The Application of the "EU ABS Regulation" on Compliance Measures regarding Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization[1]

31 May 2019

Guidance Document for the Cosmetics Industry

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[1] 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 Utilisation in the Union; OJEU L 150/59, 20.05.14.

ANNEXES

I. INTRODUCTION AND PURPOSE OF THIS DOCUMENT

The cosmetics industry fully supports the objectives of the Convention[2] on Biological Diversity[3] (the Convention) and of the Nagoya Protocol[4], the international instrument adopted on 29 October 2010 by the Parties to the Convention.

It also welcomes the EU ABS Regulation which establishes rules governing compliance with access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the Nagoya Protocol.

The purpose of this document is to help companies and associations in the cosmetics industry understand the requirements of the EU ABS Regulation and to provide practical guidance, wherever possible. This is a 'living document' which will evolve as knowledge and experience are gained through the application of the Regulation.

This document has been developed by Cosmetics Europe, the Personal Care Association, in cooperation with EFfCI, the European Federation of Cosmetic Ingredient Suppliers and UNITIS, the European Organisation of Cosmetic Ingredients Industries and Services.

It represents the three associations' current understanding of the Regulation's requirements and is expected to evolve as these requirements are further clarified, e.g. through further guidance issued by the European Commission.

The reader should note that interpretation of the EU ABS Regulation by national Competent Authorities may vary and may, in some cases, be different from the guidance provided in this document, e.g. regarding derivatives and in particular those that are chemically modified. The reader is therefore advised to check national rules and requirements before accessing genetic resources and/or traditional knowledge.

[2] www.cbd.int

[3] Approved on behalf of the European Union in accordance with Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity (OJEU L 309, 13.121993, p.1)

[4] Annex I to Document UNEP/CBD/COP/DEC/X/1 of 29 October 2010, approved on behalf of the European Union in accordance with Council Decision 2014/283/EU of 14 April 2014 (OJEU L 150, 20.05.2014, p. 231).

I. 1 Definition of Terms

For the purposes of this document, the definitions listed in the Convention and the Nagoya Protocol, as well as the EU ABS Regulation 511/2014 apply.

Out of these, the definitions that are the most relevant for this document are listed below. Additional definitions are provided in, or derived from, the European Commission's 'Horizontal Guidance'[5], and they are indicated by '*'.

ACCESS: the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol.

ASSOCIATION OF USERS: an organisation, established in accordance with the requirements of the Member State in which it is located, that represents the interests of users and that is involved in developing and overseeing the best practices.

BIOTECHNOLOGY: any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

COLLECTION: a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities.

COMMODITY*: a genetic resource, such as agricultural, fisheries or forestry product which is traded or exchanged for direct consumption or as an ingredient, but for which no utilisation takes place.

COUNTRY OF ORIGIN*: the country which possesses the genetic resources in *in-situ* conditions.

DATE OF ACCESS: the date of acquisition of genetic resources and/or of traditional knowledge as determined by the national legislation of a provider country that exercises sovereign rights over its natural resources.

DERIVATIVE*: a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

GENETIC MATERIAL: any material of plant, animal, microbial or other origin containing functional units of heredity.

GENETIC RESOURCE (or "GR"): a genetic material of actual or potential value.

[5] European 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, OJEU C 313, 27.8.2016 [a.k.a. "Horizontal Guidance"]

ILLEGALLY ACCESSED GENETIC RESOURCE: genetic resource and traditional knowledge associated with a genetic resource which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of the provider country which is a Party to the Nagoya Protocol requiring prior informed consent.

IN-SITU CONDITIONS: conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

INTERNATIONALLY RECOGNISED CERTIFICATE OF COMPLIANCE: a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the user and the utilisation specified therein by a competent authority in accordance with Article 6(3)(e) and Article 13(2) of the Nagoya Protocol, that is made available to the Access and Benefit-Sharing Clearing House established under Article 14(1) of that Protocol.

MUTUALLY AGREED TERMS (or "MAT"): the contractual agreements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent application and commercialisation.

PARTY[6]: a state or an organisation (e.g. the European Union) which has formally expressed its consent to be bound by the Nagoya Protocol by means of a ratification, approval, accession or acceptance instrument.

PRIOR INFORMED CONSENT[7] (or "PIC"): an administrative permit given by the competent authority of a provider country to a user, prior to accessing genetic resources. The term is also used to indicate the right of indigenous and local communities to make a free and informed choice on whether they wish to give access to genetic resources or traditional knowledge associated with genetic resources.

PROVIDER COUNTRY*: the country of origin of the genetic resource or any (other) Party to the Protocol that has acquired the genetic resource in accordance with the Convention.

RESEARCH & DEVELOPMENT[8]* (or "R&D"): for the purposes of the EU ABS Regulation the interpretation should be based on their ordinary meaning in the context they are used and in the

[6] Additional information can be found at: http://www.cbd.int/world/ratification.shtml

[7] See the EC's Glossary available at: http://ec.europa.eu/environment/nature/biodiversity/international/abs/material_en.htm

[8] http://www.oecd.org/innovation/inno/frascati-manual.htm http://www.oecd.org/innovation/inno/frascatimanualproposedstandardpracticeforsurveysonresearchandexperimentaldevelopment6thedition.htm

light of the purpose of the Regulation. Examples can be found in the EC Horizontal Guidance and this guidance document for the cosmetics industry.

TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES (or "TK"): traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources.

USER: any natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources. [See also 'utilisation of genetic resources']

UTILISATION OF GENETIC RESOURCES: to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

SUBSEQUENT USER*: a natural or legal person who receives a material, which is subject to contractual obligations entered into when the material was accessed and utilises it in the context of the Regulation.

I. 2 Abbreviations

The following abbreviations are used throughout this document (also see the corresponding definitions in Section I.1 above):

EC: European Commission
EU: European Union
GR: genetic resource(s).
PIC: prior informed consent.
MAT: mutually agreed terms.
R&D: research and development.
TK: traditional knowledge associated with genetic resources.

II. THE INTERNATIONAL CONTEXT

II.1 The Convention on Biological Diversity

Opened for signature at the Earth Summit in Rio de Janeiro in 1992, and entered into force on 29 December 1993, the Convention on Biological Diversity (CBD) is an international treaty with 3 main objectives:

- the conservation of biodiversity,
- the sustainable use of the components of biodiversity,
- the equitable sharing of the benefits derived from the use of GR.

The Convention seeks to address all threats to biodiversity and ecosystem services including threats from climate change, through scientific assessments, the development of tools, incentives and processes, the transfer of technologies and good practices and the full and active involvement of relevant stakeholders including indigenous and local communities, youth, NGOs, women and the business community. It is therefore also considered as a tool for economic development.

For further information on the Convention please visit www.cbd.int

II.2 The Nagoya Protocol

The Nagoya Protocol is an international agreement on *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation*. It aims at preserving biological diversity, promoting the sustainable use of its components and sharing the benefits arising from the utilisation of GR in a fair and equitable way.

It was adopted by the Conference of the Parties on 29 October 2010 in Nagoya, Japan and it implements the 3rd objective of the Convention on Biological Diversity (CBD).

With 53 ratifications at the time, the Nagoya Protocol entered into force on 12 October 2014.

For further information please visit the following website: http://cbd.int/abs

III. THE EUROPEAN UNION's BIODIVERSITY STRATEGY

On 3 May 2011, the EC adopted a new strategy to halt the loss of biodiversity and improve the state of EU species, habitats, ecosystems and services by 2020 (hereinafter "EU 2020 Biodiversity Strategy"')[9]. This strategy was partly the result of failure of previous EU biodiversity policies in reaching their targets (e.g. the establishment of Natura 2000, the world's largest network of protected areas) and partly due to international commitments made by the EU and its Member States at the tenth Conference of the Parties (COP10) to the Convention on Biological Diversity held in Nagoya in 2010. In particular, the COP10 led to the adoption of a global strategic plan for biodiversity 2011-2020 incorporating a 2050 vision, a 2020 mission and 20 targets[10] (the so-called "Aichi Biodiversity targets"). The EU 2020 Biodiversity Strategy incorporates some of the global targets. It is developed around six targets covering the following:

1. full implementation of EU nature legislation;
2. better protection and restoration of ecosystems and the services they provide, and greater use of green infrastructure;
3. more sustainable agriculture and forestry;

[9] Communication of 3 May 2011 from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of Regions entitled "Our life insurance, our natural capital: an EU biodiversity strategy to 2020" available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0244&from=EN

[10] A summary of the 20 targets is available at: http://www.cbd.int/sp/targets/default.shtml

4. better management of EU fish stocks and more sustainable fisheries;
5. tighter control on invasive alien species; and
6. greater EU contribution to averting global biodiversity loss.

Implementation of the Nagoya Protocol is mentioned as one of the key actions to provide a greater EU contribution to averting global biodiversity loss[11] as required by the global target[12].

On 21 June and 19 December 2011, the Council adopted its conclusions[13] approving the EC's Biodiversity Strategy until 2020. Specifically, the Council welcomed that the strategy responded to obstacles that prevented previous EU targets being achieved. These obstacles included insufficient integration of biodiversity protection in other EU policies, inadequate funding, policy gaps as well as knowledge and data gaps. The conclusions also highlighted the need to integrate biodiversity objectives into relevant sectorial policies, such as the Common Agricultural Policy, the common fisheries policy and EU cohesion policy and, inter alia, called for a quick adoption by the EC of a proposal for the timely ratification and implementation of the Nagoya Protocol.

On 20 April 2012, the EU Parliament adopted a resolution[14] which mostly welcomed the EC's Biodiversity Strategy pointing nonetheless out that the major challenge would be the integration of biodiversity in all policy fields and translations of action plans in concrete legislative measures.

In 2015, the EC published a mid-term review of the Biodiversity Strategy to 2020. Overall, biodiversity loss and the degradation of ecosystem services in the EU have continued since the EU 2010 biodiversity baseline. This is consistent with global trends and has serious implications for the capacity of biodiversity to meet human needs in the future. While many local successes demonstrate that action on the ground delivers positive outcomes, these examples need to be scaled up to have a measurable impact on the overall negative trends.

IV. THE EU ABS REGULATION

The EU ABS Regulation implements at EU level the requirements of the Nagoya Protocol imposing upon the Parties (i) to ensure that users of GR comply with the relevant legislation of the provider countries of such resources in terms of PIC and MAT setting out the sharing of benefits and (ii) to monitor obligations by requesting evidence of compliance by users of GR or TK associated with them at specific checkpoints or by carrying out compliance checks.

It is up to each EU Member State in the exercise of its sovereign rights over its own resources[15] to establish the specificities of the terms of access and benefit-sharing, if any.

[11] Target 6.

[12] Target 16 of the Aichi Strategy.

[13] Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0244&from=EN and http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2011978%202011%20INIT

[14] Available at: http://ec.europa.eu/environment/nature/biodiversity/comm2006/pdf/EP_resolution_april2012.pdf

[15] See Article 15(1) of the CBD.

Note: Provider countries of GR or of TK associated to such resources are free to decide whether they want to establish access legislation or not. If they decide not to introduce any rules, access to their GR is considered to be free. However, EU Member States have the obligation to designate competent authorities to monitor the compliance with the EU ABS Regulation in their countries and to define and apply sanctions in case of non-compliance.

Certain requirements – regarding the Register of Collections, Due Diligence Declarations and Best Practices – are further detailed in the EC's Implementing Regulation[16].

IV.1 Structure

The EU ABS Regulation is divided into three main Chapters:

CHAPTER I: subject matter, scope and definitions;
CHAPTER II: user compliance;
CHAPTER III: final provisions.

Chapter I clarifies the nature of the ABS Regulation as a set of rules governing compliance with access and benefit-sharing requirements (if any) for GR and TK associated with such resources. It also describes the scope of the Regulation and provides a list of relevant definitions. For further details, see section IV.2 below.

Chapter II is the core part of the ABS Regulation focusing on the "due diligence" concept. In practice, it enumerates users' obligations for being compliant with local access legislation and benefit-sharing mechanisms, where relevant. Moreover, this chapter clarifies how compliance checks may be conducted at Member State level and defines general criteria for penalties. For further details, see section IV.3 below.

Chapter III contains provisions on cooperation between national competent authorities and with the EC, complementary measures to be adopted by the EC and the Member States to facilitate and boost compliance with the ABS Regulation, committee procedure for the adoption of implementing acts by the EC and the establishment of a consultation forum to discuss issues related to the implementation of the Regulation. Lastly, this Chapter clarifies the report and review procedures to be followed by Member States and the EC[17] respectively, as well as the entry into force of the Regulation.

IV.2 Objectives and Scope

Objectives

[16] 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, OJEU L 275, 20.10.2015

[17] Member States must report to the EC on the application of the ABS Regulation by 11 June 2017 and at five-year intervals after that date. The EC must report to the EU Parliament and Council on the effectiveness of the Regulation one year later and every 10 years after its first report.

The EU ABS Regulation brings the EU in line with the international commitments undertaken through the Convention on Biological Diversity and the Nagoya Protocol, namely the contribution to the conservation of biological diversity and sustainable use of its components and a framework ensuring that GR and TK associated with such resources are accessed in compliance with the provider country's requirements on access and benefit-sharing (if any).

Scope

The EU ABS Regulation applies to GR over which States exercise sovereign rights and to TK associated with such resources that are accessed and used after the entry into force of the Nagoya Protocol for the Union (12 October 2014) and to which access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol are applicable. Articles 4 (obligations of users), 7 (monitoring user compliance) and 9 (checks on user compliance) entered into force one year later, on 12 October 2015.

The requirements of the EU ABS Regulation apply to users of GR and of TK associated with GR, namely to their acquisition (after 12 October 2014) **when and only if combined with R&D activities (utilisation) on the genetic and/or biochemical composition of such GR, including through the application of biotechnology.**

For the EU ABS Regulation to apply, the following cumulative conditions must be met:

- **material scope:** The EU ABS Regulation applies to the utilization of **GR** and/or **TK associated to GR**;
- **geographic scope:** the EU ABS Regulation applies to the utilization **in the EU** of GR and/or associated TK from **Parties to the Nagoya Protocol with access legislation in place**;

- **temporal scope**: the GR must have been accessed on or after 12 October 2014 and after the entry into force of the ABS legislation of the provider country.

The EU ABS Regulation does not apply to GR for which the access and benefit-sharing is governed by specialized international instruments that are consistent with, and do not run counter to, the objectives of the Convention and the Nagoya Protocol[18], e.g. the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

In addition, the EU ABS Regulation does not concern trade and exchange of commodities. As long as no R&D is carried out on commodities entering the EU, the EU ABS Regulation does not apply.

If and when R&D is carried out on commodities in the EU, there is a change in their status as they are no longer commodities but GR, and they become subject to the EU ABS Regulation. In this case, users are expected to contact the provider country and clarify whether PIC and MAT are required. The EC Horizontal Guidance recommends to those who are planning to carry out R&D

[18] See Article 2.2 of Regulation (EU) 511/2014).

on commodities, to access the resources directly from the provider country so that the provenance is clear as well as the applicability of the Protocol[19]/of the EU ABS Regulation.

Note: Human GR are excluded from the scope of the Nagoya Protocol as well as GR obtained from areas beyond national jurisdictions (e.g. high seas)[20].

As regards TK associated to GRs, they must be related to the utilization of GRs and must be covered by the relevant contractual agreements[21].

Please see Annex 1 which provides some theoretical illustrative examples of scenarios that are either in or out of the scope of the EU ABS Regulation and Annex 2 which aims to help clarify the scope of utilisation (R&D) through some theoretical case studies.

IV.3 The central principle: users' obligation to demonstrate due diligence

IV.3.1 Due Diligence Obligations

To ensure the effective implementation of the EU ABS Regulation – and thus of the Nagoya Protocol – all users of GR and TK associated with GR must exercise due diligence to ascertain that GR and TK associated with them have been accessed in accordance with applicable legal or regulatory requirements of the provider country. They must also ensure that, where relevant, benefits are fairly and equitably shared.

The exercise of due diligence involves the collection, retention and transmission to subsequent users of a specific set of information.

IV.3.1.1 Information to be collected, kept and transferred

Users shall exercise due diligence when accessing and utilising GR and TK associated with such resources to make sure that they were accessed and utilised in accordance with the applicable PIC and MAT requirements of the provider country.

In particular, users must seek, keep (for 20 years after the end of the period of use of the GR or of the TK) and transfer to subsequent users the following information[22]:

- the **internationally-recognised certificate of compliance**, as well as information on the **content of the MAT** relevant to subsequent users

or, where the internationally-recognised certificate is not available, information and relevant documentation on:

[19] See the EC Horizontal Guidance, page 7.
[20] See Recital (8) of the EU ABS Regulation.
[21] See the EC Horizontal Guidance, page 7.
[22] See Article 4.3 of the CM-ABS Regulation.

- the **date and place of accessing** the GR or the TK associated with GR;
- the **description** of the GR or of TK associated with GR utilised;
- the **source** from which the GR or TK associated with GR was directly obtained, as well as subsequent users of GR or TK associated with GR;
- the **presence or absence of rights and obligations** relating to access and benefit sharing, including rights and obligations regarding subsequent applications and commercialisation;
- **access permits**, where applicable;
- **MATs**, including benefit-sharing arrangements, where applicable.

As a general rule, a user needs to check that the information in his or her possession is sufficient and does not give rise to doubts about the legality of the access and utilisation. Given that many uncertainties[23] persist in some national legislations, users are advised to document the due diligence process very carefully.

Otherwise, users must either obtain the missing information or discontinue the utilisation of the GR and/or the TK associated with GR.

Suppliers who have performed R&D on the GR should provide their customers who buy the product developed via the utilisation of the GR with a statement of compliance (see Annex 3) indicating that the GR utilised has been legally accessed. If further R&D activity is to be carried out by their customers on the GR, suppliers will transfer the required set of information and documentation as specified above.

Users acquiring a GR from a collection included in the Register of Collections within the EU, referred to in Article 5.1 of the EU ABS Regulation, are considered to have exercised due diligence as regards the seeking of information required under Article 4.3 of this Regulation[24]. Nevertheless, users have to check whether their planned R&D activities are covered by the conditions of use of GR and/or TK described. If this is not the case, users have to exercise their due diligence obligations.

Users also have an obligation to declare to the national Competent Authorities that they exercised due diligence.

[23] "(...) it is widely recognized that the level of national ABS implementation is low and often incomplete. Countries have reached different levels of implementation and have adopted different approaches to regulation, reflecting their national administrative structures, priorities, and cultural and social realities. Some countries have only adopted one measure – generally legislation – while others have adopted a package of measures such as a national strategy, legislation or regulations and guidelines. However, many countries do not have a complete system because legislative or administrative developments at different levels of government (e.g., regional, national/federal and state/provincial level) are ongoing." (CISDL, Swiss Federal Office for the Environment, Overview of national and regional measures on access and benefit sharing: challenges and opportunities in implementing the Nagoya Protocol, third edition, 25 June 2014)

[24] See Article 4.7 of the EU ABS Regulation.

In this context, and where available, national Competent Authorities must accept internationally-recognised certificates of compliance (IRCC) as evidence that the GR covered were legally accessed and that MAT were established for the user and the utilisation specified therein.

The due diligence obligation also requires users, in case the intended use of a GR changes, to seek new (or modify the previous) PIC from the provider country and establish MAT for the new use. If a GR is transferred, this should be done in accordance with the MAT, which may imply the entry into the contract by the transferee.

For further details on users' obligations, please see section V.4 and the flowchart in Annex 4.

IV.3.1.2 Due Diligence Declarations

The EC has provided a web-based application (**DECLARE**) to allow users' submission of Due Diligence Declarations online. The manual for users of DECLARE provides explanations for its use.

IV.3.1.2.1 At the stage of research funding

"Funding for research" means any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources.

Recipients of funding for research (or project coordinators in case the same research project involves more than one recipient or is funded from more than one source) involving utilisation of GR and TK associated with GR, shall make a due diligence declaration to the competent authority of the Member State in which the recipient (or the project coordinator) is established; if the recipient (or the project coordinator) is not established in the EU and the research is conducted in the EU, the due diligence declaration shall be made to the competent authority of the Member State in which the research is carried out.

The declaration shall be made after the first instalment of funding has been received and all the GR and TK that are utilised have been obtained, but no later than at the time of the final report or, in the absence of such report, at the end of the project.

Annex II of the Implementing Regulation provides the template to be used for this declaration.

IV.3.1.2.2 At the stage of final development of a product

The concept of "stage of final development" is defined by the EC in the Implementing Regulation, Article 6. For GR used in the formulation of cosmetic products, this is the moment of the product's notification under Article 13 of the Cosmetic Products Regulation (Regulation (EC) No 1223/2009). For GR used in the development of a cosmetic ingredient, this is the moment when placing the ingredient on the market. Additional situations where the declaration is due include the case where the result of the utilisation is sold or transferred in any other way to a natural or legal person within

the EU in order for that person to notify the product or place the ingredient on the market as well as the case where the utilisation in the EU has ended and the outcome is sold or transferred in any other way to a natural or legal person outside the EU[25].

The declaration shall be made only once, prior to the occurrence of the first of the events described above.

Annex III of the Implementing Regulation provides the template to be used for this declaration.

IV.4 Entry into force and application of the ABS Regulation

The Nagoya Protocol entered into force on 12 October 2014[26].
The EU ABS regulation applies since the entry into force of the Nagoya Protocol for the EU (i.e. since 12 October 2014).

Some of the key obligations applicable within the EU (namely, users' due diligence obligations, monitoring and checks by the competent authorities) only entered into application one year after that date (i.e. on 12 October 2015)[27].

IV.5 Link with national legislation on access and benefit-sharing

The EU ABS Regulation is a general compliance framework depicting: (i) users' due diligence obligation to assess their compliance with national legislation on ABS and (ii) national authorities' monitoring and enforcement of users' due diligence obligations in the EU. This Regulation complements the national legislations which may be established by provider countries detailing specific requirements for access and benefit-sharing.

The list of Parties to the Nagoya Protocol can be found on the Convention's website:
http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml

On this same website, users can find the list of regions and countries which have implemented national access and benefit-sharing measures: http://www.cbd.int/abs/measures/default.shtml
https://absch.cbd.int/ (Access and Benefit-Sharing Clearing House)
https://absch.cbd.int/countries

[25] See Article 6(2) of the Commission Implementing Regulation (EU) 2015/1866 laying down detailed rules for the implementation of Regulation (EU) 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1866&from=EN

[26] See press release dated 14 July 2014 available at: http://www.cbd.int/press-releases/default.shtml
[27] See EC's webpage on access and benefit-sharing available at:
http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

V. PRACTICAL IMPLICATIONS FOR THE COSMETICS INDUSTRY

V. 1 Which cosmetic ingredients are within the scope of the EU ABS Regulation?

The scope of the EU ABS Regulation covers the GR, wild, domesticated or cultivated (plant, animal, microbial), which are utilised in any economic sectors, including food production, forestry, medicine etc., over which provider countries exercise sovereign rights and to which local access and benefit-sharing legislation or regulatory requirements are applicable. The provider country should be a Party to the Nagoya Protocol with applicable access measures.

The cosmetic ingredients concerned are those developed via the utilisation (R&D) of GR and of TK associated with these GR and which have been accessed after the entry into force of the EU ABS Regulation (i.e. after 12 October 2014) from a provider country which is a Party to the Nagoya Protocol and has ABS legislation in place at the time of access.

The identification of ingredients which could be included in the scope of the EU ABS Regulation represents only a first step regarding the applicability of the Regulation and the identification of obligations.

Companies which access (obtain) GR are not considered as users (and therefore do not fall under the scope of the EU ABS Regulation) if:

- these GR are ingredients included in the formulation of cosmetic products without any R&D operations being performed on them
- the GR were accessed before the entry into force of the EU ABS Regulation (i.e. before 12 October 2014) or before the entry into force of the ABS legislation in the provider country.

Derivatives

In the context of the Nagoya Protocol and the EU ABS Regulations, and therefore for the purpose of the present Guidance, a derivative is defined as ''a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resource, even if it does not contain functional units of heredity'' (Art. 2(e) of Nagoya Protocol). Derivatives are therefore understood to be the extraction products of GR or part thereof, or products produced and secreted by GR, like proteins, lipids, enzymes, RNA or organic compounds like flavonoids, oils or resins.

Examples of derivatives which are used in the cosmetics sector are (see also Figure 1):

- From plant: oils from food plants and/or non-food plants: palm oil, palm kernel oil, rapeseed oil, apricot kernel oil, *Aloe vera* gel Juice, essential oils, plant carbohydrates, flavonoids, triterpenoids, saponins, tocopherol, plant extracts (e.g. from green tea, coffee beans, lemon peel, …), plant resins, waxes such as from jojoba, carnauba, vitamins, etc.
- From microorganisms: vitamins, e.g. coenzyme Q10 or biopolymers e.g. polysaccharides, polyesters, and polyamides.
- From animals: wool grease, honey, beeswax, milk, etc.; and

- From marine organisms: algae extract.

In contrast, a material which is the result of a chemical reaction by intentional human intervention is not a "naturally occurring" component and, as a consequence, does not qualify as a derivative within the meaning of the Nagoya Protocol and the EU ABS Regulation. Such ingredients ("chemically modified compounds or extracts") are herein referred to as "synthetics" (see last column of Figure 1).

Some of such synthetics contain both a chemical part and a biological part; generally, these cosmetic ingredients have undergone a chemical reaction, for example, esterification, saponification or acetylation processes. Examples are: methyl esters of plant oils, fatty alcohols, methyl rutin or acetyl eugenol.

Another example could be two separate biological ingredients that are synthetically fused (engineered, combined, etc.) into a new substance. For example, some surfactants illustrate this kind of components, they are called bio-based surfactants such as alkyl polyglycosides which are based on glucose derived from plant starch and fatty alcohol obtainable via chemical synthetic steps from plant oils.

Certain plant species, their harvest, plant oils, molasses and other refinery products, animal by products such as milk, silk, wool grease, beeswax, are traded as commodities. Chemical modification of such basic naturally occurring compounds leads to chemically modified commodities which are not only "modified" but instead must be considered as novel chemical entities called "synthetics", which are solely bio-based but gain their functionality from the chemical synthesis steps. Thus, R&D directed towards such chemically synthesised compounds using bio-based raw materials such as starches and/or oils does not target the genetic or biochemical composition or any property of the GR but instead targets the properties and activities of chemically synthesised molecules.

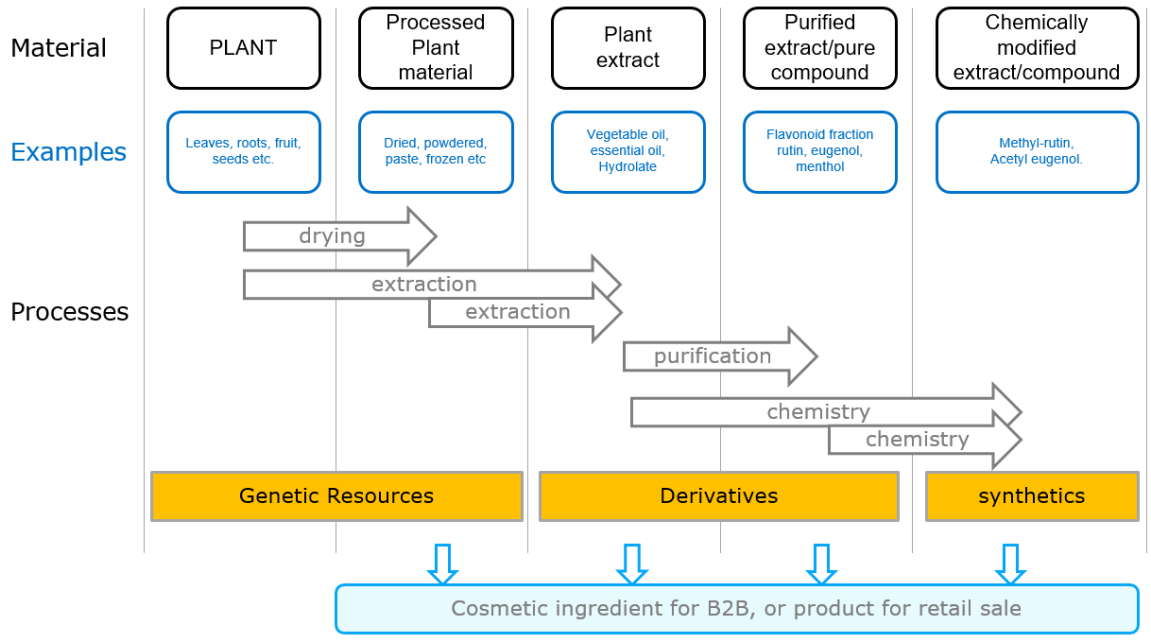

Figure 1: Use of GR, derivatives and synthetics in Cosmetics R&D

Furthermore, all compounds purely derived from the petrochemical industry are likewise not naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources. Thus, such compounds which may be used as synthetic cosmetic ingredients, e.g. carbomers, siloxane, octocrylene, dimethicone, are not subject to the EU ABS Regulation.

The EC Horizontal Guidance provides the EC's interpretation of the conditions upon which derivatives and their utilisation fall in scope of the EU ABS Regulation.

According to the EC Horizontal Guidance, *"access to derivatives is covered when it also includes genetic resources for utilisation, i.e. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained."* The document further elaborates as follows: *« Research and development to be carried out on such derivatives should be addressed in mutually agreed terms that are concluded when accessing the genetic resources themselves. In sum, research and development on derivatives (whether or not containing functional units of heredity) is within scope where they are 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 addressed in mutually agreed terms*[28]*. »*

It is understood that the access to a derivative "combined" with access to the GR from which it is derived refers to an ascertainable level of continuity between the production of the derivative from the GR and the R&D activities conducted on the derivative so obtained, i.e. to the existence of a relationship between the access to the derivative and the access to the originating GR. This however does not necessarily mean that the derivative and the original GR are accessed at the same time and/or by the same actor in the course of such R&D activities.

With this in mind, it is of outmost importance for companies to be in the position to exclude the continuity between the production of the derivative from the GR and the R&D activities conducted on such derivative. For the sake of clarity, an R&D activity on a derivative where no continuity with its production occurs, falls outside the scope of the Regulation.

Where the continuity can be ascertained, the companies should verify whether PIC and MAT exist for a material they access and/or for a material from which a derivative they access is derived, so as to determine whether and the extent to which activities they intend to undertake on the material/its derivative are covered in such documents.
Some examples:

1) R&D operations conducted on a green tea extract freely available on the market leads to a new ingredient by isolation of specific compounds with new properties: out of scope of the Regulation.

[28] See page 9 of EU Guidance document on ABS.

2) Company A has an agreement with Company B to produce a particular flavonoids rich green tea extract originating from India, used by Company A as starting material in an R&D activity to obtain a new active ingredient: in scope of the Regulation; Company A should get PIC and MAT to access green tea GR.

Commodities *(source: the EC Horizontal Guidance)*

Trade and exchange of GR as commodities (such as agricultural, fisheries or forestry products — whether for direct consumption or as ingredients, e.g. in food and drink products) fall outside the scope of the Regulation. The Protocol does not regulate issues related to trade but is applicable only to *utilisation* of GR. As long as there is no R&D on GR (thus no utilisation in the sense of the Protocol — see Section 2.3.3 below), the EU ABS Regulation does not apply.

However, if and when R&D is carried out on GR which originally entered the EU as commodities, the intended use has changed and the new use falls within the scope of the EU ABS Regulation (provided the other conditions for application of the Regulation are also met). For example, if an orange placed on the EU market is used for consumption, this is outside the scope of the Regulation. However, if the same orange is subject to R&D (e.g. a substance is isolated from it and incorporated into a new product), this would fall under the rules of the EU ABS Regulation.

In the case of such changes in the use of what was until then considered as a commodity, the user is expected to contact the provider country and clarify whether requirements to obtain PIC and establish MAT apply to this utilisation of such GR (and if yes, obtain the necessary permits and establish MAT).

If users wish to utilise (in the sense of carrying out R&D) a commodity which is a GR, they might be well advised to access that resource directly from the provider country so that its provenance is clear and the applicability of the Protocol can be clearly established from the outset.

V.2 Am I a user in the meaning of the EU ABS Regulation?

Only "users" (as defined in the ABS Regulation) must comply with the obligations arising from this Regulation.

The simple acquisition of a GR does not necessarily mean that the acquirer has to comply with this Regulation. It is only the utilisation of a GR – i .e. to conduct R&D activities on the genetic and/or biochemical composition of the GR - that makes him/her fall under the scope of this Regulation, and that makes the legal or the natural person who has acquired the GR a "user" according to the EU ABS Regulation.

What does "utilisation" mean?

"Utilisation" means conducting R&D on the genetic and/or biochemical composition of a GR, including through the application of biotechnology. According to the CBD, biotechnology means

"any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".

R&D is not defined in the EU ABS Regulation. A definition is proposed by the cosmetics industry – see section I.1 Definition of terms.

Some examples:

1) R&D operations conducted on shea butter purchased from Mali leads to a new ingredient by isolation of specific compounds with new anti-aging properties, ignored until this time.

2) By means of a new technical procedure, it is possible to extract new anti-wrinkle active ingredients from jasmine essence purchased from Italy.

3) Preparation of an anti-aging extract from the seed of a local plant used as food in Central Africa.

How the term R&D (or utilisation) should be understood in the context of the implementation of the Nagoya Protocol in the EU can be derived from the Frascati Manual. This standard of conduct for R&D surveys in the OECD and the EU, that was recognised in the context of the EC's Framework for state aid for R&D as an authoritative document for the classification of activities, identifies both basic research (research "without a particular application or use in view") and applied research (research aimed at the development of new products and technologies exploiting the findings of basic research) as activities falling within the term R&D.
Furthermore, it has been suggested by Morgera and Geelhoed to interpret the term R&D as "two intimately related processes by which new products and new forms of old products are brought into being through technological innovation".[29]

The EC Horizontal Guidance gives further insights:

Typically, the results of basic research are published and as such they may become the basis for further applied research with commercial relevance. Researchers involved in basic research may not necessarily be aware of it at that stage, but their findings may still turn out to have commercial relevance at a later stage. Depending on the specific activity undertaken, both basic and applied research may be considered as 'utilisation' in the sense of the Protocol and Regulation. Similarly, various types of scientific institutions can be concerned by the Regulation.

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 — e.g. the maintenance and management of a collection for conservation purposes, including storage of resources or quality/phytopathology checks, and verification of material upon acceptance.

[29] Morgera E, and Geelhoed M. 2016. Consultancy on the notion of "utilisation" in the Nagoya Protocol and the EU ABS Regulation for the upstream actors. University of Edinburgh.

Similarly, the mere description of a GR in phenotype-based research such as morphological analysis normally would also not amount to utilisation. However, if the description of a GR is combined with research on that resource, i.e. to discover specific genetic and/or biochemical properties, this would qualify as utilisation in terms of the Protocol and the Regulation. As a type of 'litmus test', users should ask themselves whether what they are doing with the GR creates new insight into characteristics of the GR which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and therefore falls under the term 'utilisation'.

V.3 Which key departments in my company are impacted by the EU ABS Regulation?

As companies are organised in different ways, and also considering that key departments which have an important role regarding the EU ABS Regulation may be named differently, the best way to identify these departments is by defining their activity in the cosmetics field.

The key departments which could be involved are those which have a determinant role from the prospecting, sourcing, and purchasing of GR for the production of cosmetic ingredients and of finished cosmetic products.

These key departments are:

- In the framework of internal development of new ingredients from GR (with internal R&D activities) or in the framework of the activity of purchasing ingredients "ready to use" from suppliers (who subject these ingredients to R&D in order to improve their properties before selling them to the cosmetics industry) those departments which:
  carry out activities of:
  - prospecting for biological materials and new ingredients in the field;
  - sourcing of plants or extracts from local structures and organisations;
  - selecting new ingredients; and/or

  are in charge of:
  - the formulation and homologation of these ingredients;
  - R&D activities;
  - purchasing the quantities needed for the R&D activities;
  - purchasing industrial quantities; and

  Legal / Regulatory departments including Intellectual Property departments.

- In the framework of the purchase of finished cosmetic products from manufacturers/ subcontractors, departments which:
  carry out activities of:
  - sourcing of new finished cosmetic products;
  - selection of new finished cosmetics products; and/or

  are in charge of purchasing;
  Legal / Regulatory departments including Intellectual Property departments, and
  Marketing department (marketing communications / claims).

V. 4 What do I have to do as a user of GR and/or of TK associated with GR?

V.4.1 Steps to take **before** accessing GR and TK associated with GR

Context: the user has identified a GR or TK associated with the GR on which he or she would like to start R&D activities.

V.4.1.1 Identify the provider country for each GR and associated TK and the date of access

GR may be sourced from own collections (the information regarding the provider country and the date of access is in your possession), from the provider country (also in this case, the information regarding the provider country and the date of access is in your possession), from third party suppliers (in this case, you must ask for the information) or from collections registered in the European Register of Collections (the information will be communicated to you).

Users acquiring a GR from a collection included in the Register of Collections within the EU, referred to in Article 5.1 of the EU ABS Regulation, are considered to have exercised due diligence as regards the seeking of information required under Article 4.3 of this Regulation[30]. Nevertheless, users have to regularly check whether their planned R&D activities are covered by the conditions of use of GR and/or TK described. If this is not the case, users have to exercise their due diligence obligations.

V.4.1.2 Check whether the provider country is a Party to the Nagoya Protocol and whether there are any national access and benefit-sharing legislation or regulatory requirements

Depending on the provider country of the GR or of the associated TK, national access and benefit-sharing legislation or regulatory requirements may exist.

The list of Parties to the Nagoya Protocol can be found on the Convention's website:
http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml

On this same website, users can find the list of regions and countries which have implemented national access and benefit-sharing measures: http://www.cbd.int/abs/measures/default.shtml
https://absch.cbd.int/ (Access and Benefit-Sharing Clearing House)
https://absch.cbd.int/countries

[30] See Article 4.7 of the EU ABS Regulation.

These laws or regulatory requirements must be identified and complied with. The due diligence obligation in the EU ABS Regulation essentially aims to ensure that users check their obligations when accessing and using GR and/or associated TK, and that they are able to demonstrate compliance with legal or regulatory requirements of the provider country.

V.4.1.3 Identify the national Competent Authority (CA)

National Competent Authorities of provider countries can be found through the following link (go to Parties, click on country): http://www.cbd.int/abs/measures/default.shtml

V.4.1.4 Obtain PIC and establish MAT

Once identified, work with the national Competent Authority of the provider country to check how to comply with any national legal or regulatory requirements on access and benefit sharing.

If you access the GR and/or associated TK directly from the provider country, you must obtain a PIC from the national competent authority and establish MAT; if you obtain the GR and/or associated TK from a third party (you are a subsequent user), check if the PIC and MAT or the internationally-recognised certificate of compliance cover your use of the GR and/or TK.

In their absence, obtain from the provider country PIC and establish MAT, as and where required by applicable legislation or regulatory requirements.

Where there is no internationally-recognised certificate of compliance, you may ask the provider country from which you obtained the PIC to convert it into an internationally-recognised certificate of compliance. Note, however, that the internationally-recognised certificate of compliance may involve confidentiality issues as your PIC will be made public.

Because users are typically part of a complex supply chain, users who access GR are encouraged to anticipate the involvement of subsequent users in the supply chain, to ensure that the PIC and MAT explicitly address the rights and responsibilities of these subsequent users (i.e. parties that did not directly contract with the provider country) and to transfer such PIC and MAT to them.

Subsequent users should undertake reasonable due diligence to ensure that for all GR incorporated into their final product that fall within the scope of the EU ABS Regulation:

- the user provides the internationally-recognised certificate of compliance of the GR or written documentation of PIC and confirmation of MAT as well as any additional information and documentation required by the EU ABS Regulation (see section III.1);
- the PIC and/or the MAT authorises the subsequent utilisation of the GR. If this is not the case, the subsequent user will have to request new PIC and / or negotiate new MAT with the provider country.

Examples of terms and elements typically included in MAT are listed in Annex 5.

Users who obtain GR or associated TK from collections in the voluntary EU Register of Collections [to be set up by the EC] are considered as having exercised due diligence as regards the seeking of all necessary information.
If the Terms and Conditions under which the Collection obtained the GR do not cover the users' utilization, they must request PIC and establish MAT.

If a provider country has not established requirements for PIC and/or MAT, users should keep a record of the following information:

- date and place of access of the GR and/or associated TK
- description of the GR and/or associated TK
- source from which the GR and/or associated TK have been obtained.

V.4.2 Steps to take **after** accessing GR and TK associated with GR

Context: the user accessed the GR and obtained PIC and MAT from the provider country and/or a copy of the internationally-recognised certificate of compliance. The user decides to perform R&D on the GR. At this point, he or she must keep the required information (see below) and be ready to transfer it at the appropriate time.

V.4.2.1 Keep the set of required information

See the set of required information in Section IV.3.1.1 above.

This information is to be kept for 20 years after the end of the period of utilisation.

Other relevant records include, but are not limited to:

- records of any storage, transportation or physical movement of the GR;
- records regarding any utilisation of the GR before the entry into force of the EU ABS Regulation.

Users should be prepared to share such records, provided that adequate protection is provided for confidential business information, with national Competent Authorities of third countries assessing compliance of a product to be introduced into their market with the requirements of the Nagoya Protocol and of the provider country.

Users should take all reasonable steps to prevent the disclosure of information provided in confidence by a member of an indigenous or local community and handle such information in accordance with the terms specified by the community that has provided the information, which should be included in the Agreement where possible.

V.4.2.2 Declare the exercise of due diligence:

See section IV.3.1.2 above.

From a practical point of view:

Every time a user is interested in a GR, he/she must:

- ✓ make contact with the Competent Authority of the relevant provider country in order to acquire knowledge of the access conditions;
- ✓ (where required under local law of the provider country), obtain PIC and sign MAT in order to obtain access rights to the GR. (depending on the provider country, different ways of compensation could be accepted in the framework of the MAT agreement);
- ✓ fulfil the obligations contained in the MAT, depending on the nature of the project (research only, or commercial use).

If the company itself is not considered as a "user", but it purchases GR from a supplier who is considered as a "user":

- ✓ even though in strict application of the EU ABS Regulation, it is not supposed to meet the users' obligations, in order to respect the "spirit" of this Regulation, it is important to check that the supplier, in case it has carried out R&D operations on GR, is entitled to perform these activities and owns a recognised certificate of compliance. The supplier could be asked to transmit the following pieces of evidence to the client (cosmetic product manufacturing company):
  - a statement of compliance indicating that the GR utilised has been accessed legally; if further R&D activity is to be carried out by the client on that GR, suppliers will transfer the required set of information and documentation, as specified in section V.4.1.

V.4.2.3 Ensure fair and equitable sharing of benefits

Users who enter into an Agreement with a provider country who has adopted national legal or regulatory requirements on benefit-sharing should ensure fair and equitable sharing of benefits resulting from the anticipated use of the GR and/or of associated TK.

Users will also have to check whether the national requirements prescribe any specific form of benefit-sharing and abide by it.

The terms of the agreed benefit sharing, including its applicability to third parties, new uses, or changes in intent, should be included in the written Agreement.

Timing of benefits:

The time-frame of benefits should be considered on a case by case basis and should definitely be stipulated and be explicitly limited in time (to be negotiated in MAT).

Types of benefits:

These may include, but are not limited to those detailed in the Annex to the Nagoya Protocol entitled "Examples of Monetary and Non-Monetary Benefits" (see Annex 6 to this document)

V.4.2.4 Transfer to subsequent users the required information

See the required information in Section IV.3.1.1 above.

V.4.3 Traceability system to be put in place

Context: having a traceability system in place is fundamental in order for the company to be able to prove its compliance.

To facilitate your due diligence obligations, as a user you should:

- establish an inventory of your GR / TK portfolio including the dates of access;
- keep records of any R&D activities and date of access of the GRs concerned;
- ensure the awareness and involvement of relevant departments in your company: R&D, Legal, Procurement/Purchasing, Regulatory/Government Affairs, Finance, marketing/PR, Import/Export, Corporate Social Responsibility/External Relations etc.;
- ensure that subsidiaries of your company are aware of national legal and regulatory requirements on access and benefit-sharing.

A flowchart illustrating the compliance with the due diligence process is included in Annex 4.

V.5 What penalties apply in case of non-compliance?

Penalties are established at EU Member State level. Pursuant to Article 11 of the EU ABS Regulation, they must be “effective, proportionate and dissuasive”.

EU ABS Regulation
Guidance Document for the Cosmetics Industry **Annex 1**

Examples of conditions for the applicability of the EU ABS Regulation

Notes:
(1) it is assumed that R&D activities are performed in EU
(2) national legislations are potentially subject to change; companies should check these regularly, on a case by case basis
(3) this annex should be used together with the flowchart illustrating the due diligence process (Annex 4)

Ex n°	Genetic Resource (GR) / Traditional Knowledge (TK)	Provider Country	Date of Access	Provider Country is Party to the Nagoya Protocol at the date of access	ABS national law regulating access to GR in place on date of access in the provider country	Scope of activities vs R&D definition	IN or OUT of the scope of the EU CM-ABS Regulation						Comments
							OUT (not a GR / TK)	OUT (because of date of access)	OUT (provider country not Party to the Nagoya Protocol)	OUT (no ABS national law existing in provider country at the date of access)	OUT (no R&D activity)	IN	
1.	Cone flower (Echinacea purpurea) root water extract for skin moisturization (GR)	USA	15 Nov. 2014	No	No	Safety tests			X	X	X		OUT because the USA are not Party to the Nagoya Protocol and have no national ABS legislation and no R&D is performed on the GR
2.	Great yellow gentian (Gentiana lutea) flower aquous extract (GR)	Switzerland	26 May 2015	Yes	Yes (since 1.02.2016)	New skin benefit eg antioxidant				X			OUT because accessed before the entering into force of the national access legislation 1 February 2016
3.	Acai Oil (Euterpe oleracea) (GR)	Brazil	30 June 2015	No	Yes	Hair texture benefit shampoo and conditioner			X				OUT because Brazil is not a Party at this date. But must comply with national legislation.

4.	Coleus (Coleus ssp.) (GR with associated TK)	India	02-Apr-15	Yes	Yes	Cosmetic use for ayurvedic plant						X	IN because date of access is after 12 October 2014 and must comply with national Indian regulations of NBA (National Biodiversity Authority)

5.	Wild lavender flower (Lavandula angustifolia) (GR)	USA	20-Nov-14	No	No	Scalp soothing properties			X	X			OUT because the USA are not Party to the Nagoya Protocol and have no national ABS legislation
		then switch to Spain	18 July 2016	Yes	Yes	Yes						X	IN because R&D activity is performed on the GR sourced in Spain
6.	Patchouli (Pogostemon cablin) (GR)	Indonesia	28 June 2015	Yes	No (but draft law in preparation)	Only extraction, distillation for incremental quality improvement				X	X		OUT, because no national ABS legislation and the activities performed are not R&D
7.	Rooibos fruit (Aspalathus linearis) (GR)	South Africa	1 Dec 2008	Yes	Yes	Dry well known process		X			X		OUT because date of access is before 12 October 2014 and there is no R&D but must comply with South African law which requires bioprospecting permit, PIC and MAT for uses other than tea.
8.	Orange fruit oil (Citrus sinensis) (GR)	Mexico	11 May 2005	Yes	Yes	Included in the formula of an anti-wrinkle cream for its fragrance properties		X	X		X		OUT because date of access is before 12 October 2014 and there is no R&D. But must comply with national ABS legislation
9.	Wild rose petals (Rosa sp.) (GR)	France	15 June 2017	Yes	Yes	New hair care properties						X	IN + must comply with French Law
10.	Argan Oil (Argania spinosa) (TK)	Morocco	10 July 2015	No	No	Introduced in skin care formula			X	X	X		OUT because Morocco is not a Party and does not have national ABS legislation
11.	Unidentified species from family Rubiaseae (GR)	Peru	10 March 2015	Yes	Yes	Find and developped novel essential oil for use in cometics.						X	IN - It is a GR native to Peru accessed after 12 october 2014 and R&D is performed on it. Must also comply with national legislation (PIC and MAT).

12.	Use of Orchidaceae in local washing practice (TK)	India	10 May 2015	Yes	Yes	Research to find and develop new actives						X	IN - accessed after 12 october 2014 and R&D is performed on it. Must also comply with national Indian regulations of NBA (National Biodiversity Authority)
[1] Genetic resource													
[1] Free access to the GR; minimum information to be kept for 20 years after the end of utilisation (proof of origin, purpose of research, date of access)													
[1] Prior Informed Consent													
[1] Mutually Agreed Terms													

Annex 2

Case Studies focusing on Research & Development (R&D) activities that are either or not considered as 'utilisation' in the meaning of the EU ABS Regulation

1. Sourcing

Case 1

Title	**Sourcing plant materials for the purpose of obtaining novel cosmetic ingredients**
Description	Whole plants, plant parts or their seeds (of cultivated or wild species) are imported directly from a farmer or via a wholesaler from a country which is a Party to the Nagoya Protocol by a cosmetic (ingredient) company; several aqueous or oil-based extracts are produced to search for certain new (bioactive) extracts. Optionally, new (bioactive) compounds are identified. The extracts or naturally occurring compounds are developed as new ingredients for cosmetic products.
Analysis	Whole plants, plant parts or their seeds are genetic resources. These are used to produce extracts (derivatives), which are studied for their biochemical composition. Access to those derivatives is therefore combined with access to the genetic resources form which they are derived. The genetic resources and the derivatives are the subject of research and development, and therefore these activities constitute utilisation in the meaning of the EU ABS Regulation.

Case 2

Title	**Sourcing plant materials for the purpose of obtaining improved cosmetic ingredients**
Description	It is known from published literature that blueberries are rich in vitamin A, C and E. An ingredient supplier wishes to identify a blueberry variety with a significantly higher level of vitamin A, C and E. It is not known where to source such blueberries and how the vitamin content varies with blueberry varieties. The ingredient supplier purchases samples from wild and cultivated blueberry plants from different countries, including from countries which are Parties to the Nagoya Protocol), and conducts research on the biochemical composition of all received samples in order to select the best source for the improved cosmetic ingredient.

Analysis	Blueberries are plant genetic resources. Since some of them are purchased from a country which is a Party to the Nagoya Protocol (i.e. accessed) and their biochemical composition is studied in order to obtain an improved cosmetic ingredient constitutes utilisation, such activity qualifies as utilisation in the meaning of the EU ABS Regulation.

Case 3

Title	**Sourcing plant materials for novel fragrances**
Description	Whole plants, plant parts or their seeds (from cultivated or wild species) are imported directly from a farmer or via a wholesaler from a country which is a Party to the Nagoya Protocol by a fragrance company; for the first time, new essential oils are extracted in a search for certain new fragrance ingredients. Volatile compounds are identified.
Analysis	Whole plants, plant parts and their seeds are plant genetic resources. The extraction of essential oils and volatile compounds (which are derivatives) and the study of their biochemical composition and properties constitute utilisation of the genetic resource in the meaning of the EU ABS Regulation.

Case 4

Title	**Obtaining and using associated Traditional Knowledge (associated TK)**
Description	A cosmetic ingredient supplier meets with a local community located in a country which is a Party to the Nagoya Protocol to discuss which plants they use for wound healing. The indigenous community provides information in combination with plant seeds and/or leaf samples of the wound-healing plant species; the company uses the plant species and the knowledge on the wound-healing effects to develop a new cosmetic ingredient with skin-firming properties.
Analysis	The company accesses the genetic resources and the associated TK from a country which is a Party to the Nagoya Protocol. The use of the plant as well as the associated knowledge on its wound-healing effects in R&D activities to find a new cosmetic ingredient constitute utilisation. In addition to the conditions for access to the plant, the usage of the associated TK has to be incorporated in the

	mutually agreed terms covering the utilisation of the accessed genetic resources.

Case 5

Title	**Sourcing plants from an intermediary, based in a country which is not a Party to the Nagoya Protocol**
Description	Plant seeds are acquired for the purpose of conducting R&D from an entity in a country which is not a Party to the Nagoya Protocol that itself obtained the plant seeds from an entity in a country which is a Party to the Nagoya Protocol.
Analysis	The sourcing of plant material in view of its utilisation from an intermediary in a country which is not a Party to the Nagoya Protocol can still constitute access to the genetic resource i.e. when the access in the country which is a Party to the Nagoya Protocol took place after the entry into effect of the Nagoya Protocol and the national legislation in said country. To the extent that R&D activities are foreseen on that genetic resource, the actor should exercise due diligence to determine the country of origin of the plant and the potentially applicable national ABS legislation. The actor may have to obtain PIC and MAT from the country of origin. R&D activities on such materials constitute utilisation in the meaning of the EU ABS Regulation.

Case 6

Title	**Sourcing of plant materials from the market for the purpose of improving a cosmetic ingredient**
Description	Grapes are available on the market and have since long been used as a cosmetic ingredient for their anti-aging skin care activities. The cosmetic ingredient supplier producing the cosmetic ingredient sources grapes from various origins to investigate their biochemical composition in order to improve its cosmetic ingredient.
Analysis	Whereas the grapes were traded as commodities, they were obtained to study their biochemical properties (other than the known anti-aging skin care activities). Their acquisition for this purpose qualifies as access to genetic resources, and the study of their biochemical composition towards an improved cosmetic ingredient, e.g. a more active version of the cosmetic ingredient with additional functionality, constitutes utilisation in the meaning of the EU ABS Regulation. The actor is required to fulfil his due

	diligence obligations and to undertake a search for the country of origin of the accessed grapes in order to obtain PIC and MAT.

Case 7

Title	**Sourcing an essential oil in combination with access to the plant from which it is derived**
Description	A plant is harvested by company A based in a country which is a Party to the Nagoya Protocol, in order to obtain through performing R&D a new essential oil, at the specific request of a fragrance company B in the EU. Company A produces the essential oil. This essential oil is purchased and imported by fragrance company B, and further R&D activities are performed by Company B.
Analysis	The plant (a genetic resource) is accessed by company A to perform R&D to obtain a new essential oil which constitutes not a genetic resource but a derivative. Although the EU-based company B does not access the genetic resource itself but a derivative thereof, there is a continuum in the activities conducted by both companies, from the access to the GR and the production of the derivative by company A to the further R&D activities performed in the EU by company B. This continuum is evidenced (in the present case) by the specific request placed by Company B on Company A to produce the derivative. In such case, access to the derivative is combined with access to the genetic resource from which it was obtained, and the R&D activities conducted by the fragrance company B constitute utilisation.

Case 8

Title	**Importing natural compounds used as ingredients for production**
Description	Isolation and identification of bio-active compounds obtained from a locally accessed genetic resource is performed by a research institution based in a country which is Party to the Nagoya Protocol. As a next step, a local company in the same country extracts these bio-active naturally occurring compounds from the plant. These compounds are then imported by a cosmetics producer into the EU in the form of cosmetic ingredients. The cosmetics producer uses the cosmetic ingredient in the form in which it has been purchased to prepare formulations. The cosmetics producer then offers the finished cosmetic product for sale to wholesalers.
Analysis	The cosmetic producer based in the EU acquires biological material which he uses for product formulation without

	performing R&D on the genetic and/or biochemical composition of the genetic resource. The activity of the cosmetic producer based in the EU does not constitute R&D and therefore it does not constitute utilization in the meaning of the EU ABS Regulation.

Case 9

Title	**Sourcing of biochemical compounds**
Description	Plants are harvested in a country which is a Party to the Nagoya Protocol. The isolation and chemical modification of plant constituents is done by a local company in the provider country, for commercialisation (export) purposes of the synthetic compounds. These synthetic compounds are imported into the EU by a cosmetics company, and further modified (e.g. hydrogenated) for use as new cosmetic ingredients.
Analysis	The materials acquired by the EU company are synthetic compounds which are produced by chemical synthesis. Although a derivative is used as a starting material, those compounds do not constitute a naturally occurring compound (i.e. that could occur in a natural manner, without special intervention). These are, therefore, neither genetic resources nor derivatives. In addition to that, those compounds have not been acquired in combination with an access to any genetic resources or a derivative thereof. Any further chemical modifications of those synthetic compounds are considered not to constitute utilization in the meaning of the EU ABS Regulation.

Case 10

Title	**Sourcing of orange oil available on the market**
Description	Orange oil is acquired by a fragrance company on the market, for further use as the subject of a research program in the EU.
Analysis	The fragrance company sources the orange oil from the market where it is traded as a commodity. The orange oil is considered to be a derivative, but the fragrance company does not source this derivative in combination with access to the genetic resources from which it is derived. Indeed, there is no relationship between the production of the essential oil and its placing on the market on the one hand, and the research programme on the essential oil conducted in the EU on the other hand. Therefore, the research and development activities performed on the essential oil do not qualify as utilisation in the meaning of the EU ABS Regulation.

Case 11

Title	**Sourcing of a plant without using the available associated traditional knowledge**
Description	According to an indigenous community a plant can be used as traditional anti-cancer medicine. The plant is imported by a cosmetic company from Mexico. The company extracts a new compound from the plant and uses the compound as a new fragrance molecule.
Analysis	The plant genetic resource has been accessed for R&D purposes and a new cosmetic ingredient has been identified. Identifying the extracted compounds and establishing a new use for them constitutes R&D on the biochemical composition of the genetic resource as the compounds are directly derived from the metabolism of the plants and thus utilisation of the genetic resource. However, the associated traditional knowledge is not used by the company in the framework of its research and development. Consequently, no utilization of associated traditional knowledge has taken place in the meaning of the EU ABS Regulation.

Case 12

Title	**Synthesis of a cosmetic ingredient based on the use of published information**
Description	A cosmetic company synthesizes compounds based on structural information from a scientific journal wherein it is stated that those compounds had been isolated from a plant.
Analysis	The company never physically acquired the genetic resource or its derivatives within the meaning of the EU ABS Regulation and the information used is in the public domain. The synthesis of a cosmetic ingredient did not require access to a genetic resource or its derivative and therefore this activity does not constitute utilisation in the meaning of the EU ABS Regulation.

2. Characterising

Case 13

Title	**Identification and storage**

Description	Plant seed or microbial samples thereof are obtained from a country which is a Party to the Nagoya Protocol. After regular quality, viability and/or sanitary checks have been carried out, these samples are stored. Furthermore, taxonomic classification is carried out. In the study of taxonomic relationships DNA sequencing and other genetic tools such as molecular markers are increasingly applied.
Analysis	Morphological description for the purpose of describing and analysing genetic diversity and taxonomic relationships is increasingly replaced by molecular genetic methods. The mere description of a genetic resource by morphological and genetic characterization does not amount to utilisation in the meaning of the EU ABS Regulation. However, if the description of a genetic resource is combined with research on that resource, i.e. to discover specific genetic and/or biochemical properties, this would qualify as utilisation. As a type of 'litmus test', users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of potential benefit to the further process of product development. If this is the case, the activity itself should be considered utilisation.

Case 14

Title	**Phenotypic characterisation that proves to be a crucial tool for R&D**
Description	A cosmetic company carries out sequencing of a new organism accessed from a country which is a Party to the Nagoya Protocol, for the purpose of taxonomic classification. Analysis of the DNA sequence reveals the presence of novel and potentially useful proteins. This finding results in the use of an extract of the genetic resource or in the purification of a protein from the organism, or in the use of the organism itself, to develop novel cosmetic ingredients.
Analysis	Taxonomic identification is followed by DNA sequence analysis for the purpose of discovering novel genetic sequences and/or biochemical properties which create new and useful insight into the potential use of the genetic resource. If the cosmetic company decides to develop a product on the basis of the new property, such activity would qualify as utilisation in the meaning of the EU ABS Regulation.

Case 15

Title	**Characterising plant materials from local markets**
Description	A perfumer visits a local market and smells different kinds of flowers for inspiration for the purpose of creating a new perfume. He purchases a bunch of a particular type of flower which he brings to his laboratory for further analysis to determine the chemical composition for the purpose of using that knowledge to assist in the creation of a new perfume.
Analysis	Because the perfumer purchases the flowers, he accesses genetic resources. The R&D conducted on the flowers constitute utilization of the GR in the meaning of the EU ABS Regulation. The perfumer should fulfil his/her due diligence obligations and undertake to identify the country of origin of the flowers and, once positively identified, request PIC and MAT from the country of origin of the flowers. By contrast, if the flowers are not purchased or collected, no acquisition takes place. Consequently, there is no "access" if the perfumer relies only on his imagination and skills to create his perfume. The smelling of the flowers in such conditions would not constitute utilisation in the meaning of the EU ABS Regulation.

3. Processing

Case 16

Title	**Preparing new extracts and/or purifying new compounds as potential novel cosmetic ingredients**
Description	Whole plants, plant parts or their seeds (cultivated or wild species) are imported by a cosmetic (ingredient) company; several aqueous, solvent and/or oil-based extracts are prepared to search for certain new (bioactive) extracts. New (bio-active) naturally occurring compounds are purified from promising extracts. The extracts and/or naturally occurring compounds are investigated for the use as new cosmetic ingredients.
Analysis	The extraction and purification provides new extracts and novel naturally occurring compounds, respectively, both of which are considered to be derivatives. The extracts and the purified

	compounds therefrom come from the metabolism of the genetic resource and thus this investigation of the biochemical composition of a plant genetic resource in order to evaluate the potential of its derivatives as new cosmetic ingredient constitutes utilisation in the meaning of the EU ABS Regulation.

Case 17

Title	**Preparation of novel essential oils to find new fragrance ingredients**
Description	Whole plants, plant parts or their seeds (cultivated or wild species) are imported by a fragrance company; new essential oils are produced by solvent extraction for the first time to search for certain new fragrance ingredients. Volatile compounds are purified and identified.
Analysis	The extraction and purification of new essential oils and new volatile compounds, respectively, from a genetic resource, and the evaluation of their potential as new fragrance ingredients constitutes R&D on the biochemical composition of the plant genetic resource. Thus, this activity is considered utilisation in the meaning of the EU ABS Regulation.

Case 18

Title	**Processing of raw materials for production**
Description	Plant genetic resources are accessed in a country which is a Party to the Nagoya Protocol. These materials are processed (e.g. extracted) to obtain known extracts, such as Aloe Vera, Shea nut or butter, and baobab extracts, or rose essential oils. A known biochemical compound is purified from such an extract, for example rutin. The properties of the extracts are already known, and so is the biochemical compound isolated from the extract. Extracts and/or purified biochemical compounds are marketed and/or further processed by third parties. Often those processed materials are sold to downstream actors prior to incorporation into cosmetic products.
Analysis	Supply and processing of relevant raw materials for subsequent incorporation in a product where the properties of the biochemical compound contained in the genetic resources are already known and no research and development creating new insight into the genetic and/or biochemical composition of the

	genetic resource is carried out. Thus, these activities are not considered utilisation in the meaning of the EU ABS Regulation.

Case 19

Title	**Preparation of a formulation prototype**
Description	Ginseng extracts are known for their many cosmetic properties, one of which is the anti-oxidative effects. A producer of finished cosmetic products obtains the Ginseng extract from an ingredient supplier and confirms the anti-oxidant efficacy of it in various prototype formulations to finalise a new finished cosmetic product formulation.
Analysis	The properties of the derivative Ginseng extract contained are already known. Newly combining ingredients with well-known properties does not require research and development on the genetic and/or biochemical composition of the genetic resource and therefore these activities do not constitute utilisation in the meaning of the EU ABS Regulation.

4. Synthesising

Case 20

Title	**Use of bio-based sucrose and coconut oil to develop novel bio-based surfactants**
Description	R&D is targeted towards novel cosmetic surfactants with improved characteristics such as mildness on skin and hair, foaming behaviour and compatibility with other surfactants. Alkyl polyglycosides are found to have all these advantageous properties. Alkyl polyglycosides can be synthesized from known fatty alcohol and glucose or polymerised glucose such as starch. Fatty alcohols can be obtained from coconut or palm kernel oil via transesterification followed by hydrogenation while glucose and starch can be derived from various plant sources (e.g. corn, potato or wheat).
Analysis	Alkyl polyglycosides, and many other synthetic molecules used in the cosmetics sector, are based on biological raw materials but gain their functionality from the chemical synthesis steps. They are prepared from the derivative glucose and starch which are well characterised commodities. Another necessary component for the synthesis, the fatty alcohol is an already known synthetic compound that is

	produced by chemical synthesis from the biological raw material palm or coconut oil which are considered to be derivatives. In these activities, R&D is directed towards the synthesis of synthetic compounds and the characteristics thereof. No R&D is performed on the genetic and/or biochemical composition of the genetic resources from which the biological raw materials were originally derived from. Therefore such R&D activities are not constituting utilisation in the meaning of the EU ABS Regulation.

Case 21

Title	**Synthesising novel cosmetic ingredients**
Description	A company A produces from plants certain materials or compounds in the country where the plant material is accessed and commercialises them as biological raw materials. The company A exports these raw materials (often in bulk quantities). These materials or compounds are imported into the EU by a cosmetics company, to produce by known processes a synthetic molecule e.g. by hydrogenation. Then, the cosmetics company characterises this synthetic compound for use as novel cosmetic ingredient.
Analysis	Company A prepares certain biological raw materials or compounds which can be regarded as derivatives and markets them as biological raw materials for production purposes. The additional modifications done in the EU are not utilisation since the hydrogenation entails no R&D and the further characterisation (R&D) is conducted on compounds that are not derivatives (naturally occurring biochemical compounds) and does not target the genetic and/or biochemical composition of the genetic resources in the meaning of the EU ABS regulation. Thus, these activities do not constitute utilisation in the meaning of the EU ABS Regulation.

5. Testing

Case 22

Title	**Conducting efficacy tests as part of R&D**
Description	A plant was imported from a country which is a Party to the Nagoya Protocol into another country which is not a Party to the Nagoya Protocol. An extract was obtained from the plant and was characterised by performing research in the country

	not being a Party. As a continuation of those studies, additional efficacy tests have been performed to provide new insights into the characteristics of the extract in the EU.
Analysis	The above-described efficacy tests in the EU provide new insights into the genetic and/or biochemical composition of the plant genetic resource and are part of the development of a cosmetic ingredient; R&D takes place on the extracts considered as derivatives from the accessed plants; therefore, the R&D activities carried out in the EU constitute utilisation in the meaning of the EU ABS Regulation.

Case 23

Title	**Conducting safety tests in research and development**
Description	A safety test is carried out on a plant imported into Europe from a country which is a Party to the Nagoya Protocol to assess the non-toxicity of its components. Such a safety test is not taking place on the end-product of research and development, which is ready for marketing.
Analysis	If a safety test is carried out to assess the non-toxicity of a new ingredient, the result can be the starting point of utilization within the meaning of the EU ABS Regulation. As a type of 'litmus test', users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of potential benefit to the further process of product development. If this is the case, the activity itself should be considered utilisation.

Case 24

Title	**Analysis of the mode of action**
Description	Grapes are available on the market and are used as a cosmetic ingredient for their anti-aging skin care activities. The cosmetic ingredient supplier producing this ingredient investigates potential molecular modes of action, i.e. the way the human tissue responds (e.g. the modulation of Versican expression on human fibroblasts, the inhibition of specific human proteinases or the induction of lysyl oxidase expression in keratinocytes) of the cosmetic.
Analysis	The human tissue is not subject of the EU ABS Regulation because it is of human origin. Nonetheless, the identification of the mode of action in response to the grape material

	constitutes utilisation of the grape genetic resource in the meaning of the EU ABS Regulation.

Case 25

Title	**Testing performed by a subcontractor on behalf of a cosmetics company**
Description	Dried plants (of cultivated or wild species) are imported directly from a farmer or via a wholesaler from a country which is a Party to the Nagoya Protocol by a cosmetics company. The plant material is transferred by the cosmetics company to a subcontractor. The subcontractor is requested to identify new bioactive extracts and/or isolated compounds for and on behalf of the cosmetic company. The production of extracts and/or search for active extracts and/or naturally occurring compounds is performed by the sub-contractor of the cosmetics company.
Analysis	The activities of the sub-contractor of the cosmetic company constitute utilisation in the meaning of the EU ABS Regulation, and therefore the subcontractor is required to fulfil the due diligence obligations in the framework of the EU ABS Regulation. Only if the terms of the contractual relationship between the cosmetics company and the subcontractor explicitly determine that the person who shall fulfil the due diligence obligations if the conditions set out by the EU ABS Regulation are met is the cosmetics company, then the cosmetics company may fulfil the due diligence obligations on behalf of the subcontractor. In particular, in case where the sub-contractor acts on behalf of a cosmetic company and has no ownership on the genetic resources nor the results of the R&D activities he/she shall execute for the cosmetic company, the parties may decide that the due diligence obligations shall remain with the cosmetics company.

Case 26

Title	**Development of a novel test system**
Description	A research institute located in the EU develops a new *in vitro* test (also often called target test) for a specific cosmetic effect based on a plant cell line acquired from a country which is a Party to the Nagoya Protocol, and supplies the test to other institutions and companies in the EU.
Analysis	The activity of the research institute studies the genetic and/or biochemical composition of the plant cell line. Thus it

	constitutes utilisation of genetic resources (here, the plant cell line) in the meaning of the EU ABS Regulation. The supply of this test system to other institutions and/or companies in the EU may be considered to be the checkpoint at which the due diligence declaration is to be submitted. Once the test has been supplied, its use by a cosmetic manufacturer that has purchased the test would not be considered utilisation of the plant cell line used to develop the test in the meaning of the EU ABS Regulation, as no further R&D is done on the genetic and/or biochemical composition of the plant cell line.

Case 27

Title	**Confirmation of properties/quality and identity checks**
Description	The cosmetic properties of plants, their extracts and/or a biochemical compound purified from it are known and the plant extracts are sold by a company to a manufacturer of finished cosmetic products. During the entire life cycle of a finished cosmetic product, the cosmetic producer runs tests to check the quality of the input materials e.g. by confirmatory tests of already known properties and characteristics and/or to check if extracts are not counterfeited or altered, without the intention of seeking or finding new properties.
Analysis	As the properties of the genetic resource and its derivatives are already known and no new properties are sought, these identity and quality check activities do not constitute utilisation in the meaning of the EU ABS Regulation.

Case 28

Title	**Toxicological studies to fulfil regulatory requirements**
Description	In order to put it on the EU market as cosmetic ingredient, a plant extract has to be tested for mutagenicity by the OECD method 471 Bacterial Reverse Mutation Test requested by the SCCS (Scientific Committee on Consumer Safety) guidance (9th revision) according to the EU regulation on cosmetics.
Analysis	These regulatory required testing activities on the cosmetic ingredient before it is placed on the market do not create any new insight into the properties of the plant extract (confirmation of absence of mutagenicity) and do therefore not constitute utilisation in the meaning of the EU ABS Regulation.

Case 29

Title	**Use of research tools to understand cellular processes**
Description	A green-to-red photo switchable fluorescent protein derived from an *Octocorallia* species accessed from a country which is a Party to the Nagoya Protocol is purchased from a commercial vendor and used in Europe as a tool for tracking dynamics of a cosmetic ingredient and monitoring selective cell fate.
Analysis	In this activity, the protein derived from a genetic resource is an R&D tool; the R&D activities are carried out with, and not on the genetic resource or its derivatives, and so this is not utilisation in the meaning of the EU ABS Regulation.

Case 30

Title	**Applying a genetic resource as a reference to validate an *in vitro* test model for anti-aging activity**
Description	A test for measuring the activity of a cosmetic ingredient is developed on the basis of a commercially available human proteinase. It is validated with a plant extract with anti-aging activity obtained from a genetic resource accessed from a country which is a Party to the Nagoya Protocol.
Analysis	The human proteinase is not subject of the EU ABS Regulation because it is of human origin. Validation of the test is done with a plant extract from a country which is a Party to the Nagoya Protocol; no R&D is carried out on the genetic and/or biochemical composition of the plant genetic resource itself. Thus, validation cannot be considered utilisation in the meaning of the EU ABS Regulation.

Annex 3

Example of Statement of Compliance with the Due Diligence requirements of Regulation (EU) No 511/2014 (EU ABS Regulation)

We, **[company name]**, confirm that the product **[product name]** was developed via the utilisation of a genetic resource and/or of associated traditional knowledge, as defined in the above-mentioned regulation.

We, **[company name]**, declare that our utilisation of the genetic resource and/or associated traditional knowledge is compliant with the EU Regulation 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 Utilisation in the Union (Reg. (EU) No 511/2014), which entered into force on 12 October 2014, and with the relevant national legislation in place when this genetic resource was accessed after this date.

In case your company intends to carry out research & development on the genetic resource **[product name]** purchased from us, we, **[company name**], will provide you with the required[1] set of information and documentation.

Date:

Name:

Function/Job title:

Signature:

[1] As per Article 4.3 of Regulation (EU) No 511/2014.

Due Diligence Compliance Flowchart

Context: a company identifies a genetic resource (GR) / traditional knowledge (TK) on which it envisages to perform Research and Development (R&D) activities

Is it a GR and/or a TK associated with a GR? **(1)**

NOT GR/TK → OUT OF SCOPE

YES

Is the provider country known?

NO → STOP UTILISATION

YES

What is the date of access of the GR / TK?

BEFORE Oct. 12 2014 and AFTER local law → Comply with National Legislation on ABS of the provider country

BEFORE Oct. 12 2014 and BEFORE local law → OUT OF SCOPE

- Access freely and use the GR/TK
BUT
- Keep minimum information **(3)**

AFTER 12 Oct. 2014

Is there any national legislation on ABS in the provider country? **(2)**

NO → (- Access freely and use the GR/TK BUT - Keep minimum information **(3)**)

YES

Does the scope of activities on the GR fall under the definition of R&D? (4)

NO → OUT OF SCOPE

YES

Information-related requirements **(5):**

In the provider country:

- Obtain PIC for access and
- Establish MAT (for as many R&D activity phases and subsequent uses as it is possible to foresee)

or

- Obtain national permit (PIC + MAT) and/or, where possible, an Internationally Recognised Certificate of Compliance (IRCC) including information on the content of the MAT (check any confidentiality issues with the certificate, as it will be public)

Comply with any other applicable legal requirements of the provider country

NO → STOP UTILISATION

YES

Start R&D activities

Make the due diligence declaration in case of research funding **(6)**

Is the GR intended to be commercialised in the EU as a cosmetic ingredient? Has the cosmetic product developed via the GR reached « final stage of development »? (R&D successful) **(7)**

NO → Check in your MAT if benefit sharing still applies

YES

Make the due diligence compliance declaration **(8)**
Note: this is not required if the R&D is conducted outside the EU.

Place cosmetic ingredient or cosmetic product on the EU market
Transfer relevant information to subsequent users, if any **(9)**

(1) GR and/or TK: genetic resource and/or traditional knowledge associated with the genetic resource

(2) See CBD Clearing House website; in case of any doubt, contact the National Competent Authority or the Focal Point in the provider country

(3) Keep a record of:
- Proof of origin of the GR/TK
- Purpose of the research
- Date of access

All documentation to be kept during 20 years after the end of utilisation

(4) Definition of R&D as described in the EC Horizontal Guidance, with reference to the OECD's Frascati Manual (http://www.oecd.org/innovation/inno/frascati-manual.htm)

and related guidance (http://www.oecd.org/innovation/inno/frascatimanualproposedstandardpracticeforsurveysonresearchandexperimentaldevelopment6thedition.htm)

(5) See section IV.3.1.1 in the Guidance document on information collected, kept and transferred

(6), (7) and (8) See section IV.3.1.2 in the Guidance document on declarations of compliance with due diligence.
Note: if the provider country is not a Party to the Nagoya Protocol (i.e. it has not ratified it), there is no obligation to declare compliance with due diligence

(9) See section IV.3.1.1 in the Guidance document on information to be transferred

Annex 5

Examples of terms and elements typically included in Mutually Agreed Terms (MAT)

MAT would typically include terms covering the following:

- benefit-sharing arising from the use of the samples
- handling or transfer of the samples
- dispute settlement
- subsequent third party use
- type and quantity of genetic resources to which access is sought
- starting date and duration of the activity
- geographical prospecting area
- evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access the intended use and any limitations thereof
- anticipation of how and where the use will take place
- anticipation of how and when the use will end
- identification of local bodies for collaboration in the use
- treatment of confidential information and intellectual property rights.

- In order to anticipate the involvement of third parties in the supply chain and to ensure that the PIC and MAT explicitly address the rights and responsibilities of these third parties, the following suggested elements could be considered for inclusion in MAT:
- the rights of the party accessing the Genetic Resource to transfer it to third parties and under which conditions;
- the conditions under which a third party is required to seek new PIC and/or MAT;
- the documentation that the party accessing the genetic resource is required to provide to subsequent third parties;
- the responsibilities of subsequent third parties to retain documentation and to pass that documentation on to subsequent entities in the supply chain;
- the operation of the benefit sharing provisions upon transfer of the genetic resource to a third party;
- any rights or responsibilities of the third party with respect to any dispute settlement provisions established in the Agreement.

ANNEX 6

Examples of Monetary and non-Monetary Benefits[1]

1. Monetary benefits may include, but not be limited to:

(a) Access fees/fee per sample collected or otherwise acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) Licence fees in case of commercialization;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

(a) Sharing of research and development results;
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;
(e) Admittance to ex situ facilities of genetic resources and to databases;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer;
(h) Institutional capacity-building;
(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;

[1] Annex to the Nagoya Protocol

(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.