



Due diligence on ABS

Setting up systems for companies in the cosmetics sector





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Aim and implications of due diligence

- Objective is to ascertain that utilization of genetic resources and associated traditional knowledge complies with ABS requirements (Article 4.1 EU regulation on ABS)
- “Due diligence” requires seeking, keeping and transferring information relevant to determine legal compliance (Article 4.3)
- Ascertain means find out for certain: If information insufficient or uncertain, secure permit or discontinue utilization (Article 4.5)
- What does it mean in practice?
 - Standard of care
 - Systematic approach
 - Adequate information gathered and transmitted
 - Actions and decisions are documented and supported



How to get there?

- Specific steps or procedures to implement due diligence are left to the actors, which may adapt them to their specific circumstances
- Within any specific company...
 - Defining structure and elements of due diligence system
 - Identifying strategic and procedural approaches



Due diligence elements and tools

1. Committing to compliance with ABS requirements

- Policy establishing commitment and describing approach to due diligence
- Procedures that define scope, steps and responsibilities for due diligence

2. Gathering and managing information

- Questionnaires to gather information from suppliers and other actors
- Platforms for managing and sharing information along R&D processes

3. Assessing applicability and implications of ABS requirements

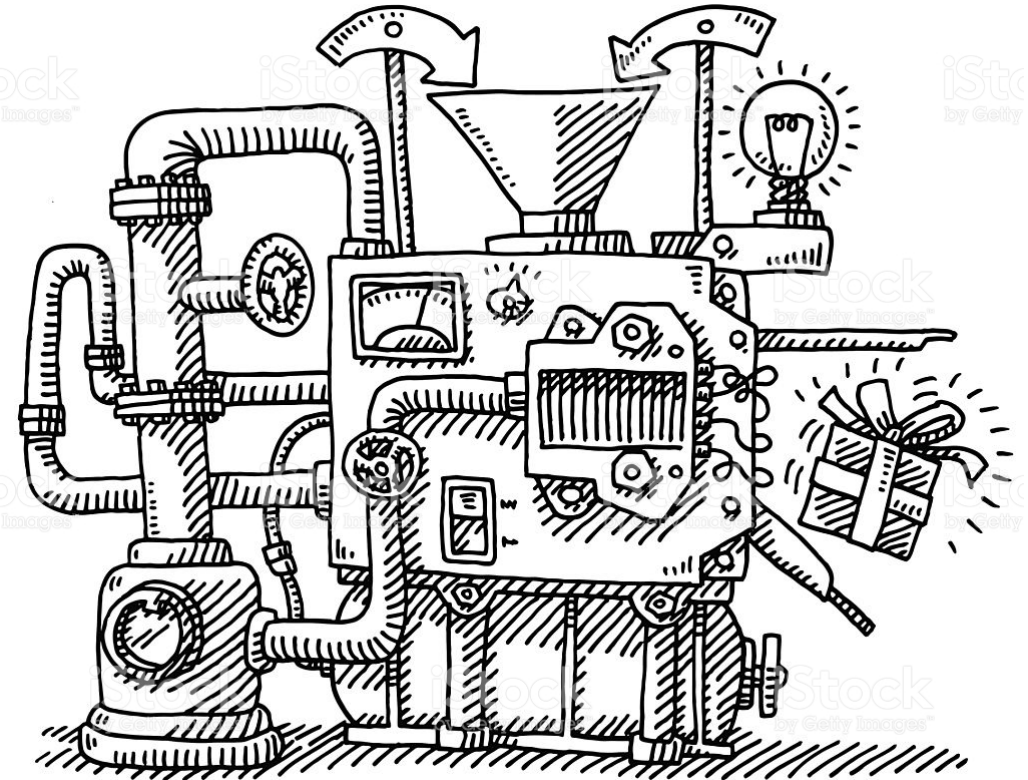
- Checklist to determine applicability of ABS requirements
- Decision tree to guide next steps in context of corporate strategies

4. Taking measures to ensure compliance

- Projects to apply or support securing ABS permits and agreements

Steps in setting up a due diligence system

- A. Defining scope of procedures
 - What are “genetic resources”?
 - What is “utilization”
 - What are processes involved?
- B. Identifying control points on ABS
 - Where should ABS be assessed?
 - How to gather necessary information?
 - How to make decisions?
- C. Formalizing the system
 - Elaborating policies and procedures
 - Ensuring availability of tools and support
 - Raising awareness and building capacities
- D. Implementing the system, including monitoring and evaluation





Defining the scope of procedures

- What are “genetic resources”?
 - AVOID legal definitions
 - Define what samples and compounds are covered
 - Use terminology familiar to researchers
 - Provide list of examples of what is included and excluded
 - Commodities?
 - Extracts and other physically modified ingredients?
 - Chemically modified ingredients?
 - Fragrance compositions?
 - Third-party manufactured products?

Defining the scope of procedures

- What qualifies as “utilization”?
- In cosmetics, “utilization of genetic resources” may be...



Novel ingredient
or fragrance



Characterization



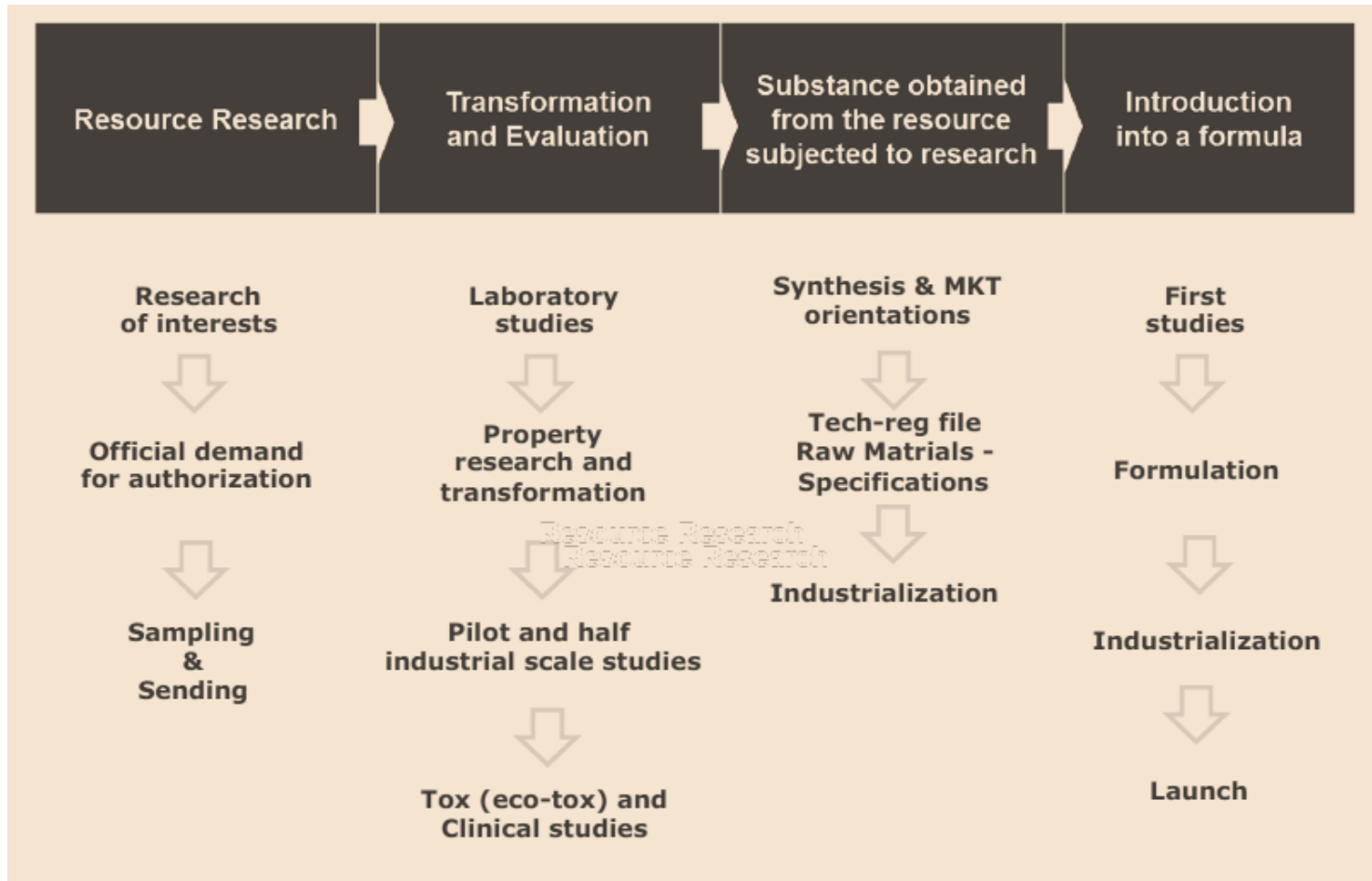
Improved
ingredient



Efficacy

- Compliance with due diligence vs. compliance with ABS requirements
- Changes in use (e.g. new projects on coded raw material)

Defining the scope of procedures



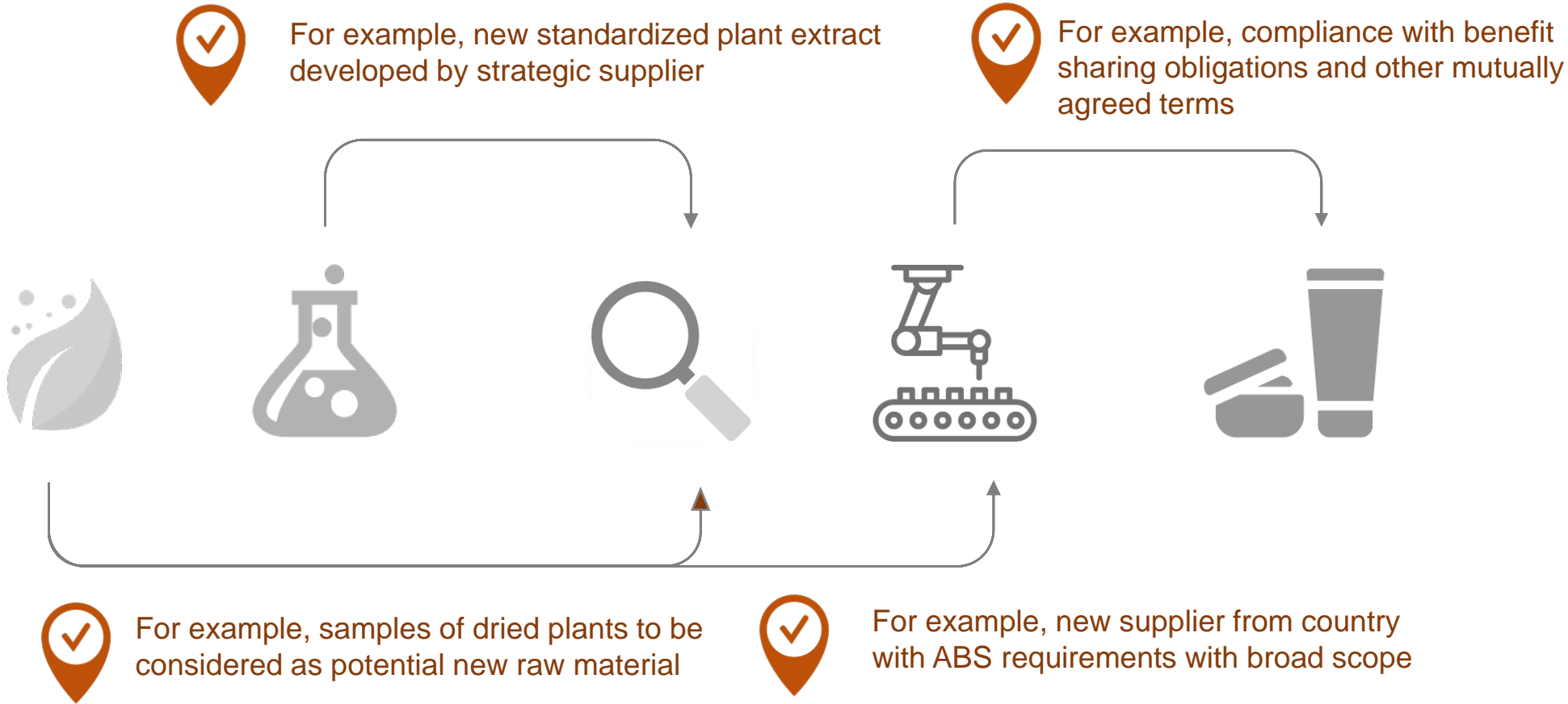
- What are processes and departments involved in R&D?
- Not only R&D, but sourcing, purchasing, regulatory, sustainability, etc.



Identifying control points on ABS

- Where should ABS be assessed?
- Entry points for genetic resources
 - i.e. How do samples of raw material enter the R&D process?*
 - Sample sent by potential supplier
 - Samples from joint research projects
 - Sample from production line
- Key gates in the sourcing, R&D process
 - i.e. Where are possible control points for ABS compliance?*
 - Test outcomes on identity and basic properties
 - Efficacy
 - Proof of concept
 - Industrial feasibility

Examples of controlling ABS compliance





Identifying control points on ABS

- Prerequisite for due diligence process is access to a level of information that allows taking substantiated decisions on the applicability and compliance with ABS requirements.
- **Necessary information** is listed in Article 4.3 of the EU regulation on ABS. It includes:
 - Country of origin and status in relation to Nagoya Protocol
 - Existence, scope and requirements of ABS laws and regulations
 - Biological material, name of species involved, production details
 - Existence of associated traditional knowledge
 - Source and subsequent users of biological material
 - Existence, scope and requirements of ABS permits or agreements

Identifying control points on ABS

- How to gather necessary information?

Type of information	Suppliers	Internal sources	External sources	External support
Country of origin	⊙	⊙		⊙
Nagoya status			⊙	
ABS requirements	⊙		⊙	⊙
Genetic resources	⊙	⊙		
Traditional knowledge	⊙	⊙	⊙	⊙
Source and users	⊙			
ABS permits	⊙		⊙	

Legend: ● Direct source ⊙ Indirect source



Identifying control points on ABS

- **How to gather necessary information?**

- **Internal sources**

- Certificate of origin
- Other product documentation
- Information from research projects
- Corporate databases

- **External sources**

- ABS Clearing House (<https://absch.cbd.int>) – for ABS measures, authorities and internationally recognized certificates of compliance
- National focal points
- Competent national authorities in provider country and EU member
- Certification (e.g. UEBT ESS and natural ingredient certification)

- **External support**

- Independent audits
- Technical and legal support



What if there is no response?

- Reminders after appropriate time
- Involve EU member competent authority
- Document communication attempts



Identifying control points on ABS

- How to gather necessary information?
- Gathering information from suppliers
- Three points
 1. Informing suppliers of aim and context, requesting collaboration
 2. Secure consent through specific commitment or introducing commitment in contracts or other supplier documentation
 3. Requesting and securing necessary information on ABS
 - Supplier questionnaire ≠ due diligence
 - Supplier questionnaire ≠ supplier declaration
 - Due diligence requirement cannot be “transferred” to supplier
 - Confidentiality? Risk assessment, certification, independent audits



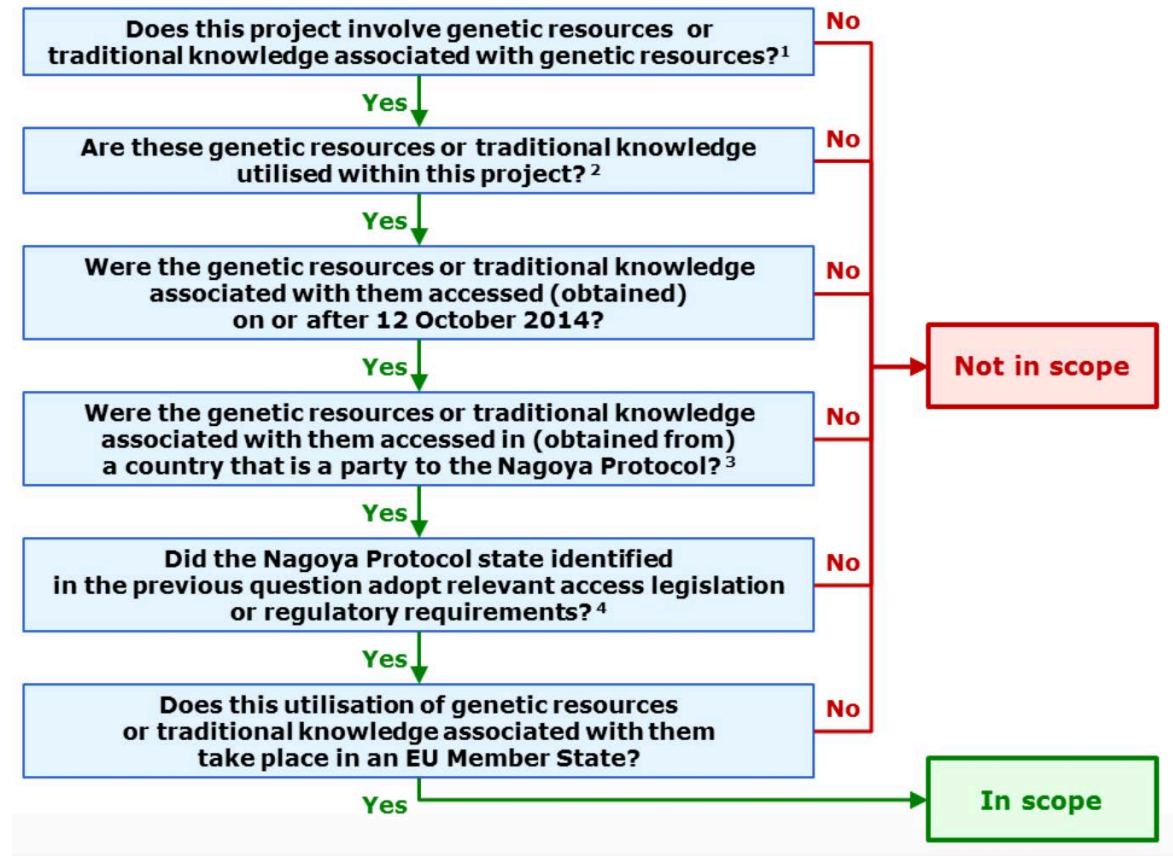
Identifying control points on ABS

- How to gather necessary information?
- Do's and don'ts in supplier questionnaires
 - ~~SUPPLIER declares that its utilisation of the genetic resource is compliant with the EU Regulation on ABS and the relevant national legislation in place when this genetic resource was accessed after this date.~~
 - ~~Statement of Compliance with the Nagoya Protocol: Ingredient Out of Scope: SUPPLIER confirms that PRODUCT sourced from COUNTRY is out of scope of EU rules on ABS because it was developed from raw materials that are not genetic resources or is not a result of R&D on a genetic resources.~~
 - SUPPLIER declares that INGREDIENT contains PLANT PART from PLANT SPECIES obtained from CULTIVATION/WILD COLLECTION from COUNTRY.
 - Laws and regulations establishing requirements on access and benefit sharing in COUNTRY include LIST RELEVANT LAWS
 - INGREDIENT does not fall within the scope of these ABS requirements for the following reasons: LIST REASONS SUCH AS SPECIES OR ACTIVITIES EXEMPTED

Identifying control points on ABS

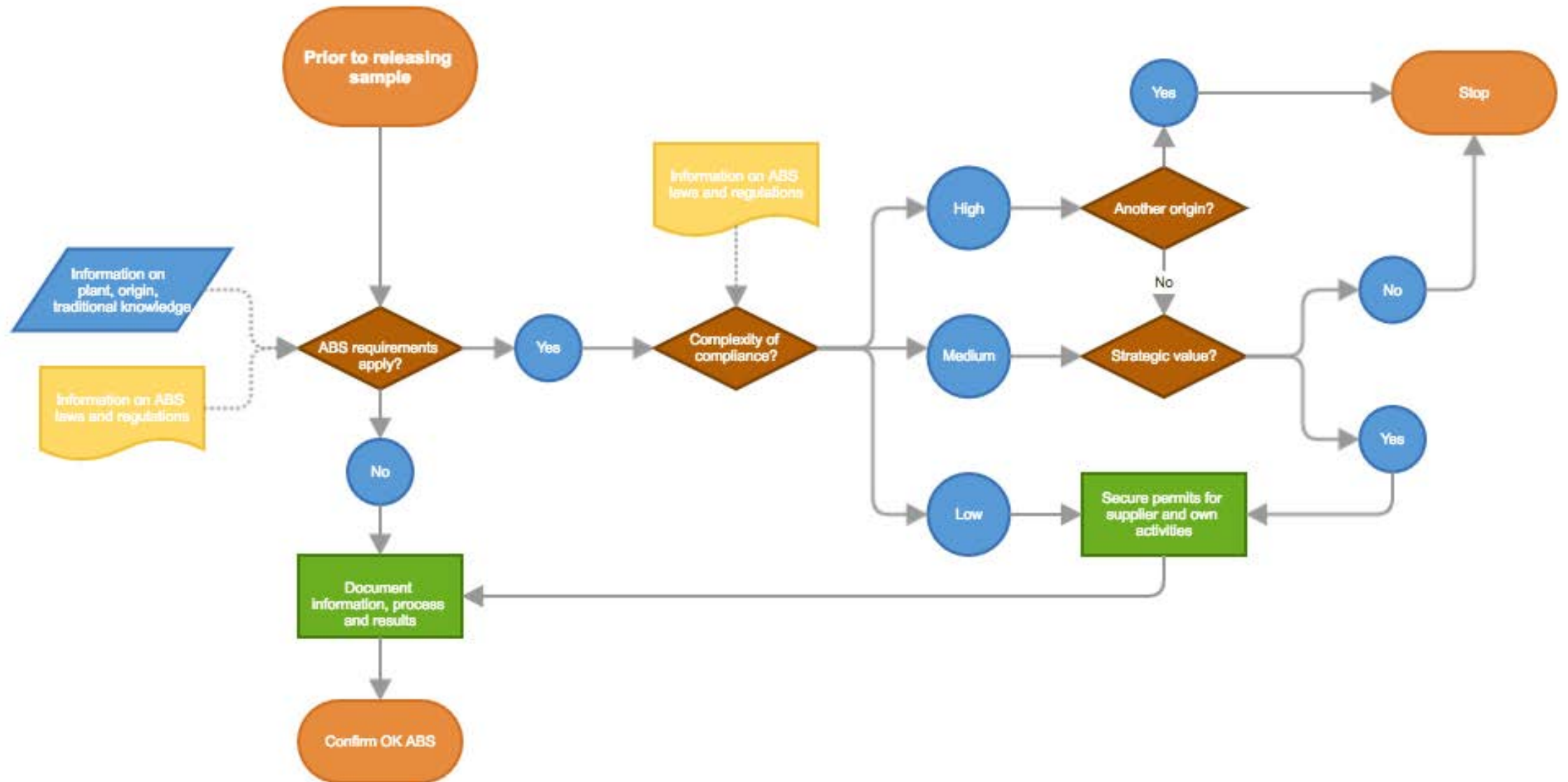
- How to make decisions?

- How to assess information?
- What are parameters for decision-making?
- What are possible outcomes?



Source: Ethics Appraisal Procedure EU-funded activities under Horizon 2020

Identifying control points on ABS



Source: UEFT (2019)



Formalizing the system

- What are **policies and procedures** required to establish due diligence system?
- What are **tools and additional measures** required for an effective implementation of due diligence?
- What are approaches to **raise awareness and build capacities** among relevant staff, suppliers and partners?



Implementing the system

- Observing ABS due diligence policies and procedures
- Documenting steps and findings of due diligence
- Monitoring level of implementation
- Evaluating outcomes, addressing any gaps or confusions
- Evaluating system, based on experiences

Due diligence elements and tools

	Possible support
1. Committing to ABS compliance	
ABS policy	Best practices, sectoral associations, technical support
Procedures for due diligence	Best practices, sectoral associations, technical support
2. Managing information	
Supplier questionnaires	Best practices, sectoral associations, technical support
Information management	Existing R&D, sourcing systems
3. Assessing ABS requirements	
Checklist of ABS requirements	ABS Clearing House Mechanism, national focal points, competent authorities, UEFT fact sheets, technical support
Decision tree	Best practices, sectoral associations, technical support
4. Taking measures to ensure compliance	
Projects or pilot cases	Public private partnerships, technical support

Thank you.





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