Federal Agency for Nature Conservation

UNION FOR ETHICAL BIOTRADE
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EU rules on due diligence on ABS

Obligations and considerations for companies in the pharmaceutical sector

Table of contents

- What are general issues for companies in putting in practice ABS?
- What are particular issues in implementing EU rules on ABS for companies in pharmaceutical sector?
  - “Utilization” of genetic resources
  - “Genetic resource” and “derivatives”
  - Defining roles of users and other supply chain actors
  - Implications for 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):
  - 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

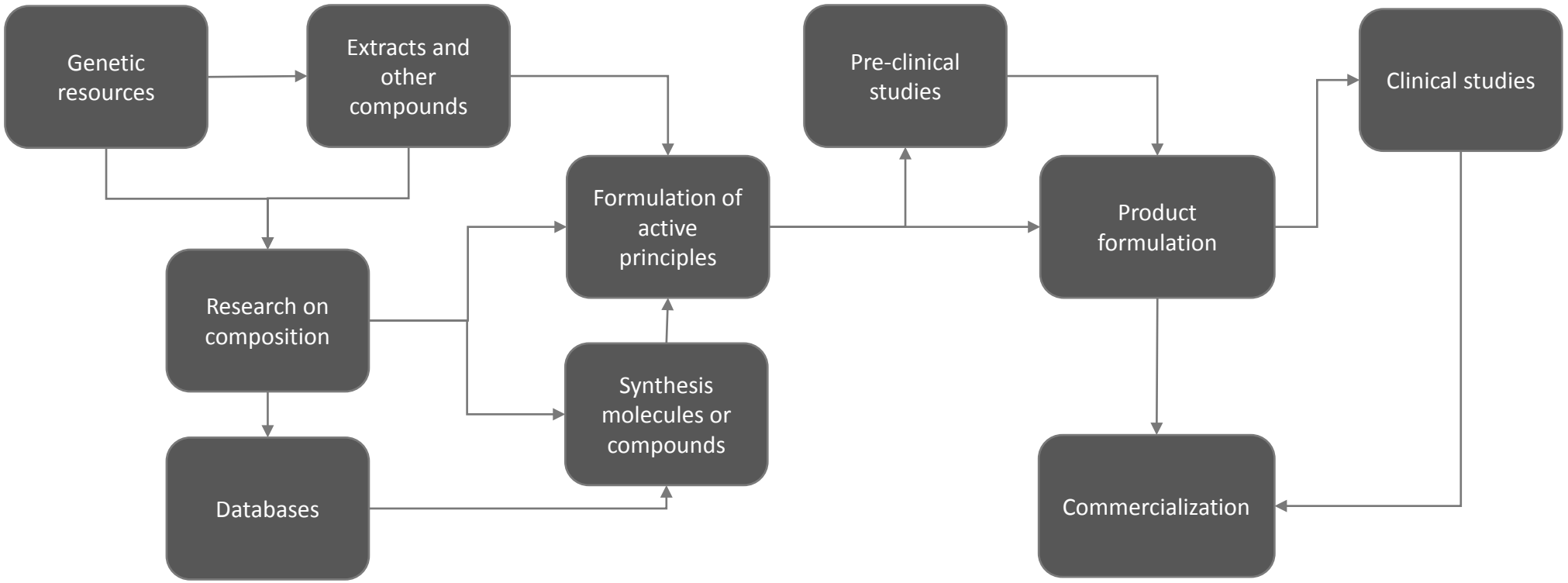
Specific issues re EU rules on ABS

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

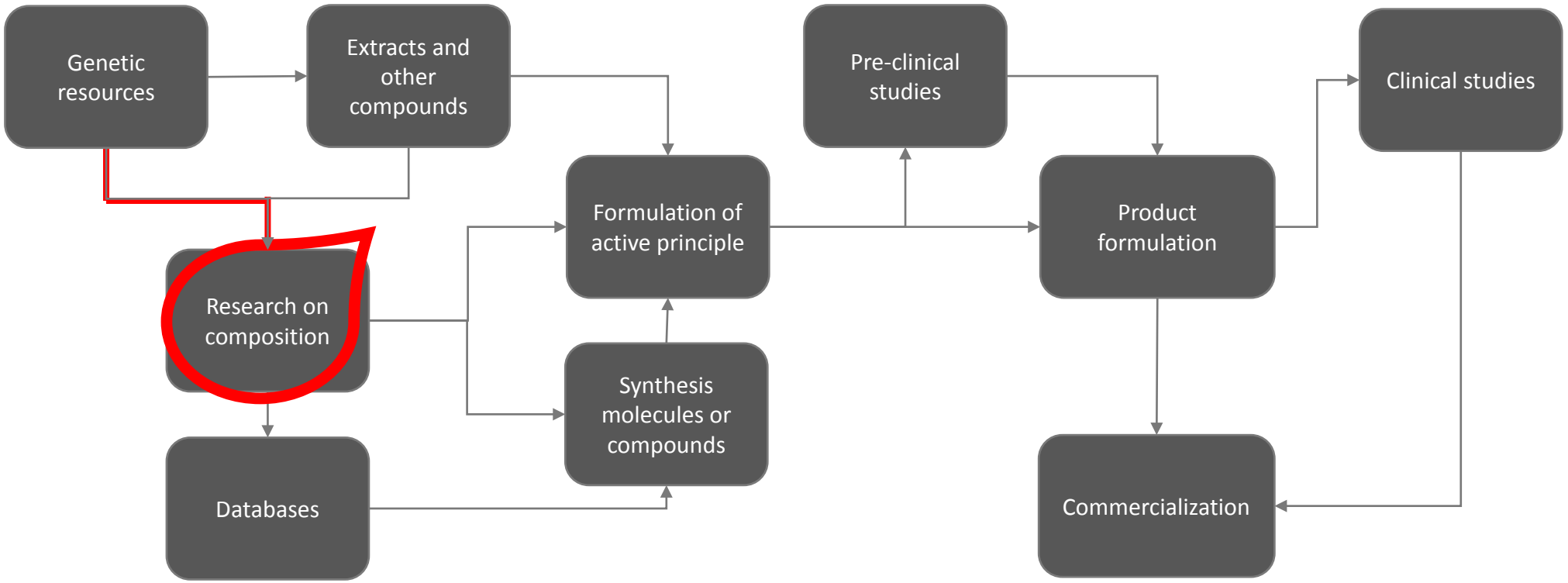
Considerations for declaration requirements

1a What is “utilization of genetic resources” in pharmaceuticals?



Simplified scheme of use of biodiversity for phytopharmaceuticals and drug development

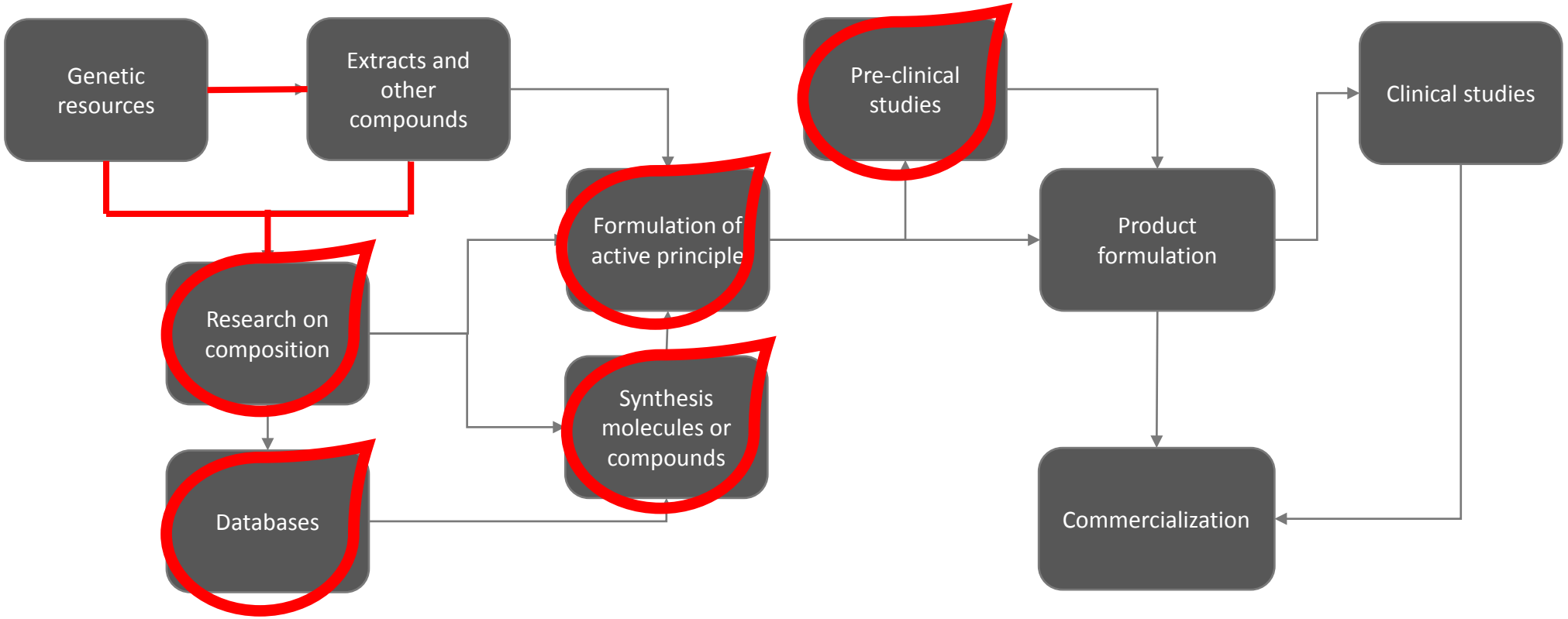
1b What is “utilization of genetic resources” in pharmaceuticals?



Simplified scheme of use of biodiversity for phytopharmaceuticals and drug development

Utilization of genetic resources?

1c What is “utilization of genetic resources” in pharmaceuticals?



Simplified scheme of use of biodiversity for phytopharmaceuticals and drug development

Utilization of genetic resources?

1d What is “utilization of genetic resources” in pharmaceuticals?

NOT

Phytopharmaceuticals

- Production of extracts
- Cutting plant parts for herbal infusion
- Use as reference material for analytical purposes
- Toxicological studies for regulatory approvals
- Optimization of extract processes
- Extension of existing use within similar parameters

Source: Waimer et al (2018), Implementation of the Nagoya Protocol

1e What is “utilization of genetic resources” in pharmaceuticals?

Drug development

- Using compounds isolated from GR as development candidates
- Access of soil samples for the isolation of GR
- Research on hit compounds isolated from GR
- R&D on a medicinal plant for new indications
- Synthesizing drug candidate based on information

R&D tools

- Use of animals in test models and toxicological studies
- Use of pathogenic bacteria to test efficacy of new antibiotic
- Use of pathogen to develop vaccine

Biopharmaceuticals

- Development of a new protein production system based on GM plant
- Use of animal cells for vaccine manufacturing
- Selection of animal cells for optimal virus production properties

1. What is “utilization of genetic resources” in pharmaceuticals?

- 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

2. What are “genetic resources”?

- In pharmaceuticals, there is use of material, compounds and information from plants, animals, fungi and microorganisms – as well as humans
- Are these “genetic resources”?
  - Human genetic resources NOT included, but what about:
    - Viruses? Not sufficient genetic information to exist independently…
    - Human microbiome? The term “human” is not defined – does it include normal functions of human organism, including microbes?
  - Pathogens ARE included, except if (i) unintentional introduction, and (ii) urgency in addressing health and safety implications

2a What are “derivatives”?

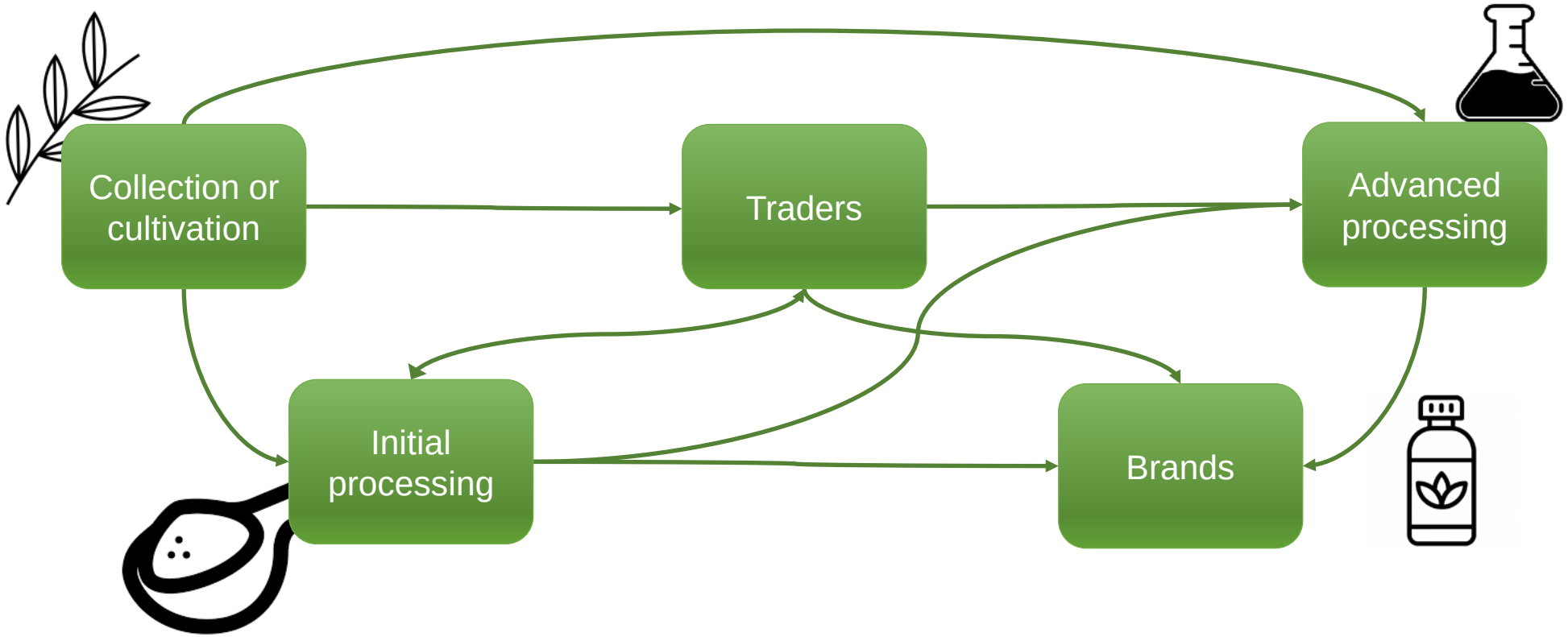
- What are derivatives?
  - Nagoya Protocol defines as “naturally-occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.”
- “Derivatives” for R&D
  - Examples include extracts, metabolites, enzymes, etc.
  - Not to be confused with use of “derivatives” as ingredients having gone through, often extensive, chemical processing
- Are chemically-modified derivatives covered by EU regulation?
  - Alteration in the structure of a molecule by chemical means
  - Still a derivative or a synthetic (non-naturally occurring) compounds?

2b What are “derivatives”?

- 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

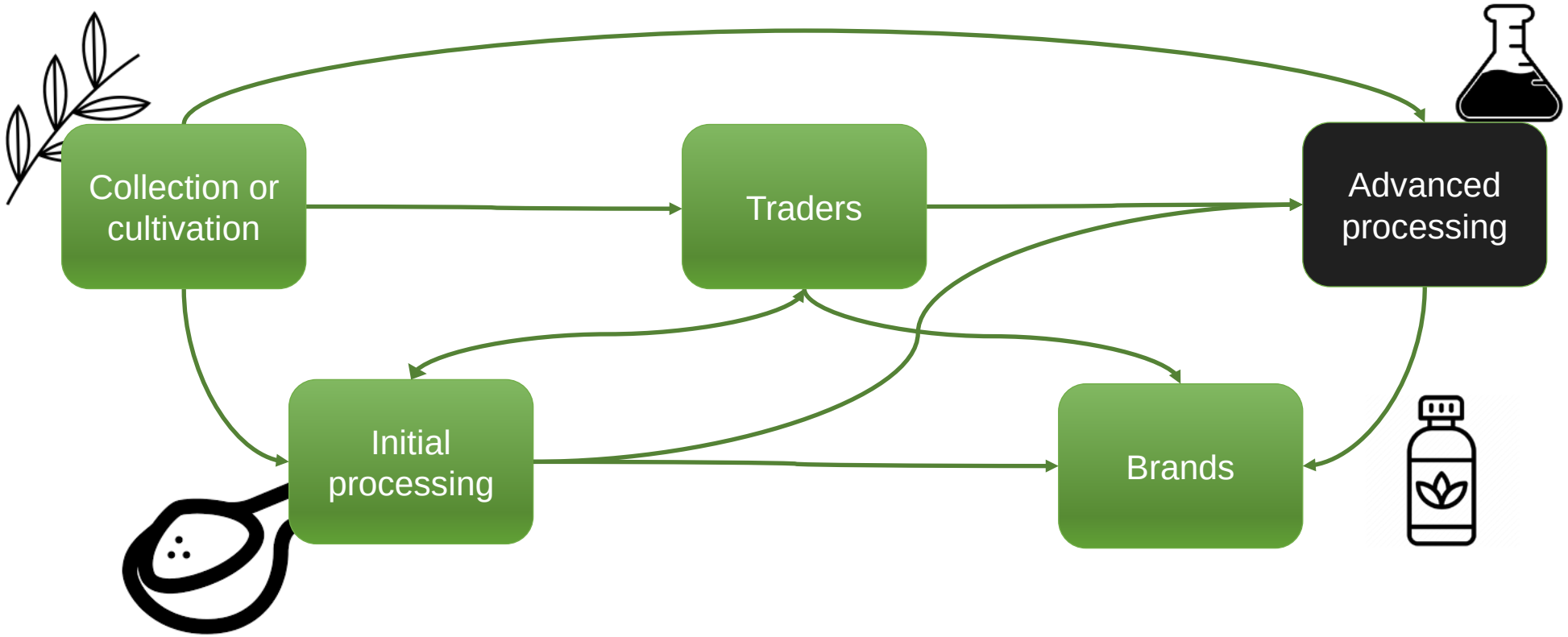
*A guidance document on the scope of the EU ABS Regulation was adopted on 22 August 2016 and published in the Official Journal on 27 August 2016. It is available at: http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

3a Users and other actors



Phytopharmaceuticals

3b Users and other actors



Phytopharmaceuticals

3. Users and other actors

Pre-discovery	Discovery	Early stage development
Pharmaceutical companies Academia	Pharmaceutical companies Consortium Academia PP Partnerships Specialized companies (e.g. biotech) Contract research organizations	

Drug development process

3. Impact on due diligence systems

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

3. Impact on declaration requirements

Who?	When?		How?
User	Receiving research funding	• After the first instalment and access to genetic resources, but before final report or end of project • Grants, not internal budget	DECLARE, available at https://webgate.ec.europa.eu/declare/
	Product notification, authorization or placing on market	• "Product" not defined • Reference seems to be finished 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	• Responsibility remain with users, which must make declaration once: o Results of utilization transferred within EU for the placing of a product in the market o Outcomes of utilization transferred outside EU	

Looking forward

- Importance of “translating” concepts and requirements to the specific sectoral circumstances
- Possibility of development industry best practices, but addressing issues at company-level remains fundamental
- Following sessions will focus on how to take forth the process of addressing and mainstreaming ABS due diligence in company policies and procedures

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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