ABS and the cosmetics sector: derivatives – the concept of ‘continuum’

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We personally care
The cosmetics sector

• Manufacturing a wide variety of **cosmetic ingredients, fragrance compounds and mixtures**, as well as **finished cosmetic products** (from skin care, oral care and hair care, to make-up, toiletries, sun protection products and perfumes)

• The **value chain** comprises 5 main stages:

• **Companies** range from large multi-nationals to SMEs, of which there are currently more than 4 600 in the EU

• **Natural ingredients** represent 7% of the global cosmetics market; for fragrances, 15 - 20% of the materials are of natural origin
Research & Development in the cosmetics sector

Covers:

- Research to obtain **new cosmetic ingredients**, in some cases based on or via materials of biological origin, and/or
- The development of **new applications** for existing cosmetic ingredients, and/or
- Development of **new formulations** based on existing ingredients

### Activities in the different phases of R&D:

<table>
<thead>
<tr>
<th>Phase</th>
<th>New cosmetic ingredients</th>
<th>New application</th>
<th>New formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities</td>
<td>Sourcing, Processing, Synthesising, Characterising, Testing</td>
<td>Characterising Testing</td>
<td>Sourcing Testing</td>
</tr>
</tbody>
</table>

**Samples of genetic resources and/or derivative**

- Characterization (pre-screening)
- Processing, synthesizing and/or testing of new ingredient

**Existing cosmetic ingredient**

- Testing new application of ingredient
- Testing new combination of ingredients

**Formulation of new cosmetic product**
Derivatives

Definition: naturally-occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity.
(Nagoya Protocol, Article 2(e))

Examples: plant oils, flavonoids, saponins, resins, waxes, vitamins, biopolymers, algae extracts, honey, milk, beeswax, etc.
The scope of the ABS Regulation vs derivatives

There are **no provisions** in the operative parts of the CBD, the Nagoya Protocol or Regulation (EU) 511/2014 on the extent to which access and/or utilisation of Derivatives falls in the scope of the Nagoya Protocol and/or of Regulation (EU) 511/2014.

However:

- The definition of utilisation in the Nagoya Protocol refers to biotechnology which in turn refers to derivatives;

- There was an intent of the Parties to see derivatives covered, to some extent.
The scope of the ABS Regulation vs derivatives (continued)

European Commission General Guidance Document, August 2016:

Access to a derivative is in the scope of the ABS Regulation when it also includes genetic resources for utilisation, i.e. **when access to a derivative is combined with access to the genetic resource** from which that derivative was obtained:

- it should be covered by the required PIC related to the genetic resource from which it was derived

- R&D on such derivative should be addressed in the MAT established when accessing the genetic resource
Cosmetics industry position

The concept of access to a derivative combined with access to the genetic resource from which it is derived refers to an **ascertainable (or identifiable) level of continuity (i.e. link or relationship)** between the production of the derivative from the genetic resource and the R&D activities conducted on the derivative thus obtained.

Companies must ascertain whether PIC and MAT exist for the material they access and/or for the material from which a derivative they access is derived, to determine whether and to what extent their intended activities are covered.
Such level of continuity would *inter alia* be expected to exist:

- In situations where activities conducted on a derivative form part of an on-going research project covering the genetic resource from which the derivative was obtained.

  *For example, a collaboration between a Company A and a Research Institute B. The latter produces the derivative for Company A to conduct further R&D activities on that derivative. Continuity could be expected to exist even if B never accessed the genetic resource from which the derivative was obtained.*

- Anytime a user would initiate the generation of a derivative from a genetic resource or would request such generation from a third-party upon a specific order.
Reasoning supporting the ‘continuum’ concept

• The scope for access/utilisation of derivatives must be narrower than the scope for access/utilisation of genetic resources (the latter are the only terms explicitly covered in the definition of access and utilisation whilst access/utilisation of derivatives are not)

• In the absence of a clear wording of the legal rule, the extent to which derivatives are covered is determined by (a) the purpose and (b) the context of the legal rule (cf. European Court of Justice Case Law)

• The cosmetics industry’s interpretation:
  • Ensures achievement of the purpose of the Nagoya Protocol and of Regulation (EU) 511/2014, i.e. derivatives would be covered effectively (no ‘salami-slicing’ of the ABS obligations)
  • Adequately reflects the context (no explicit / definite scope of application for derivatives in the EU ABS Regulation or the Nagoya Protocol due to lack of agreement between the negotiating Parties)

• The ‘continuum’ concept provides for an operative and proportionate criterion which helps to distinguish between situations that fall in or out of the scope of the ABS Regulation and allows users to ascertain their obligations (enhancing legal certainty)
**Case study 1**

<table>
<thead>
<tr>
<th>Title</th>
<th>Sourcing an essential oil in combination with access to the plant from which it is derived</th>
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<tbody>
<tr>
<td>Description</td>
<td>Company A harvests a plant in a country that is a Party to the Nagoya Protocol and performs R&amp;D to obtain a new essential oil, at the request of a company B located in the EU. Company B purchases the new essential oil and imports it into the EU to perform further R&amp;D activities on it.</td>
</tr>
<tr>
<td>Analysis</td>
<td>The plant (genetic resource) is accessed by Company A for the purpose of obtaining, through R&amp;D, a new essential oil (derivative). Although Company B does not itself access the plant, and only accesses the derivative of this plant, there is a continuum in the activities conducted by both companies, from the access of the plant and the production of the derivative by Company A, to the further R&amp;D activities performed in the EU by Company B; <strong>this continuum is evidenced by the specific request by Company B to Company A to produce the derivative.</strong> In this case, the R&amp;D conducted by Company B constitutes utilisation, i.e. is in the scope of the ABS Regulation.</td>
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## Case Study 2

<table>
<thead>
<tr>
<th>Title</th>
<th>Sourcing of orange oil available on the market</th>
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<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Orange oil is acquired by a fragrance company on the market, for further use as the subject of a research program in the EU.</td>
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<tr>
<td><strong>Analysis</strong></td>
<td>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 resource 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.</td>
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