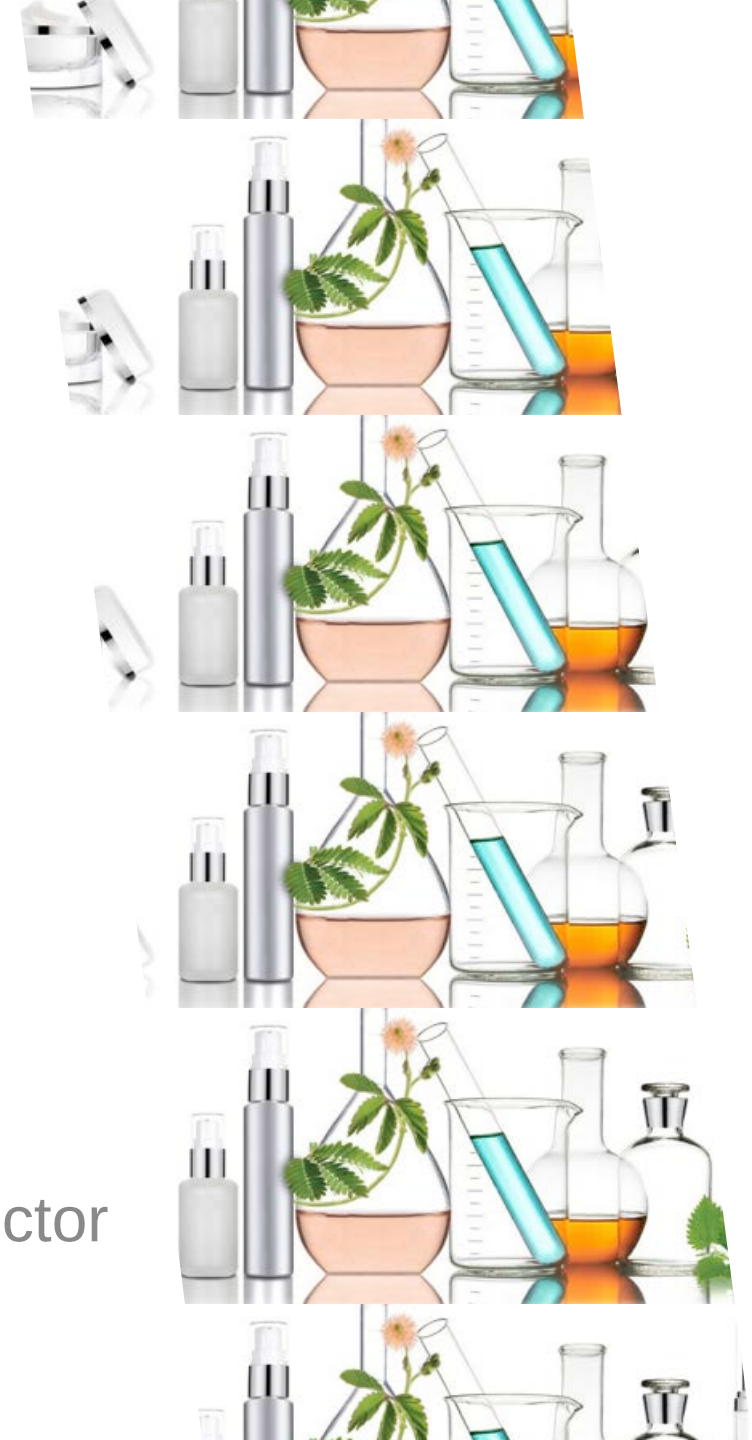
Federal Agency for Nature Conservation

UNION FOR ETHICAL BIOTRADE
SOURCING® WITH RESPECT



Due diligence on ABS

Examples of issues and situations in the pharmaceutical sector

Situation 1a

- Research collaboration with local research institutes.
- Two countries: Brazil and Viet Nam.
- Phase 0: In 2010, local research institutes identified interesting medicinal plant species, based on interviews with local populations
- Phase 1: In 2012, local research institutes collected plants, screened samples and conducted initial in-vitro testing, within parameters established by the company. Compounds and results sent to company, based in Germany.
- Phase 2: In 2019, Brazilian samples have been developed into active principle for pharmaceuticals, in last stages of development. Company is using Vietnamese samples in screening and testing linked to different targets.

Situation 1b

- Is there “utilization of genetic resources”? From which to which points?
- Who is responsible for assessing the existence and applicability of ABS requirements? How can such assessment be undertaken?
- If conducted presently, what measures would be required prior to launching Phase 0 or 1 of the project? What about Phase 2?
- What would constitute due diligence in this context? What would constitutes compliance with national ABS requirements in the provider countries?

Situation 2a

- In trade fair, phytopharmaceutical laboratory is offered sample of an extract of a known and widely-traded succulent plant native to Southern Africa. Plant is used traditionally to cure colds. This extract is newly developed, and standardized for compounds with antiviral effects, by a company based in Sweden with material obtained through South African trader.
- Laboratory conducts tests on identity and basic properties. Given potential, it orders further samples to begin developing a phytopharmaceutical. It considers ABS does not apply as this is not a novel property.

Situation 2b

- Is there “utilization of genetic resources”? From which to which points?
- Who is responsible for assessing the existence and applicability of ABS requirements? How can such assessment be undertaken?
- What would constitute due diligence in this context? What would constitutes compliance with national ABS requirements in the provider countries?

Situation 3a

- Pharmaceutical company has public private partnership. Collaboration includes an agreement with Indian university, under which graduate students collect soil samples and characterize fungi and microorganisms.
- Based on the information, an Indian biotechnology start-up identifies interesting leads for drug development and biopharmaceuticals and conducts initial testing. After the first year, it sends the pharmaceutical company a microbial protein production system; a fungal extract, and a fungal compound that has been chemically modified.
- The pharmaceutical company, based in Germany, is ready to conduct pre-clinical research, but is uncertain about its legal obligation. It has been told by its partners in India that no ABS permit are required for local researchers in India.

Situation 3b

- Is there “utilization of genetic resources”? From which to which points?
- Who is responsible for assessing the existence and applicability of ABS requirements? How can such assessment be undertaken?
- What would constitute due diligence in this context? What would constitutes compliance with national ABS requirements in the provider countries?