International Chamber of Commerce
Policy and Business Practices

EUROPEAN COMMISSION ABS SECTORAL GUIDANCE: KEY ISSUES FOR BUSINESS

SUBMISSION

Prepared by the ICC Task Force on Access and Benefit Sharing

Summary and highlights

- Meaning of utilisation
- Need for consistency of guidance on interpretation of R&D
- Screening should not constitute utilisation
- Consistent use of the definition of utilisation

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Introduction

At this important stage of the development of the European Commission ABS sectoral guidance documents, ICC wishes to put forward some key points for business across different sectors.

These relate to the interpretation of the fundamental concept of research and development, the classification of screening activities which flows from this, and the definition of the object of utilisation.

Other very important issues for business – such as derivatives - remain outstanding and we understand will be dealt with later in the process as unresolved issues. These issues are by definition very complex, and we would urge the Commission to ensure an on-going dialogue with the sectors involved during the process of finding a solution to these matters.

The lack of clarity and ambiguity around many of the concepts and definitions in the Nagoya Protocol have required countries implementing its provisions to make policy choices as to their interpretation in line with their own national situations and priorities.

The Commission will no doubt also have to make policy choices of its own in trying to resolve some of these issues, in the light of the EU's own priorities and situation. When considering such policy choices, we would urge the Commission to keep in mind the larger context and to consider the impact of different options on the Commission's broader priorities such as its General Objective 1 "A New Boost for Jobs, Growth and Investment" - cited as the primary objective to which DG Environment's Strategic priorities 2016-2020 will contribute - as well as on DG Environment's stated priority objective of greening the economy[1].

We hope that the points below will be helpful to the further development of the guidelines and look forward to making further contributions during the ensuing process.

Meaning of utilisation

1. Interpretation of R&D

a) Need for consistency of guidance

Guidance on how to interpret research and development (R&D) should be consistent in all the sectoral guidance documents and based on the definition of utilisation in Article 3(5) of EU Regulation No 511/2014 of 16 April 2014 (ABS Regulation) which is taken from the definition in Article 2 (c) of the Nagoya Protocol**.** The internationally accepted definition of R&D in the OECD 2002 Frascati Manual provides an authoritative basis for such guidance. However, care should be taken to ensure that the guidance accurately reflects the content of the Frascati Manual which is not the case in the current drafts.

[1] "*Particularly important for DG Environment is the objective of greening the economy, which entails getting more added value from materials and other natural resources, reducing waste and environmental harm through more efficient use of resources, thus contributing to growth, competitiveness and job creation. This requires innovation and investment*". Strategic Plan 2016-2020 file:///C:/Users/dye/Downloads/strategic-plan-2016-2020-dg-env_march2016_en.pdf

We therefore propose replacing the current standard text on R&D in Chapter 2.1 of all seven sectoral guidance documents with the text below. This contains two paragraphs on R&D from the January 2017 version of the Guidance Document for the Biotechnology Sector (Draft Biotechnology Guidance) - which are based on the text in the Research and Development section in the Commission Guidance Document on the Scope of Application and Core Obligations of Regulation (EU) No 511/2014 (Horizontal Guidance) and accurately reflect the definition of R&D in the Frascati Manual (see below) - plus a third paragraph concerning the relationship between knowledge creation and utilisation based on the Frascati definition.

> *Article 3(5) of the EU ABS Regulation defines utilisation as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the use of biotechnology (…)".*
>
> *The EU Commission Guidance starts off by defining "research and development" on the basis of the OECD's 2002 Frascati Manual. According to this manual, "research and experimental development comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications". This definition lists cumulative requirements, and therefore research and development is more than just gathering knowledge or merely describing (certain) features of the genetic resource, and requires further uses to be developed from that knowledge.*
>
> *Consequently, an activity does not qualify as utilisation unless it "increases the stock of knowledge" on the genetic and/or biochemical composition of a genetic resource. However, this definition also makes clear that merely creating knowledge or insight into characteristics of potential benefit is not utilisation of the genetic resource. There is no utilisation of the genetic resource until there is further development of the genetic resource on the basis of that knowledge or insight.*

The reasoning for this is as follows**:**

- R&D is a critical element in the definition of utilisation and clarity as what constitutes R&D is essential for providing meaningful guidance to users. It is thus very important that the same language on the interpretation of what constitutes R&D is used throughout all the guidance texts - in the Horizontal Guidance as well as all the sectoral guidance documents - to provide the necessary legal certainty and clarity at the operational level.

- The current standard text in Chapter 2.1 of the February 13 version of the seven sectoral documents – '*the Frascati Manual . . . identifies both basic research and applied research as activities falling within the term R&D'* – is not consistent with the text in the Horizontal Guidance and does not accurately reflect the definition in the Frascati Manual. For example, the wording 'falling within the term' does not appear in the Frascati Manual. Another example is the reference of two activities falling under R&D when Frascati actually describes three such activities: basic research, applied research and experimental development. In addition, this standard text introduces an additional interpretation by Morgera and Geelhoed.

- The multiplicity of definitions will lead to diverging interpretations and increase legal uncertainty, thereby undermining the purpose of the guidance documents. The language from the Draft Biotechnology Guidance proposed above is both consistent with the Horizontal Guidance and the Frascati Manual and thus should be used throughout the sectoral guidance documents.

b) Screening

Screening activities should not be classified as utilisation according to the Frascati Manual definition of R&D set out in the Horizontal Guidance. Compliance obligations under the EU ABS Regulation should only be triggered after the screening campaign(s), once the candidates on which R&D is to be carried out have been selected. This should be clearly articulated and applied across the seven sectoral guidance documents for the following reasons:

- In a typical product development, one or several screening campaigns may be used as an initial filter to identify the few candidates having the potential to contain traits of interest, and to filter out the vast majority of those candidates not displaying such a potential. In screening, typically large numbers (hundreds to tens of thousands) of candidates (e.g. genetic resources such as dairy culture strains, or derivatives like plant extracts or enzymes) are tested for a trait of interest, often using validated assays run in laboratory robotics set-ups. According to the Frascati Manual definition of R&D, "*work undertaken on a systematic basis in order to increase the stock of knowledge"* has to be "*creative*" and *"use the stock of knowledge to devise new applications*" to qualify as R&D.*"*

  Screening activity in itself cannot be considered to be creative and therefore cannot qualify as R&D under the definition in the Frascati Manual. Its main purpose is to eliminate the vast majority of those candidates which do not exhibit the desired property of interest, and to select the very few with which "*creative*" work is to be started, as stipulated in the R&D definition of the Frascati Manual.

- Section 2.3.3 of the Horizontal Guidance recognises that "*There are nonetheless certain upstream activities which are related to (or carried out in support of) research but should not as such be considered 'utilisation' in the meaning of the Regulation".* Screening should be considered to be such an upstream activity.

- Classifying screening as utilisation would not further the aims of the ABS Regulation and the Nagoya Protocol, and would indeed go counter to their aims. Paragraphs 9 and 18 of the preamble to the ABS Regulation state the following:

  9) It 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.

  18) The Nagoya Protocol lays down an obligation to promote and encourage research related to biological diversity, in particular research with non-commercial intent.

In keeping with the aim to "*set out a clear and sound framework"* for "*the fair and equitable sharing of the benefits arising from the utilisation of genetic resources",* the ABS monitoring process should focus on the genetic resources that are actually used to create value and benefits, that is, those that are selected for development as a result of the screening process. Requiring all GRs used in screening to comply with the obligations in the ABS Regulation would not contribute to this goal, as the vast majority of the GRs screened are not selected and will not be further developed and potentially create benefits.

- If screening is classified as utilisation, this will create huge administrative burdens and delays because of the high volume of GRs used for screening. This would go counter to the stated aims of the ABS Regulation to "*enhance[e] opportunities available for nature-based research and development activities in the Union"* and the EU's obligations under the Nagoya Protocol Article 8 *"to promote and encourage research related to biological diversity, …"*. As just one example, users in the EU have to keep documents for 20 years after the end of the period of utilisation (Art 4.6 ABS Regulation). If this applies to GR used merely for screening, the volume of documentation that would have to be stored would be massive.

  Including screening in the scope of the EU ABS Regulation would therefore not only divert user resources that could be focused on innovation on GRs that show promise, but also impose unnecessary administrative work on both government authorities and users.

2. Consistent use of the definition of utilisation

Utilisation is defined in the EU ABS Regulation in Article 3 (5) as "*to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention*". Therefore only R&D on the genetic and/or biochemical composition of genetic resources should be considered utilisation.

This definition should be strictly adhered to across all the sectoral guidance documents, and it should be clarified that R&D on genetic resources that does not involve R&D on "the genetic and/or biochemical composition of genetic resources" is not considered to be utilisation. We propose that the language from Article 3(5) of the EU ABS Regulation should be used in an accurate and consistent way in all the case studies and throughout the seven guidance documents.

To avoid confusion, use of any other definitions - such as references to "*R&D on products*", "*R&D on derivatives*" and other language not using the definition in Article 3(5) - should be deleted or amended (e.g. in Chapter 2.2 of several draft sectoral guidance documents, the following language should be made consistent with the Article 3(5) definition: "*further R&D on the product may lead to new and additional products and may hence trigger new and additional due diligence obligations*").

Inconsistent language throughout the guidance documents which does not accurately reflect the definition of utilisation will create confusion and uncertainty.

Products comprising genetic resources are often used for a multitude of experimental studies. However, most of these studies do not target the genetic and/or biochemical composition of the genetic resources. The ABS monitoring process should only focus on R&D on the genetic and/or biochemical composition of genetic resources and not apply to other cases.

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