EU rules on due diligence on ABS

Obligations and considerations for companies in the cosmetics sector
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- What are particular issues in interpreting and implementing EU rules on ABS for companies in cosmetic sector?
  - “Utilization” of genetic resources
  - “Genetic resource” and “derivatives”
  - Defining roles of users and other supply chain actors
  - Challenges in setting up due diligence systems
  - Considerations for declaration requirements
General issues for private sector

• Investments, incentives, risks, and costs linked to R&D

• International Chamber of Commerce (ICC) highlights key points for ABS requirements (and existing challenges linked to):
  o Legal certainty and predictability (especially clarity on scope)
  o Simple, efficient, timely and cost-effective process
  o Transparent requirements
  o Guidance and support for users
  o Compatibility with existing business and R&D practice
  o A cooperative and facilitative approach
Cosmetics in the lead: Brazil as example

By Feb. 2019, 38500 registrations of access to Brazilian genetic heritage

2% linked to companies – 78 in all

Among company registrations, 50% from companies specialized in natural ingredients. Manufacturers of cosmetics constitute second largest group
ABS and companies in cosmetics

• Lack of clarity and guidance on steps for compliance
• Difficulty of measuring costs and risks
• Rules made for R&D, applied to sourcing activities
• Complex supply chain structure, including multiple suppliers and traders
• Reputational risks of engagement
• Confidentiality concerns
• Value of ingredients vs. value of product vs. value of brand
Specific issues re EU rules on ABS

1. What qualifies as “utilization” of genetic resources?
2. What qualifies as “genetic resource” or “derivative”?
3. Who are users? How are other supply chain actors implicated?

Implications for due diligence systems  
Considerations for declaration requirements
1a “Utilization” in the cosmetics sector?

- Samples of plant parts or compounds
  - Large scale screening
    - Laboratory tests
      - Developing ingredient

- Existing ingredient
  - New application
    - Product formulation

- Existing ingredient
1b “Utilization” in the cosmetics sector?

- Samples of plant parts or compounds
- Large scale screening
- Laboratory tests
- Developing ingredient
- Existing ingredient
- New application
- Existing ingredient
- Product formulation

Utilization of genetic resources?
1. “Utilization” in the cosmetics sector

- **Sourcing**
  - Normally, no
  - Yes if...
  - Purpose is exploring or comparing biochemical activities and developing novel or improved ingredients

- **Characterization**
  - Normally, no
  - Yes if...
  - Purpose is analysing properties or potential applications

- **Processing**
  - Normally, no
  - Yes if...
  - Purpose is developing novel or improved ingredients

- **Testing**
  - No if...
  - Standard quality, safety, toxicity, regulatory testing
  - Yes if...
  - Efficacy, safety, toxicity for R&D

- **Formulation**
  - No
Large-scale screening one of controversial topics

LS screening is considered NOT to be covered if…

- Large numbers of genetic resource samples
- Evaluated against a specific research criterion
- Research questions of a binary nature
- Objectives are to screen out samples not of interest to research project ("negative") or identify samples with potential for further research ("positive")

LS screening would be covered if it continues beyond these parameters, building on initial findings and adopting more individualized testing regimes

End of the screening process and beginning of utilization should be clearly identifiable from the outset of the screening process

**Utilization** in the cosmetics sector
- Market brief
- Literature review
- Sampling
- Screening
- Extraction
- Laboratory tests
- Regulatory
- Toxicological
- Supplier id
- Regulatory file
- Up-scaling
- Laboratory tests
- Developing formula
- Manufacturing
- Launch
Different approaches in provider countries

- Identifying raw material
  - Market brief
  - Literature review
  - Sampling
  - Screening

- Analyzing raw material
  - Extraction
  - Regulatory tests
  - Toxicological tests

- Ingredient research
  - Supplier ID
  - Regulatory file
  - Up-scaling

- Formulation
  - Developing formula
  - Manufacturing
  - Launch

Industry perspective?
Different approaches in provider countries

- Identifying raw material
  - Market brief
  - Literature review
  - Sampling
  - Screening

- Analyzing raw material
  - Extraction
  - Laboratory tests

- Ingredient research
  - Supplier id
  - Regulatory file
  - Up-scaling

- Formulation
  - Developing formula
  - Manufacturing
  - Launch

Access requirements?
2a. “Genetic resources” in cosmetics

• Use of biological resources from
  o Plants, such as fruits, roots, leaves, bark, flowers - fresh, dried or frozen…
  o Animals, such as lanolin, carmine, guanine
  o Microorganisms, such as ”skin-friendly” bacteria
  o Fungi, such as mushrooms, yeast

• When are these “genetic resources”?
  o Genetic resources contain “functional units of heredity”
  o Contrast of term in relation to “derivatives”
    ▪ Plant parts, even if dried or powdered
    ▪ Not oils or extracts
2b. “Derivatives” and cosmetics

• What are derivatives?
  • Nagoya Protocol defines as “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.”

• Companies in Europe primarily source “derivatives” for research and product development on natural ingredients
  • Examples include vegetable and essential oils, crude and standardized extracts, proteins, lipids, enzymes, and flavonoids, etc.
  • Not to be confused with derivatives as ingredients having gone through, often extensive, chemical processing
2c. “Derivatives” and cosmetics

- EU regulation covers “utilization of genetic resources”
- Does this exclude R&D conducted, for example, not on the plant but on its compounds?
  - Horizontal guidance*: Only if covered by conditions for access to GR
  - Expert group: Notion of “continuity.” Covered if…
    - R&D on derivative part of research project covering genetic resource
    - User obtained derivative from genetic resources directly or through request to other actors (e.g. under a service agreement).
    - Derivative covered by PIC and MAT

* A guidance document on the scope of the EU ABS Regulation was adopted on 22 August 2016 and published in the Official Journal on 27 August 2016. It is available at: http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
3. Users and other actors

Source: FEBEA 2013
3. Users and other actors

- Collection or cultivation
- Traders
- Advanced processing
- Initial processing
- Brands
3. Users and other actors

- Collection or cultivation
- Initial processing
- Traders
- Brands
- Advanced processing
3. Users and other actors
3. Impact on due diligence systems

- For all sectors, identifying roles and responsibilities for ABS compliance among different actors involved in value chain.
- For companies working in cosmetics, additional challenges linked to multiple countries involved, layers of ABS compliance, lack of ABS awareness, and questions on reliability of information.

Main suppliers of essential oils to Europe (2017)

<table>
<thead>
<tr>
<th>Country</th>
<th>Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>Essential oils n.e.s.</td>
</tr>
<tr>
<td>Italy</td>
<td>Lemon</td>
</tr>
<tr>
<td></td>
<td>Other citrus oils</td>
</tr>
<tr>
<td>Brazil</td>
<td>Orange</td>
</tr>
<tr>
<td>United States</td>
<td>Peppermint oil</td>
</tr>
<tr>
<td></td>
<td>Mint oils n.e.s.</td>
</tr>
<tr>
<td>India</td>
<td>Peppermint oil</td>
</tr>
<tr>
<td></td>
<td>Mint oils n.e.s.</td>
</tr>
<tr>
<td>China</td>
<td>Mint oils n.e.s.</td>
</tr>
<tr>
<td></td>
<td>Essential oils n.e.s.</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Essential oils n.e.s.</td>
</tr>
<tr>
<td>Madagascar</td>
<td>Essential oils n.e.s.</td>
</tr>
</tbody>
</table>

Plus Viet Nam, Mexico, Guatemala, Egypt, Peru, South Africa.
### 3. Impact on declaration requirements

<table>
<thead>
<tr>
<th>Who?</th>
<th>When?</th>
<th>How?</th>
</tr>
</thead>
<tbody>
<tr>
<td>User</td>
<td>Receiving research funding</td>
<td>Declaration made at earliest event</td>
</tr>
<tr>
<td></td>
<td>After the first instalment and access to genetic resources, but before final report or end of project</td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Product” not defined</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reference seems to be finished rather than intermediate products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May not, in many cases, be same company</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Germany: No later than four weeks before end of utilization.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfer of R&amp;D results or outcomes</td>
<td>Responsibility remain with users, which must make declaration once:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Results of utilization transferred within EU for the placing of a product in the market</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outcomes of utilization transferred outside EU</td>
<td></td>
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</tbody>
</table>
Looking forward

• Importance of “translating” concepts and requirements to the specific sectoral circumstances

• Cosmetics Europe and partner organizations are developing guidance document on scope of utilization of genetic resources in cosmetics

• Guidance on “utilization of genetic resources” in fragrance being developed by IFRA and partners

• Addressing issues at company-level remains fundamental
Thank you.
Prepared by the Union for Ethical BioTrade (UEBT) for the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN)

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