

DERIVATIVES UNDER THE EU ABS REGULATION: THE CONTINUITY CONCEPT

SUBMISSION

Prepared by the ICC Task Force on Access and Benefit Sharing

Summary and highlights

- Executive Summary
- Introduction
- The current situation with respect to derivatives – complete uncertainty
- Reference to Horizontal Guidance document
- ICC position on continuity
- Arguments supporting the concept of continuity

Executive Summary

Based on the views of most key sectors, ICC has prepared the current paper to help increase the clarity needed on the issue of derivatives by both users and Member States Competent Authorities.

A difficulty faced by users when seeking to understand the nature and scope of their obligations under the EU ABS Regulation relates to so-called derivatives. Whereas no direct reference is made to obligations applying to such materials in the EU ABS Regulation, the Horizontal Guidance of the European Commission provides that access to a derivative is covered when it also includes genetic resources for utilisation. Those limited provisions, while welcomed, do not give the clarity needed by users to ascertain when, and to what extent, activities conducted on derivatives trigger compliance obligations under the EU ABS Regulation.

ICC proposes in the present paper to build upon the Commission’s interpretation of “combined access” developed in its Horizontal Guidance by endorsing the concept of an ascertainable level of continuity between R&D activities conducted on a derivative and the genetic resource from which it was generated.

For example, such continuity¹ would be expected to exist, and activities conducted on derivatives would qualify as utilisation for the purpose of the EU ABS Regulation, in the following situations:

- The R&D activities conducted on a derivative form part of a research project covering the genetic resource and including the generation of the derivative.
- A user has generated the derivative or commissioned a third party to produce the derivative in a research collaboration or as a specific service (e.g. under a service agreement).
- The derivative is acquired from a third party together with PIC and MAT conditions that cover R&D activities on the derivative.

By contrast, such continuity would not be expected to exist in case:

- The derivative is acquired from a third party as a product available on the market and it is transferred without PIC and MAT conditions that cover R&D activities on the derivative.

Continuity



R&D on a derivative takes place in a project that includes the respective genetic resource including involvement of 3rd parties at any step of the defined project



Derivative is purchased together with PIC and MAT conditions that cover R&D activities on the derivative

No continuity



Derivative is purchased without PIC and MAT conditions that cover R&D activities

Explanation of icons



¹ In any case, derivatives need to be derived from genetic resources accessed under the Protocol, covered by the required prior informed consent related to genetic resources from which they were derived, and must be addressed in mutually agreed terms.

Introduction

It is of outmost importance for users of materials potentially encompassed by the Regulation 511/2014 (or 'EU ABS Regulation') to identify and understand the scope of the obligations stemming from that Regulation.

Such expectation from users is fully in line with Recital (9) of Regulation 511/2014 which sets out as an objective for the EU ABS Regulation that "*(i)t is important to set out a clear and sound framework for implementing the Nagoya Protocol that should contribute to the conservation of biological diversity and the sustainable use of its components, the fair and equitable sharing of the benefits arising from the utilisation of genetic resources and poverty eradication while at the same time enhancing opportunities available for nature-based research and development activities in the Union*". The Regulation adds that "*(i)t is also essential to improve the conditions for legal certainty in connection with the utilisation of genetic resources and traditional knowledge associated with genetic resources*".

It is in that context that Regulation 511/2014 provides in its Article 13 that "*(t)he Commission and Member States shall, as appropriate*" (...) "*(a) promote and encourage information, awareness-raising and training activities to help stakeholders and interested parties to understand their obligations arising from the implementation of this Regulation, and of the relevant provisions of the Convention and the Nagoya Protocol in the Union*"; and "*(d) provide technical and other guidance to users (...) in order to facilitate compliance with the requirements of this Regulation*".

Whereas the term "derivative" is defined in the Nagoya Protocol (but not in the Regulation 511/2014), there are no provisions in the operative parts of the Nagoya Protocol or the EU ABS Regulation specifying if, and the extent to which, access and/or utilisation of derivatives falls within the scope of the Nagoya Protocol and/or the EU ABS Regulation.

We would like to emphasize that, with respect to the concept of derivatives, the texts of the legally binding rules (i.e. the CBD, the Nagoya Protocol and the EU ABS Regulation) do not provide the necessary clarity for users to understand the nature and scope of their obligations. This obliges users to develop their own interpretations of the applicable texts.

Therefore, for the EU ABS Regulation to fulfil its objectives (as notably set out in Recital 9) and for the EU Commission and the Member States to cope with their duties under Article 13 of the EU ABS Regulation, the nature and the scope of the obligations applying to the access and/or utilization of derivatives, if any, should be specified further.

The current situation with respect to derivatives – complete uncertainty

The definitions and the scope of application for "access" and "utilization" in the NP and, most importantly, in the EU-ABS Regulation only refer to genetic resources, but not to derivatives.

The negotiating parties to the Nagoya Protocol considered covering certain activities conducted on derivatives, but no agreement was found between the parties on the scope of potential obligations for users in that regard². Derivatives are only mentioned through the reference to biotechnology in the definition of utilization, which in turn refers to derivatives, which are themselves defined as "*naturally-occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity*".

In any event, if activities conducted on derivatives are to fall under the obligations stemming from the EU ABS Regulation, the scope of such obligations cannot lawfully be the same as for genetic

² This can notably be attested in the Report of the meeting of the group of legal and technical experts on concepts, terms, working definitions and sectoral approaches, of 12 December 2008, UNEP/CBD/WG-ABS/7/2, pages 9 to 11.

resources themselves. Otherwise, the EU legislator would have explicitly provided for obligations applying to derivatives, as it did for genetic resources. The silence of the legislator on derivatives must be respected. Since the scope of application applying on access and/or utilization of derivatives is not explicitly provided in the substantive provisions of the EU ABS Regulation, such scope shall in any case be narrower than the one of genetic resources (if any).

This creates a great deal of uncertainty for EU operators needing to understand the nature and scope of their obligations under the EU ABS Regulation and may be detrimental to their efforts to ensure operational compliance with the EU ABS Regulation.

Reference to Horizontal Guidance document

To date, the only EU document referring to possible obligations applying to derivatives is the EC Guidance document on the scope of application and core obligations of the EU ABS Regulation of 27 August 2016. It is on the basis of that document that the necessary clarifications should be brought for users to identify and understand their obligations.

In that document, the EC acknowledges that "through the concept of 'biotechnology', the definition of utilization is interlinked with the definition of 'derivatives in Article 2(e) of the [Nagoya] Protocol".

The EC further describes examples of derivatives that are encompassed by the definition provided in the Protocol. It also draws a clear distinction with synthetics by affirming that such definition does not cover material such as synthetic gene segments.

Importantly, the EC acknowledges that there is no reference to the definition or scope of application of obligations on derivatives in the substantive provisions of the Protocol, including those on utilization, whereas it is such substantive provisions which "ultimately determine its scope of application". In doing so, the EC acknowledges the need to define a limited scope of application of obligations on derivatives which should be narrower than for utilization of genetic resources.

An EU-wide harmonised interpretation of the nature and scope of the obligations falling on derivatives can be derived from the conclusion drawn by the Commission in its Horizontal Guidance:

"Access to a derivative is only in the scope of the EU ABS Regulation when it also includes genetic resources for utilisation, i.e. when access to a derivative is **combined with access to the genetic resource** from which that derivative was obtained."

Consequently the EC Guidance document clarifies that for R&D activities on a derivative to qualify as "utilization" (and fall within the scope of the EU ABS Regulation), the Provider Country of a genetic resource should have ascertained its intent to cover such "combined access" in the PIC and MAT covering access to the genetic resource. Indeed, according to the Commission, R&D on a derivative is within scope (i.e. qualifies as utilisation) if the derivative fulfils the following cumulative conditions:

- is generated from genetic resources accessed under the Nagoya Protocol,
- is covered by the required PIC to the genetic resource from which it was generated, and
- is addressed in the mutually agreed terms concluded when accessing the genetic resource.

Thus, the horizontal guidance document already highlights the need for a relationship between the derivative and the genetic resource to be established.

ICC position on continuity

ICC welcomes the development by the Commission of the concept of access to a derivative combined with access to the genetic resource from which it is derived, and of cumulative criteria for R&D activities on derivatives to be considered as utilization. However, users need to further understand the nature and scope of their obligations through more operative guidance.

In that context, the present paper based on the views of most key sectors supports an interpretation of the concept of "combined access" which requires an ascertainable level of continuity between the R&D activities conducted on a derivative and the generation of the derivative from the genetic resource.

For example, such continuity is expected to exist in the following situations:

- The R&D activities conducted on a derivative form part of a research project covering the genetic resource and including the generation of the derivative.
- A user has generated the derivative or commissioned a third party to produce the derivative in a research collaboration or as a specific service (e.g. under a service agreement).
- The derivative is acquired from a third party together with PIC and MAT conditions that cover R&D activities on the derivative.

Such continuity³ would not be expected to exist in case:

- The derivative is acquired from a third party as a product available on the market and it is transferred without PIC and MAT conditions that cover R&D activities on the derivative.

Arguments supporting the concept of continuity

The "continuum" concept developed in this paper ensures legal certainty for both users and Member State competent authorities while ensuring that the purposes of the Nagoya Protocol and of the EU ABS Regulation are met. This concept:

- ensures that provider countries remain in control of the utilisation that is made of their genetic resources including derivatives thereof, by establishing clear PIC and MAT covering activities conducted on derivatives, as appropriate;
- interprets the EU ABS Regulation in the absence of clear wording in accordance with the context and the objectives pursued by the Nagoya Protocol and the EU ABS Regulation, while clarifying the obligations stemming from utilization of derivatives and thereby enhancing legal certainty for users;
- adequately addresses the limitations stemming from the legal texts, i.e. that obligations applying to derivatives should be limited and narrower than those on genetic resources. Such clear delineation will ensure that the "salami-slicing" of obligations is avoided, i.e. anytime a relationship between a derivative and its genetic resource can be ascertained, utilisation of such a derivative may fall in scope of the EU ABS Regulation;
- provides to users an operative criterion which helps to differentiate between situations where R&D activities on derivatives may fall in or out of scope of the EU ABS Regulation;
- ensures legal certainty not only for users but also for Member State competent authorities, which also need a clear scope of application of obligations to effectively conduct their checks on user compliance.

³ In any case, derivatives need to be derived from genetic resources accessed under the Protocol, covered by the required prior informed consent related to genetic resources from which they were derived, and must be addressed in mutually agreed terms.

The International Chamber of Commerce (ICC)

ICC is the world business organization, whose mission is to promote open trade and investment and help business meet the challenges and opportunities of an increasingly integrated world economy.

With interests spanning every sector of private enterprise, ICC's global network comprises over 6 million companies, chambers of commerce and business associations in more than 130 countries. ICC members work through national committees in their countries to address business concerns and convey ICC views to their respective governments.

ICC conveys international business views and priorities through active engagement with the United Nations, the World Trade Organization, the G20 and other intergovernmental forums.

Close to 3,000 experts drawn from ICC member companies feed their knowledge and experience into crafting the ICC stance on specific business issues.

www.iccwbo.org

INTERNATIONAL CHAMBER OF COMMERCE

33-43 avenue du Président Wilson, 75116 Paris, France

T +33 (0)1 49 53 28 28 F +33 (0)1 49 53 28 59

E icc@iccwbo.org www.iccwbo.org