THE INTERNATIONAL FRAGRANCE ASSOCIATION

International Organization of the Flavor Industry

IFRA-IOFI Guidance Document for the Flavor and Fragrance Industry for dealing with the Nagoya Protocol and Access and Benefit Sharing (ABS) Regulations

Annex –European Union

IFRA-IOFI Nagoya Protocol TF

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Contents

1. The European Union and its Regulations (EC) 511/2014 and (EC) 2015/1866

The European Union is a Party of the Nagoya Protocol and, as such, has implemented obligations arising from the Nagoya Protocol through EU legislation. In addition, each Member State can decide on whether to ratify the Nagoya Protocol. However, if a Member State is or is not a Party to the Protocol, does not exempt it to comply with the regulatory requirements set by the European Union.

In that regard, Regulation (EU) No 511/2014 provides for compliance measures for users regarding the access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (entered into force on October 12th, 2015). The Regulation encompasses the geographical, material and temporal scope of the Nagoya Protocol. Additionally, it requires EU Member States to comply with the Nagoya Protocol related regulations adopted in the countries that are parties to the Protocol, since each individual party has the right to develop its own specific legislation. On November 9th, 2015, Implementing Regulation (EU) No 2015/1866 came into force, containing detailed rules on the implementation of Regulation (EU) No 511/2014, especially with regards to registering collections, monitoring user compliance, and best practice procedures. Both regulations were created to ensure that the Nagoya Protocol is being properly implemented throughout the EU.

Importantly, the Regulations (EC) 511/2014 and (EC) 2015/1866 do not go beyond the obligations set by the Nagoya Protocol. The aim of these regulations is to set the framework for regulatory compliance ensuring that the requirements set by the Nagoya Protocol are met within the European Union. Thus, unfortunately, Regulations (EC) 511/2014 and (EC) 2015/1866 do not provide further legal clarity on the scope of these obligations. Nevertheless, the European Commission has published the "*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 Utilization in the Union*" (so called Horizontal Guidance)[1] with the purpose to help users to comply with the requirements of Regulations (EC) 511/2014 and (EC) 2015/1866.

2. Regional Authorities

Article 6 of the Regulation (EC) 511/2014 obliges Member States to notify the Commission of the names and addresses of their national competent authorities and their national focal points. The European Commission serves as focal point on access and benefit-sharing responsible for liaising with the Secretariat of the CBD with regard to matters covered by this Regulation.

[1] *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 Utilization in the Union (*http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827%2801%29)

3. Access

3.1. Applicable Legislation

Regulation (EU) No 511/2014 does not set obligations regarding access to genetic resources and/or their associated traditional knowledge within the EU territory. However, some Member States may regulate access in their national ABS implementing regulations. This is the case, for example, of France and Spain, which provide for other ABS obligations than the sole requirements set by the European Union.

3.2. Main Legislative Principles

Possible obligations regarding access are regulated at the Member State level, through possible national ABS implementing regulations. Users are reminded to check at the national level whether the country of interest has access measures in place. This can be found by contacting the respective Competent Authority[2] or by consulting the country profiles at the ABS Clearing House website.[3]

4. Utilization

4.1. Applicable Legislation

Utilization of genetic resources and/or their associated traditional knowledge triggers the application of Regulation (EC) 511/2014.

4.2. Main Legislative Principles

Only if the utilization is performed within the EU (even partially), the user falls under the scope of the Regulation (EC) 511/2014.

It is only if the genetic resource and/or traditional knowledge is accessed after October 12th, 2014 that a user may fall under the scope of the Regulation (EC) 511/2014. So, even if the genetic resources are utilized after October 12th, 2014, if they were accessed before that date, then they fall out of scope. Also, outside the scope of the EU ABS Regulation are cases where research and development on an accessed genetic resource only took place prior to October 12th, 2014, and the genetic resource is still being accessed but no research and development is being performed on it anymore.

While the EU ABS Regulation did enter into force on October 12th, 2014, its Articles 4, 7, and 8 did not enter into force until October 13th, 2015. These articles are further detailed by the provisions of a separate implementing regulation, Regulation (EU) 2015/1866, which came into force on October 13th, 2015. So, for example, Article 4, which requires users to exercise due diligence, is only required for genetic resources accessed after October 13th, 2015.

Regulation (EC) 511/2014 sets an obligation for users to exercise and evidence due diligence. Overall, users shall ascertain and document that the genetic resource and/or the traditional

[2] https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/For%20EUROPA%20-%20Competent%20Authorities%20under%20the%20EU%20ABS%20Regulation.pdf

[3] https://absch.cbd.int/countries

knowledge they utilize has been accessed in accordance with the requirements of the applicable national ABS implementing legislation (e.g. PIC and MAT). Users may also have to evidence that benefits arising from utilization have been fairly shared according to the applicable MAT. The EU ABS Regulation defines a user as "any natural or legal person that utilizes genetic resources or traditional knowledge associated with genetic resources". Thus, all users are expected to apply due diligence obligations when accessing genetic resources and associated traditional knowledge which fall within the scope of the EU ABS Regulation, independent of the size of the user or the intent of the use (i.e. for profit or non-profit).

This due diligence process implies that users should collect, keep and transfer to subsequent users the information relevant to ensure compliance with the due diligence requirements. Such documentation includes the Internationally Recognized Certificates of Compliance (IRCC) or, in case such certificate is not available, any other relevant information or documentation regarding:

- The sourcing of the genetic resource and/or its traditional knowledge:
    - PIC, MAT, access permits and other information documenting the agreement of access and benefit sharing between the user and the provider country (e.g. benefit-sharing arrangements);
    - the date and place of access and the description of the genetic resource and/or its associated traditional knowledge;
    - the source from which the genetic resource and/or its associated traditional knowledge were directly obtained, as well as subsequent users of genetic resource and/or its associated traditional knowledge;
    - the presence or absence of rights and obligations relating to access and benefit sharing in the provider country.
    - The presence of obligations regarding subsequent applications and commercialization set by the provider country and/or the country in which the utilization is performed;

- The R&D activities in the meaning of the term "utilization" in the Nagoya Protocol performed on the genetic resource and/or its associated traditional knowledge

Users should ascertain that the information they collect is sufficient to demonstrate their due diligence. Moreover, the Regulation (EC) 511/2014 oblige users to keep such information for at least 20 years.

In addition to the collection and adequate transfer of information to subsequent users, users have the obligation to declare to the National Competent Authorities of their Member State that they exercised due diligence, at the end of utilization. This declaration is called Due Diligence Declaration (DDD). This DDD is notably mandatory at the stage of final development of a product which has been developed via the utilization of (a) genetic resource(s) and/or its associated traditional knowledge. Users must submit the relevant information from the IRCC or the information required under Article 7[4]. The DDD is also mandatory upon request of the National Competent Authority or the European Commission when a user receives research funding in the context of the R&D activities performed as utilization on genetic resource and/or its associated traditional knowledge.

[4] Article 7 of the Nagoya Protocol: https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-07

Importantly, Regulation (EC) 511/2014 obliges users to stop utilization in case of non-compliance with the above detailed requirements. This includes when the user accesses a genetic resource and/or its associated knowledge without PIC and MAT, or in cases of identified non-compliance with the national ABS implementing legislation of the provider country, or when the user is not able to gather all the information required in the due diligence process.

5. Known Grey Zones

Regulation (EC) 511/2014 does not provide more legal clarity on some key concepts of the Nagoya Protocol. Its scope is limited to establishing compliance measures that users and Member States should apply to ensure compliance in the EU with the requirements of the Nagoya Protocol.

For example, Regulation (EC) 511/2014 itself does not provide much more insights on what is to be understood as "utilization of genetic resources", and in particular on what qualifies as Research and Development. In its Horizontal Guidance, the European Commission uses the Oxford definition of "*research*" as well as the OECD Frascati Manual (2002) as a potential interpretation of R&D. The Horizontal Guidance also provides a non-exhaustive list of activities which would be understood as utilization in the meaning of the Nagoya Protocol. Such activities are:

- *"Research on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient (active or not) incorporated into a cosmetic product.*
- *Breeding program to create a new plant variety based on landraces or naturally occurring plants.*
- *Genetic modification — creation of a genetically modified animal, plant, or microorganism containing a gene from another species.*
- *Creation or improvement of yeasts, resulting from human action through a research and development process, to be used in manufacturing processes (but see below, example on application of biotechnology)."*

As another example, regarding the extent to which derivatives may fall under the scope of Regulation (EC) 511/2014, in the Horizontal Guidance the European Commission states that "*access to derivatives is covered when it also includes genetic resources for utilization, i.e. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained*". This would mean that access to a genetic resource and utilization of the derivative produced from that genetic resource could fall under the scope of the Regulation (EC) 511/2014[5]. However, accessing the utilization of a derivative but not combined with an accessing of the genetic resource to produce it, would not trigger any obligation under the Regulation (EC) 511/2014 in case utilization is performed on the derivative. One could consider that the utilization of a derivative is "*combined*" with an access to the genetic resource from which it is derived every time there is an ascertainable level of continuity between the access to a genetic resource and the research and development activities conducted on the derivative so obtained. This however does not necessarily mean that the derivative and the original genetic resource are accessed at the same time and/or by the same actor in the course of such research and development activities. In any case, R&D to be carried out on a derivative accessed *in combination with* their genetic resource may be addressed in MAT that are concluded covering the initial accessing to the genetic resources itelf.

This interpretation is not strictly speaking legally binding (it is arising from the Horizontal Guidance and not from the Regulation (EC) 511/2014), and therefore it is of utmost importance for

[5] Subject to confirmation in the publication of the revised European Horizontal Guidance, expected mid-2020.

companies to ascertain whether PIC and MAT exist for an ingredient (genetic resource or derivative) they access to determine whether and to which extent the R&D activities they intend to undertake on the genetic resource or its derivative are covered in such documents. Moreover, it should be remembered that member States can have different interpretations and have different legal requirements in the national ABS regulations.

At the date of the present guidance, the European Commission does not provide further clarification regarding the chemical modification of derivatives. The Horizontal Guidance states that "*as the reference to naturally occurring biochemical compounds makes clear, the definition does not cover material such as synthetic gene segments*".

6. Abbreviations

ABS	Access and Benefit Sharing
CBD	Convention of Biological Diversity
DDD	Due Diligence Declaration
EEA	European Economic Area
IRCC	Internationally Recognized Certificates of Compliance
MAT	Mutually Agreed Terms
OECD	Organisation for Economic Co-operation and Development
PIC	Prior Informed Consent
R&D	Research and Development
UE	European Union

7. References

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance
OJ L 150, 20.5.2014, p. 59–71
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0511

Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices
OJ L 275, 20.10.2015, p. 4–19
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

Commission notice — 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 C/2016/5337
OJ C 313, 27.8.2016, p. 1–19
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC

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