



EU rules on due diligence on ABS

Obligations and considerations for
companies in the cosmetics sector



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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):
 - Legal certainty and predictability (especially clarity on scope)
 - Simple, efficient, timely and cost-effective process
 - Transparent requirements
 - Guidance and support for users
 - Compatibility with existing business and R&D practice
 - A cooperative and facilitative approach

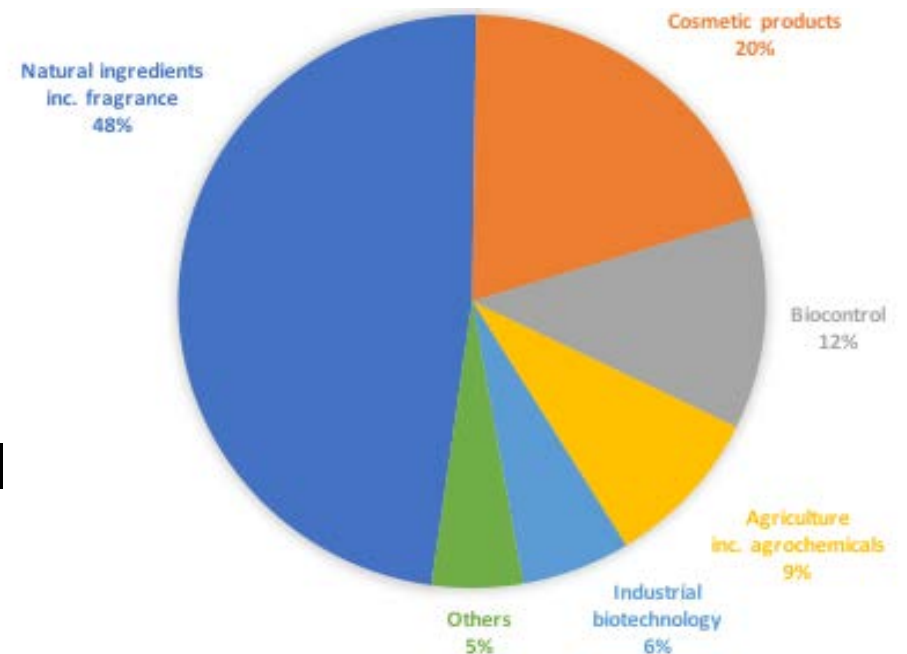


Cosmetics in the lead: Brazil as example

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



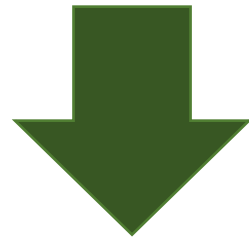
ABS and companies in cosmetics

- 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

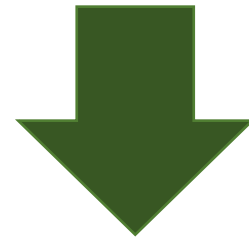


Specific issues re EU rules on ABS

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?



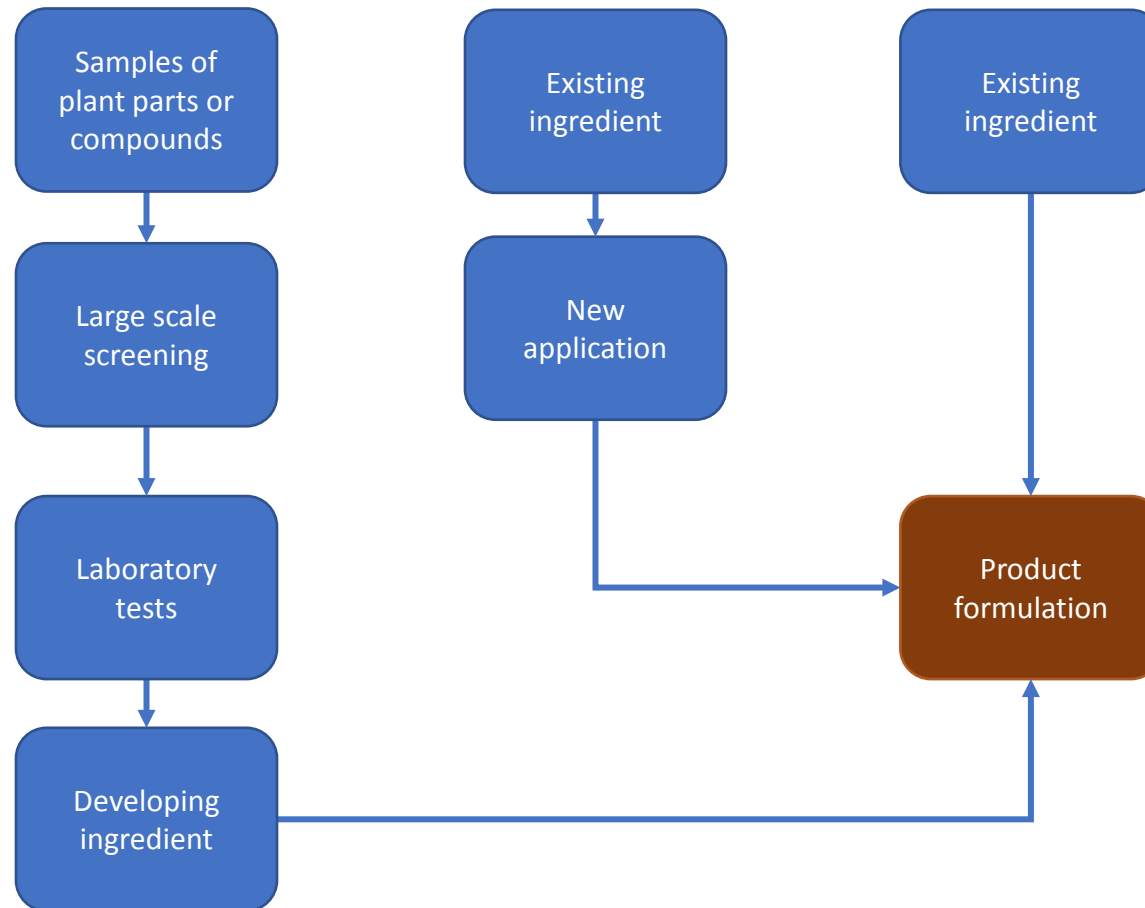
Implications for due diligence systems



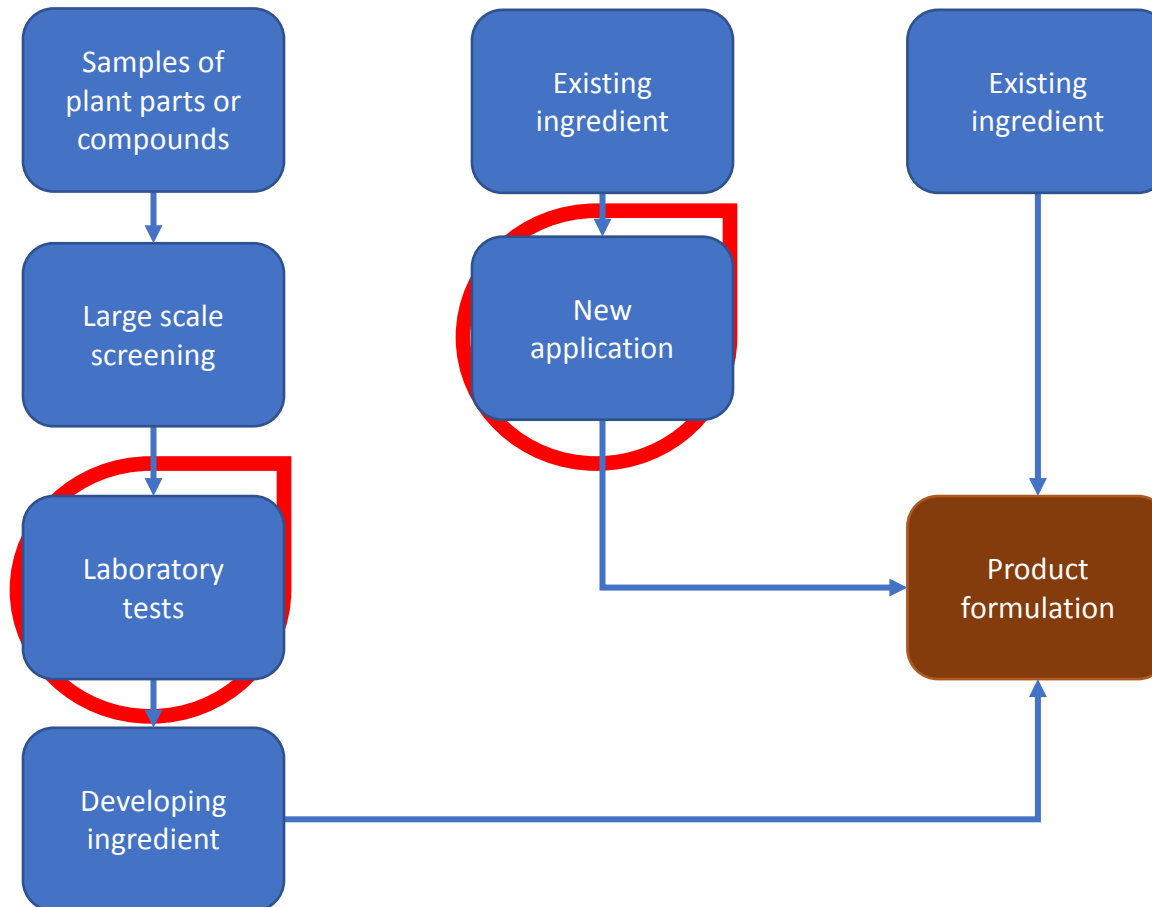
Considerations for declaration requirements



1_a "Utilization" in the cosmetics sector?

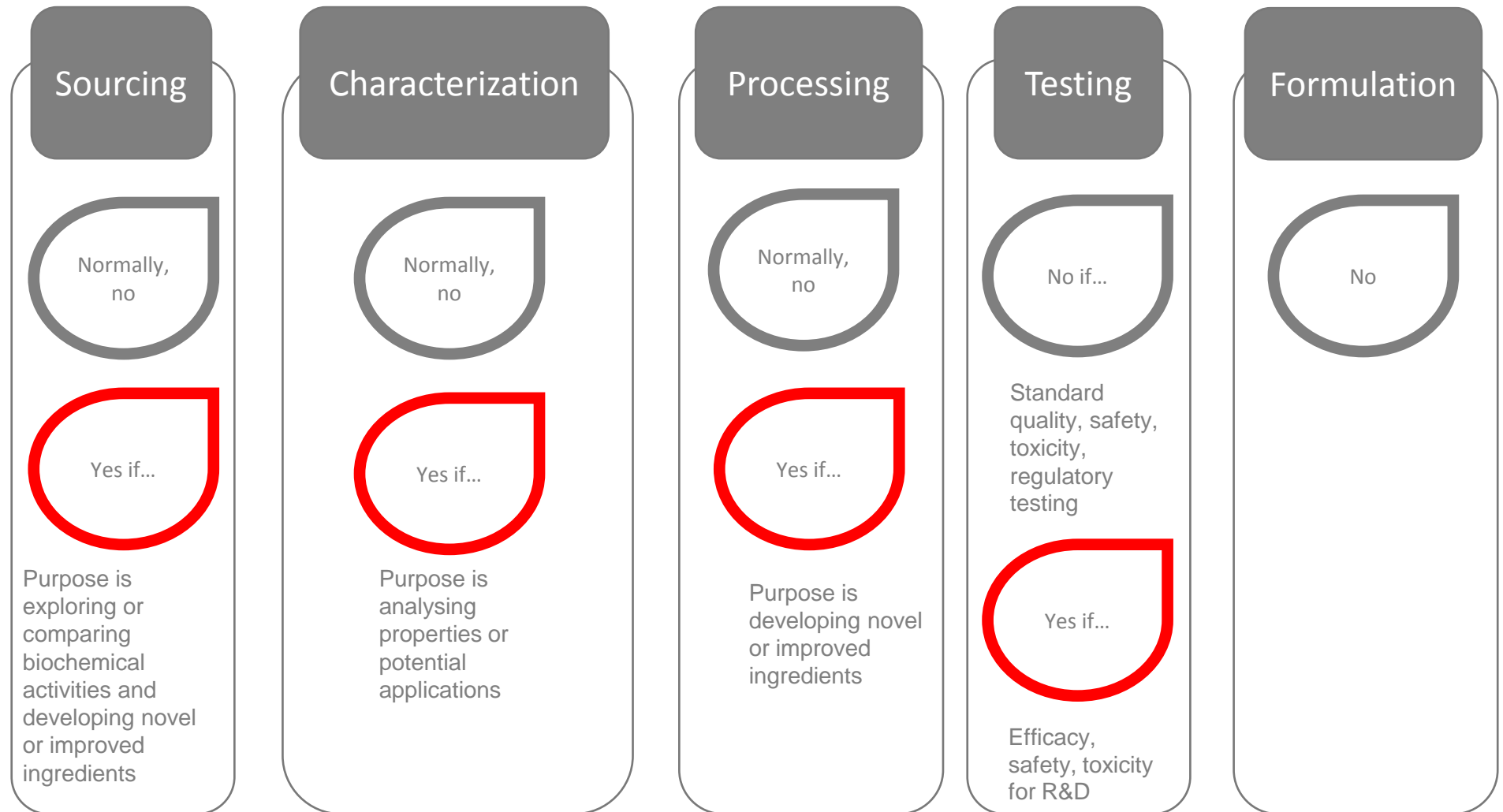


1_b "Utilization" in the cosmetics sector?



 Utilization of genetic resources?

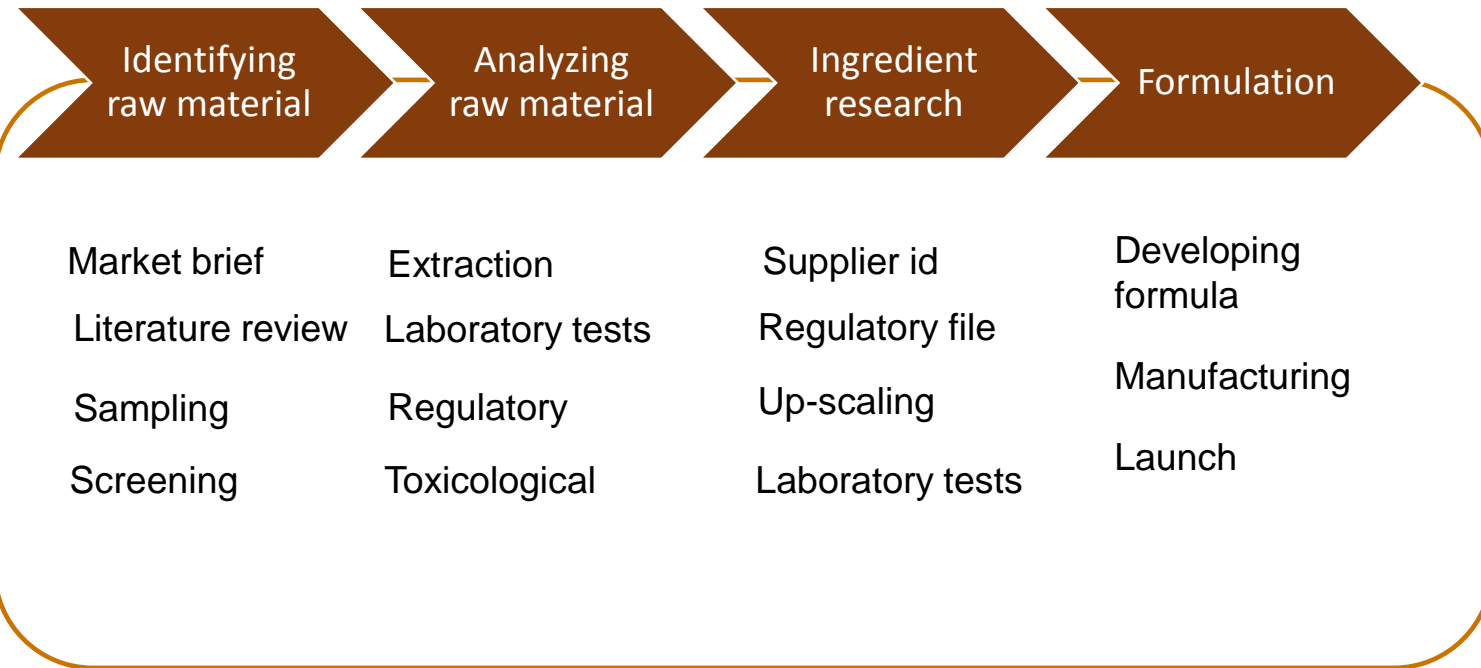
1c. "Utilization" in the cosmetics sector



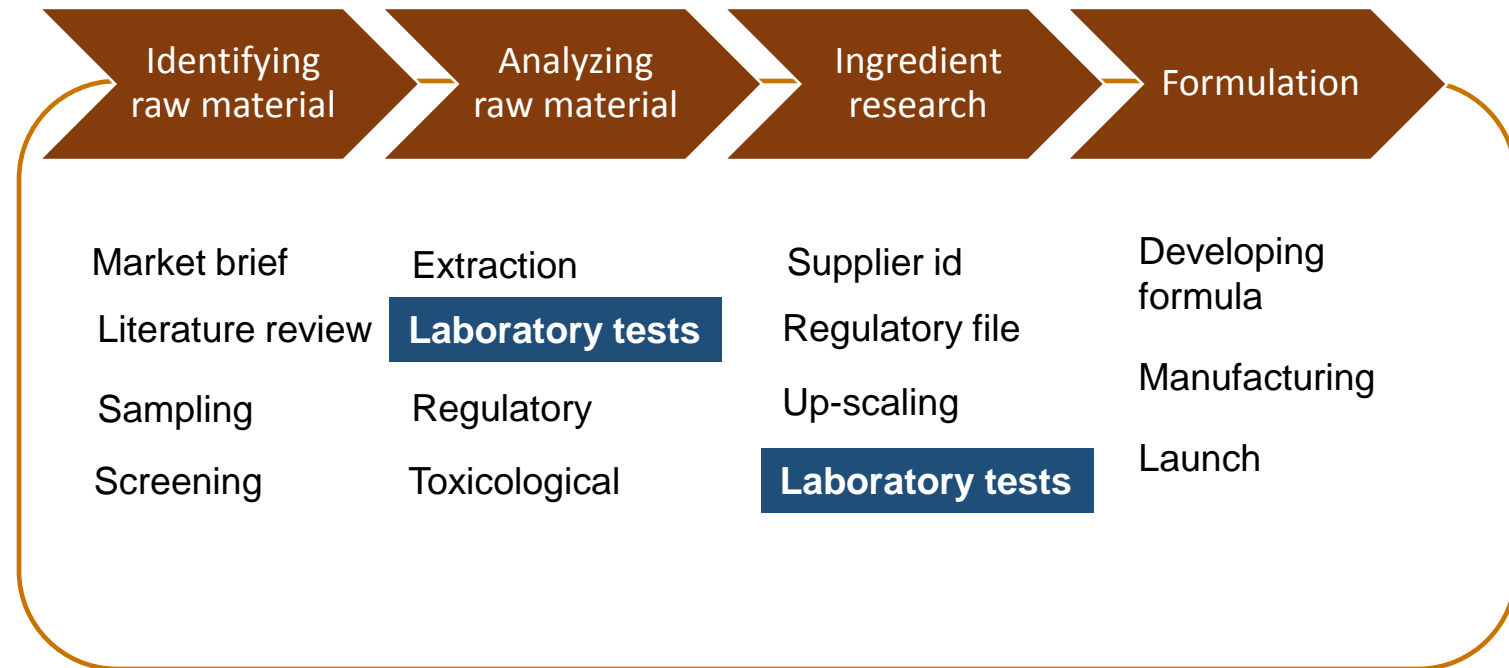
1_d “Utilization” in the cosmetics sector

- 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



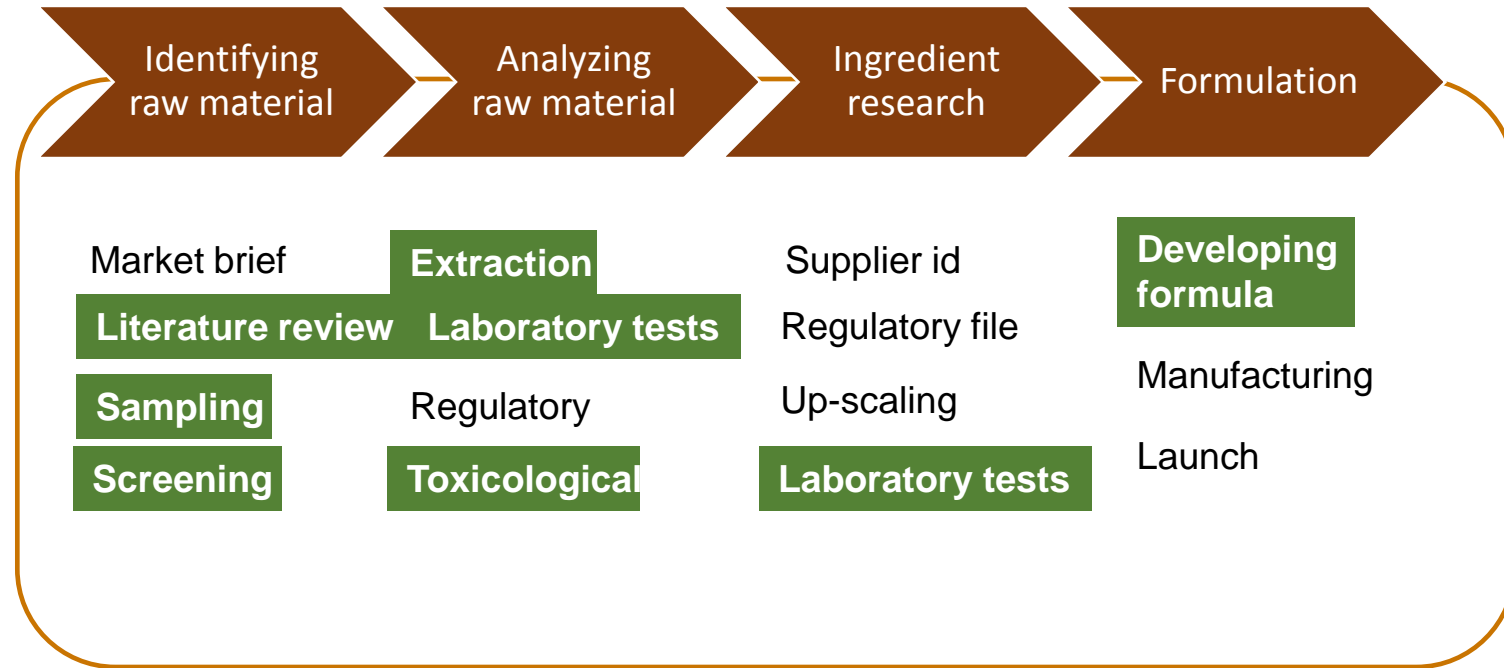


Different approaches in provider countries



Industry perspective?

Different approaches in provider countries



Access requirements?

2a. “Genetic resources” in cosmetics

- Use of biological resources from
 - Plants, such as fruits, roots, leaves, bark, flowers - fresh, dried or frozen...
 - Animals, such as lanolin, carmine, guanine
 - Microorganisms, such as “skin-friendly” bacteria
 - Fungi, such as mushrooms, yeast
- When are these “genetic resources”?
 - Genetic resources contain “functional units of heredity”
 - 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



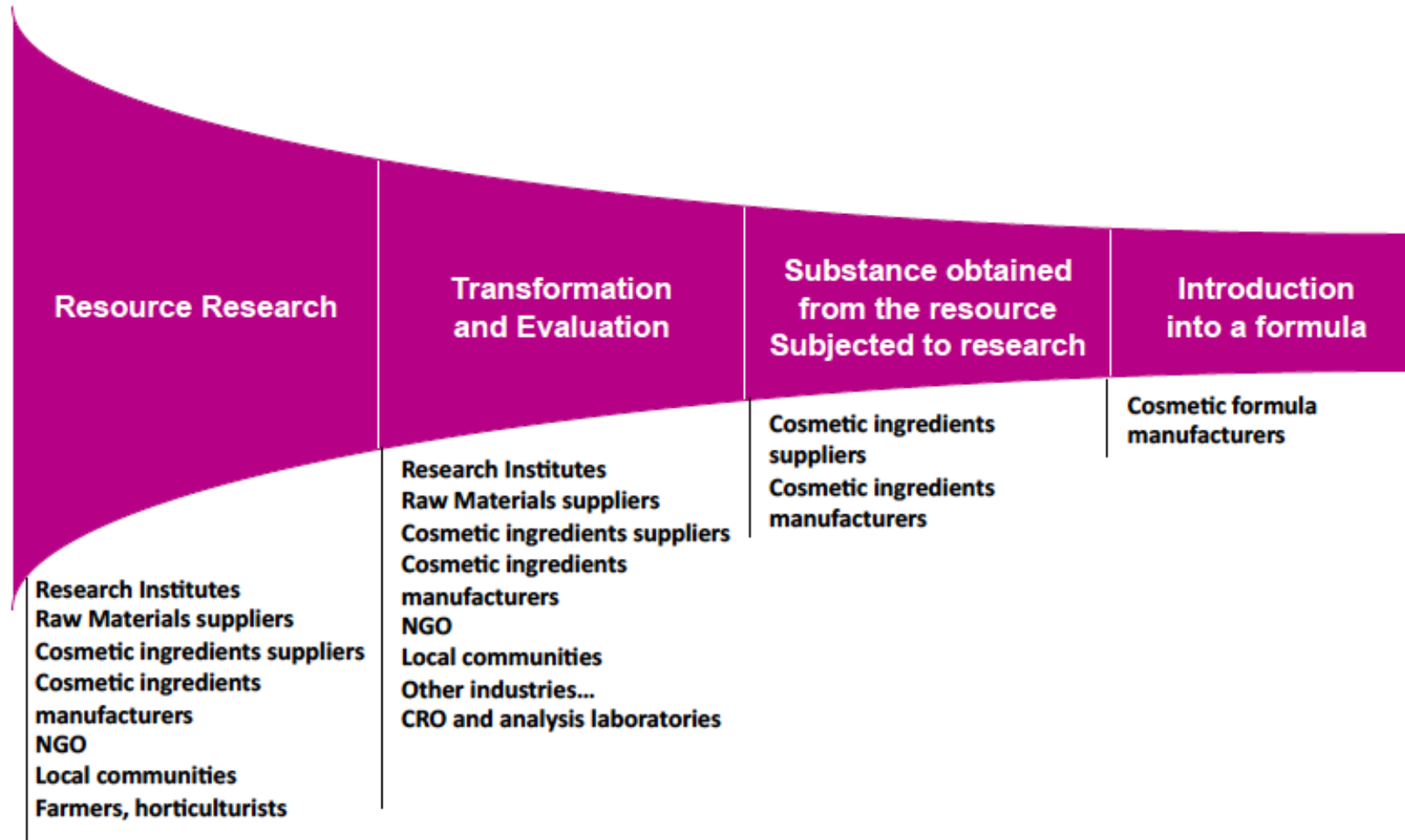
2c. “Derivatives” and cosmetics

- 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

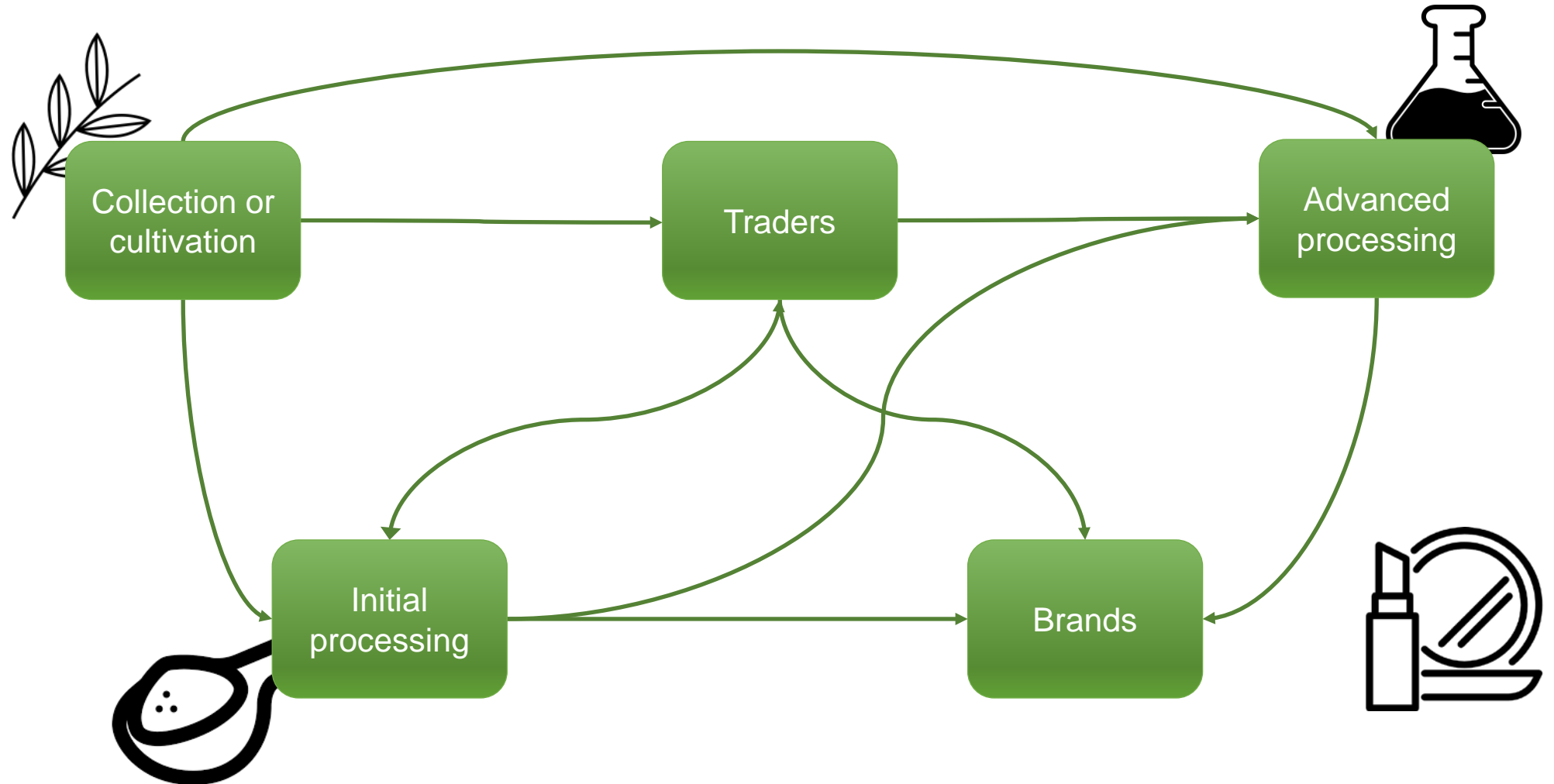


3. Users and other actors

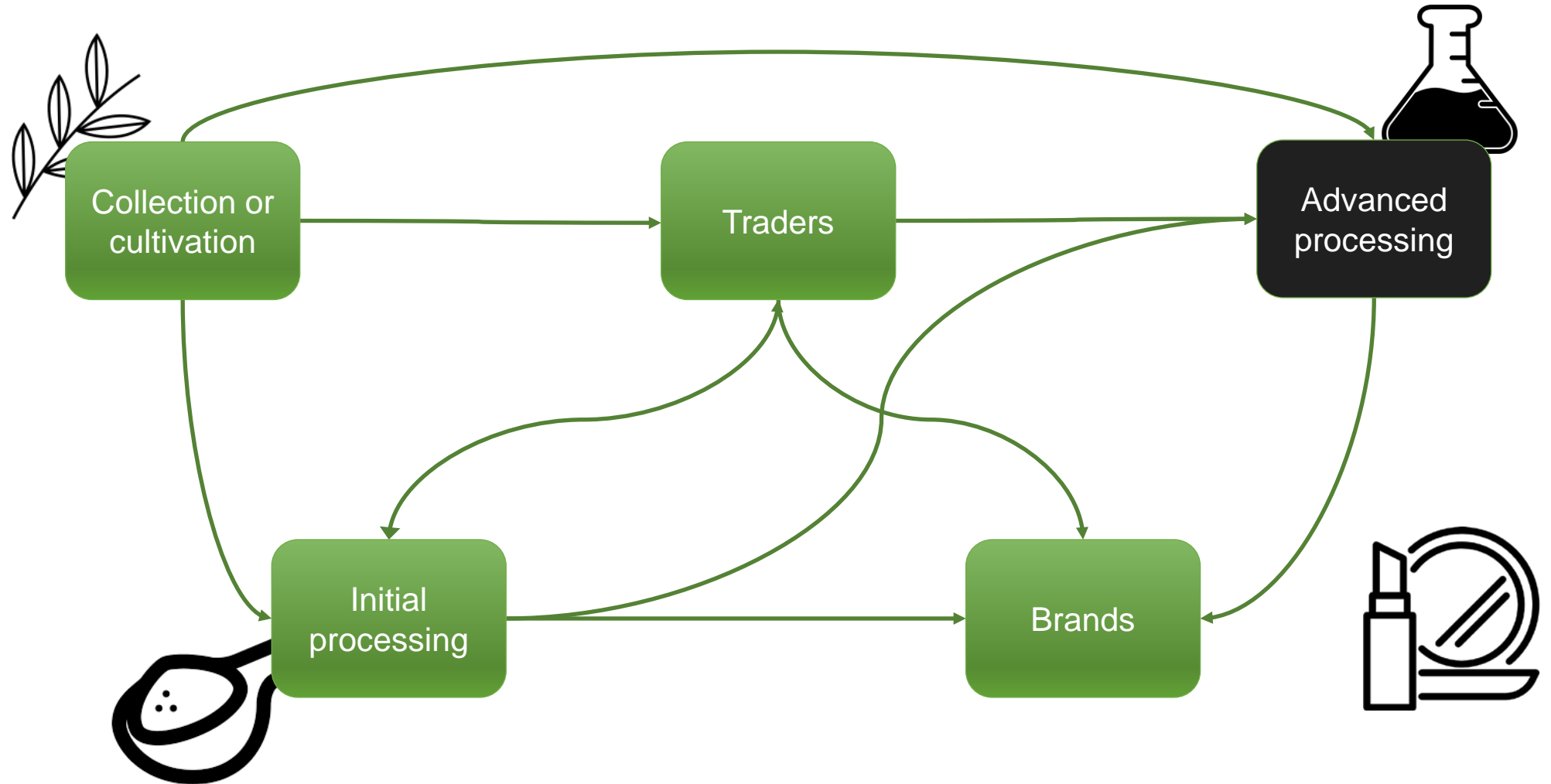


Source: FEBEA 2013

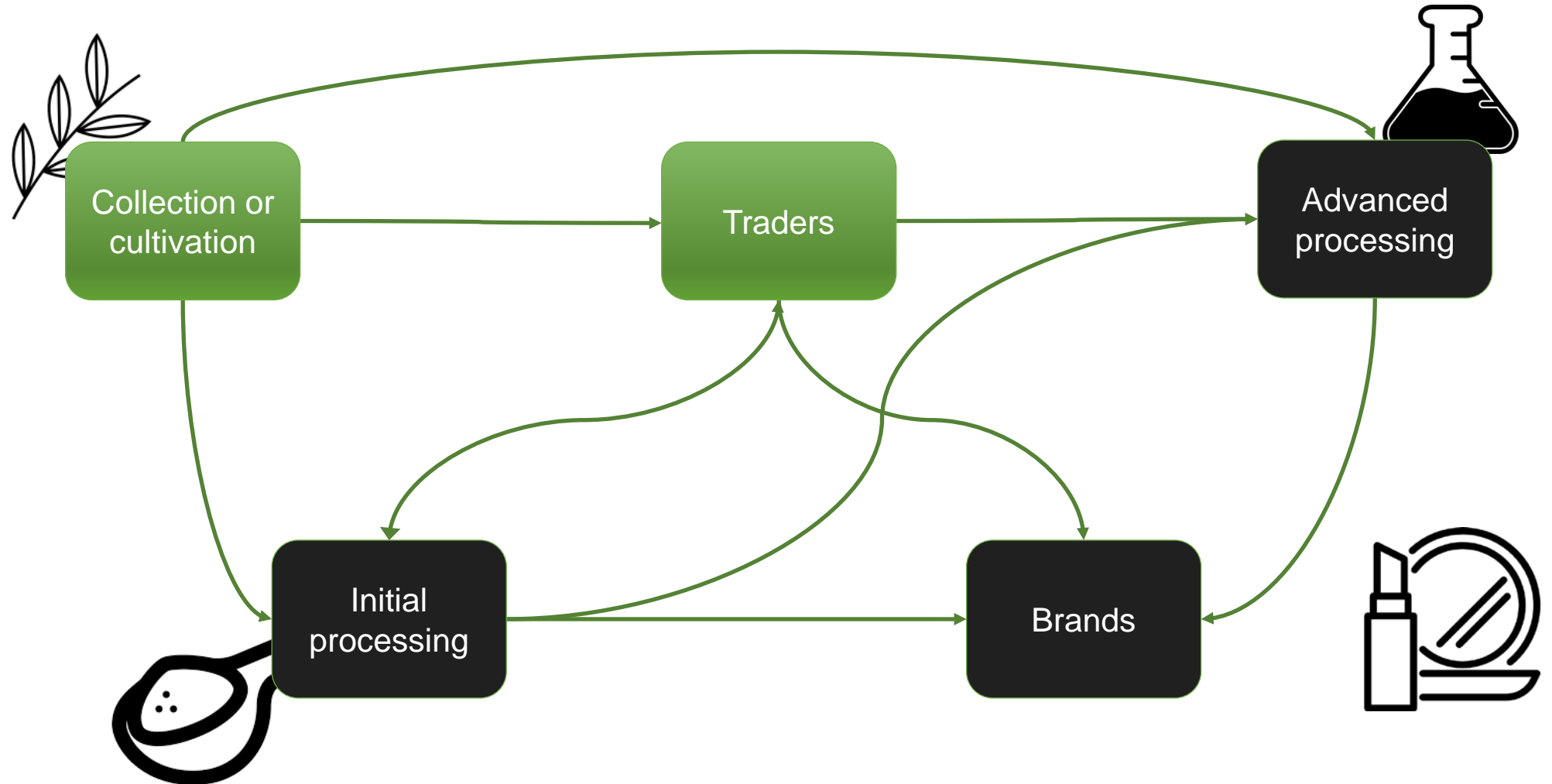
3_a Users and other actors



3_b Users and other actors



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)

Country	Types
France	Essential oils n.e.s.
Italy	Lemon Other citrus oils
Brazil	Orange
United States	Peppermint oil Mint oils n.e.s.
India	Peppermint oil Mint oils n.e.s.
China	Mint oils n.e.s. Essential oils n.e.s.
Indonesia	Essential oils n.e.s.
Madagascar	Essential oils n.e.s.

Plus Viet Nam, Mexico, Guatemala, Egypt, Peru, South Africa



3. Impact on declaration requirements

Who?	When?	How?
User	Receiving research funding	<ul style="list-style-type: none"> • After the first instalment and access to genetic resources, but before final report or end of project • Grants, not internal budget
	Product notification, authorization or placing on market	<ul style="list-style-type: none"> • “Product” not defined • Reference seems to be <u>finished</u> rather than intermediate products • May not, in many cases, be same company • Germany: No later than four weeks before end of utilization.
	Transfer of R&D results or outcomes	<ul style="list-style-type: none"> • Responsibility remain with <u>users</u>, which must make declaration once: <ul style="list-style-type: none"> ○ Results of utilization transferred within EU for the placing of a product in the market ○ Outcomes of utilization transferred outside EU

Declaration made at earliest event

DECLARE, available at <https://webgate.ec.europa.eu/declare/>



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.





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