

Biodiversity-based innovation in the European Union

Key elements and practical implications of EU regulation 511/2014

The EU Regulation 511/2014 implements the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits derived from their utilisation (ABS). Its focus is on ensuring that companies and other organisations conducting R&D in the European Union monitor and comply with ABS rules in the country where the plant or other biological material or its derived substances come from. This note summarises and illustrates the scope and obligations of the EU regulation.

When does the EU regulation on ABS apply?

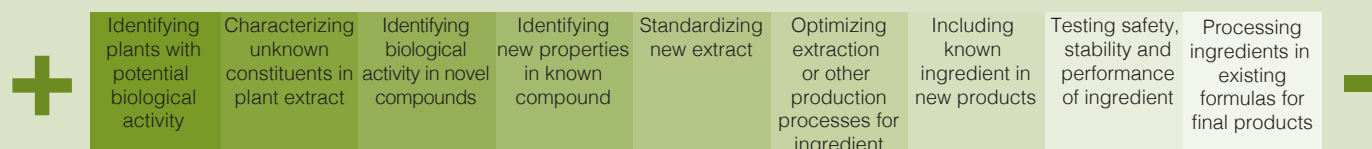
If there is utilisation of genetic resources...



The EU regulation on ABS applies to companies involved in the "utilisation of genetic resources". This term is defined as: conducting R&D on the genetic and/or biochemical composition of genetic resources.

In 2016, the European Commission is set to provide guidance on the activities that fall within and outside the "utilisation of genetic resources". For now, there are no specific parameters. However, some R&D activities in food, cosmetics and natural pharmaceuticals are more likely to fall within this definition, as illustrated below:

Likelihood of R&D activities in food, cosmetics and natural pharmaceuticals triggering ABS requirements



...that have been accessed in specific circumstances.

The EU regulation on ABS applies only if the following conditions linked to access to biological material are met:

#1

Access to the biological material takes place after
12 October 2014.

#2

Biological material is sourced from a country that has committed to the Nagoya Protocol.
70 countries*

#3

The provider country has access requirements in place, which are apply to the biological material at issue.
16 countries*



* As of April 2016, according to the ABSCHM

Obligations under the EU regulation on ABS

1. Due diligence

If their activities fall under the «utilisation of genetic resources», companies must exercise due diligence. Due diligence is a process to ascertain that any biological material obtained and used for R&D meets applicable legal requirements on ABS.

Due diligence requires managing information on:



Date, place, source for material, in order to define applicability of legal requirements



Relevant ABS permits and agreements, including those recognized through the CBD ABS Clearing House Mechanism.

The aim of due diligence is informed decision-making, but if legal compliance cannot be verified or secured, it requires discontinuation of R&D.

► Companies conducting biodiversity-based innovation in the EU now need to be able to trace biological material used in R&D and have information on the origin of samples and any conditions and restrictions for their use.



2. Declaration

The EU Regulation on ABS requires companies to make a declaration of due diligence. This will allow countries to monitor and exchange information on ABS compliance under the Nagoya Protocol. There are two «checkpoints» or situations that trigger a declaration of due diligence: receiving research grants and reaching the final stages of product development.

	Research funding	Final stages of product development
Who?	Recipient of grant for R&D, whether from commercial or non-commercial sources. This does not cover internal budgetary resources	Company or organization involved in final stages of product development
When?	Once first instalment of grant received and all biological material for R&D secured, but prior to final report or end of project	• Product notification (e.g. registration of cosmetic product into CPNP), authorization (e.g. for novel foods) or placing in market (e.g. other food products). • Transfer of R&D results or outcomes to another company within or outside the EU.
How?	Template in implementing rules	Template in implementing rules

A due diligence declaration is required only once, upon the first of relevant situations.

Information provided in the declaration is collected by competent authorities in each EU Member State. It is shared with the European Commission and the ABS Clearing House Mechanism.

For further information on ABS, please see www.uebt.org

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