for testing and reference include the utilisation of organisms resistant to e.g. pharmaceuticals for development of new (better) vaccines and antibiotics, and the use of (contaminating phages) to develop phage-resistant lactic acid bacteria (LAB) cultures for dairy production, etc.
- Screening should also be included in the list of activities not considered as utilisation, as the administrative effort necessary would become prohibitive, e.g., when attempting to screen a library of genetic resources from a public resource collection for a particular use. "Utilisation" should only be considered to start once candidates with desired properties have been selected for Research & Development.
- Benchmarking (research) is a crucial activity in the market to assess the economic fitness of a particular product (or product prototype) and should be explicitly stated not be considered as utilisation. The benchmarking tests typically assess well-established performance criteria, and are intended to rank the relative fitness of the products in relation to these performance criteria.

Derivatives

The attempt made to clarify the meaning of the term derivatives is appreciated. However, several passages remain unclear. We suggest the following to increase the clarity of this section:

- The first sentence in this section - "The definition of utilisation in the Protocol and the Regulation

applies to research and development on genetic resources and/or on any naturally occurring biochemical compounds contained in the material accessed under the domestic ABS regime, 'including through the application of biotechnology' " - appears to mix up the definition of "utilisation" with the definition of "derivatives" in the Protocol. It does not correspond to the actual wording in the Regulation, which states that "utilisation of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology…"

To avoid confusion, we suggest that the guidance refers to the exact terms of the Regulation.

- The last sentence in this section on page 16 - "Consequently, research and development on derivatives (whether or not containing functional units of heredity) is within scope where they are derived from genetic resources accessed under the Protocol, covered by the prior informed consent related to genetic resources from which they were derived and addressed in mutually agreed terms.") - is rather vague and leaves room to different interpretations.

  We would welcome explicit clarification that the use of a derivative without access to the GR from which it was derived falls outside the scope of the Regulation, for example by reintroducing language similar to that in the previous draft version of the guidance document, for example:

  > If a user accesses a genetic resource, prepares a derivative, and does R&D on the derivative, this is considered to be within the scope.
  >
  > If a user, on the other hand, accesses the derivative without recourse to the genetic resource itself, this is considered to be outside of the scope.

Relationship with sector-specific guidelines

Given the Commission's plans to develop sector-specific guidance documents on the notion of research and development, it would be useful to include a cross-reference in this guidance document to the coming sector-specific guidance documents. We recommend that the Commission confirm its intention to develop additional sectorial guidance documents to allow further and more detailed guidance on sector specific issues and to clarify the relationship between those and this horizontal guidance document. In particular, it should be indicated to what extent examples given in the present guidance may be further specified in sector-specific guidance documents.

Section 2.4. Personal scope

In the last paragraph relating to a person or entity which only commercialises the product, it should be clarified that such a person will only be bound by the contractual obligations of the person who accessed or utilised the genetic resource if those obligations are passed on in the contract between that person who accessed or utilised and the person who commercialised.

Section 3. Obligations on the user

Section 3.1. Due diligence obligation

The statement that "If a user takes reasonable measures in the seeking, keeping, transferring and analysing of information, thus applying due diligence, the user will be compliant with the EU ABS Regulation and should avoid liability vis-à-vis subsequent users." is somewhat surprising as the Regulation should not be regulating liability between private parties. It should also be recalled that each subsequent user has an independent obligation to undertake due diligence. We therefore recommend that the reference to liability be deleted.

We also suggest that the reference to "analysing" be deleted as this is not an element of the due diligence obligation.

The obligation to "discontinue utilisation" under Article 4(5) of the Regulation should be clarified to specify if this means discontinuation of further R&D or if this entails discontinuing all commercialization and the recall of relevant products.

Section 3.2. Establishing whether the Regulation is applicable

The Draft Guidance recalls the obligation under Article 14(2) of the Nagoya Protocol for Parties to publish their ABS legislation on the Clearing House.

Given that non-compliance with this obligation will greatly increase the legal uncertainty and administrative burden for users in many countries, the Commission should consider clarifying that the Regulation does not apply in such cases, or at least alleviate sanctions on good faith users relying on information in the ABS Clearing House.

In the last paragraph, the first two sentences clearly indicate that users do not need to obtain or retain written evidence that GRs in their possession are not within the scope of the Regulation. The last sentences in this section - "However, during such checks the competent authorities can ask for reasons and justifications why certain material is considered to fall outside of the scope of the Regulation. It is therefore advisable to keep evidence and proofs of such reasons and justifications." - are confusing and contradict the earlier statements, by putting an onus on the user to obtain and retain evidence. We therefore suggest this should be deleted.

Section 3.3. Demonstrating due diligence

It would be helpful to clarify the following aspects of the obligation for users to "…. retain any information relevant for access and benefit-sharing for a 20 year period after the end of the period of use."

- Does "end of the period of use" in this context mean end of utilization" (i.e. R&D) or end of commercial use?
- Does "use" refer to the first or last use?

Section 4. Different events triggering the due diligence declaration

Section 4.2. Due diligence declaration at the stage of final development

A reference is made to the publication of scientific papers in the last paragraph. It would be helpful to clarify the status, obligations and consequences of such publications under the EU Regulation.

Other comments

Transfers within the same legal entity

In businesses with operations in different locations, GRs at various stages of development may be transferred between different departments or affiliates of the same corporate entity, sometimes across borders. It should be clarified that this type of intra company transfer will be considered neither a new "access" triggering new ABS or due diligence obligations, nor a "transfer" triggering a due diligence declaration under Article 6.2 (d) and (e) of the Implementing Regulation.

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