New Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 on the compliance measures for users from the Nagoya Protocol

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A new Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2021/C 13/01) (here in after EU ABS Regulation), has been recently published in the Official Journal of the European Community (12/01/2021).

The Guidance Document was adopted by the Commission at the end of 2020 (18/12/2020) and is a new steep aligned with the EU ABS Regulation which provides also for adoption by the Commission of some additional measures by way of implementing acts, as the Commission Implementing Regulation (EU) 2015/1866.

Introduction of the Guidance document highlights that it is intended to provide guidance on the provisions and implementation of the EU ABS Regulation according to the answer to the consultations with stakeholders and experts from Member States in which it was concluded that certain aspects of the ABS Regulation needed further clarification, and mainly, the concept of utilisation which was perceived as requiring comprehensive feedback.

Therefore, the Guidance document clarifies when the EU ABS Regulation is applicable concerning temporal, geographical and material scope and explains the core obligations of the Regulation, such as due diligence or submitting due diligence declarations. However, on the one hand, regarding the concept of utilisation the Guidance document dedicates its main part for a general understanding of the requirements of the EU ABS Regulation concerning research and development activities, and on the other Annex II to the document provides for additional details on the concept of utilisation covering specific sectorial aspects.

In this sense, Annex II to the Guidance document is focused on this concept from a series of drafts produced with stakeholder engagement. Specifically Annex II clarifies that it provides further guidance on when genetic resources (falling in temporal, geographical and material scope of the Regulation) are utilised in the meaning of the EU ABS Regulation, what is relevant for the upstream and final stages of utilisation. Moreover, Annex II is structured following the (logic of) value chain in which practical examples are added.

For this reason, Annex II addresses several aspects of the value chain in the following order which starts with acquisition and continues with the analysis storage and collection management, rearing and multiplication, exchange and transfer identification and characterization of organisms and other activities at the beginning of the value chain, genetic resources as tools, breeding, product development, processing and product formulation, product testing and marketing and application.

Finally, it should be noted that the Guidance document is not legally binding. Its aim is to provide information on certain aspects of the relevant EU legislation, because as the Guidance document remember, only the Court of Justice of the European Union is competent to authoritatively interpret Union law. From a legal point of view it does not replace, add to or amend the provisions of the EU ABS Regulation and of the Implementing Regulation; furthermore, it should not be considered in isolation but used in conjunction with this legislation.

Despite the Guidance document is not legally binding it is a necessary orientation and an evidence of the importance of the subject for the European institutions.

The Guidance Document can be consulted in the following link:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2021.013.01.0001.01.ENG&toc=OJ%3AC%3A2021%3A013%3ATOC

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