

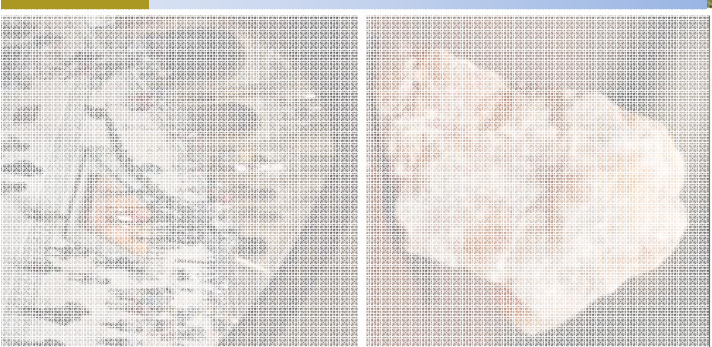
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Introduction to the CBD and the Nagoya Protocol

CETAF Legislation and Regulations Liaison Group

CETAF WORKSHOP ON ABS - Berlin, 25 June 2016



The Convention on Biological Diversity

Role:

International legal framework

Political agreement

To initiate and facilitate action

Entered into Force in 1993

The Convention on Biological Diversity

CBD 3 main **objectives**:

1. conservation of biological diversity
2. sustainable use of its components
3. **fair and equitable sharing of the benefits arising out of the utilization of genetic resources (ABS)**



**Convention on
Biological Diversity**

196 parties to the CBD

New context for researchers using genetic resources (GR)

Keywords: benefit sharing, utilization, access

The Convention on Biological Diversity

Idea behind Article 3 of the CBD: *“States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources ...”*

PARADIGM CHANGE: Genetic resources are no longer common heritage, but instead **States have sovereign rights over their genetic resources**

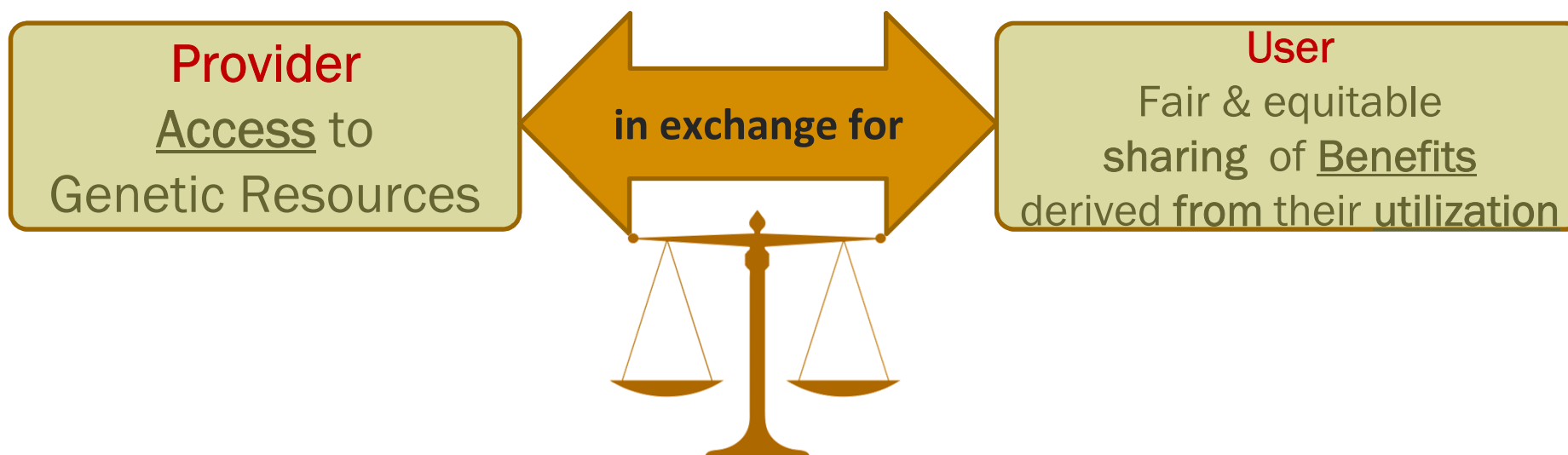
The country may determine:

- **WHO** can collect its biodiversity
- **WHAT** they can do with it

The Convention on Biological Diversity

Basic idea:

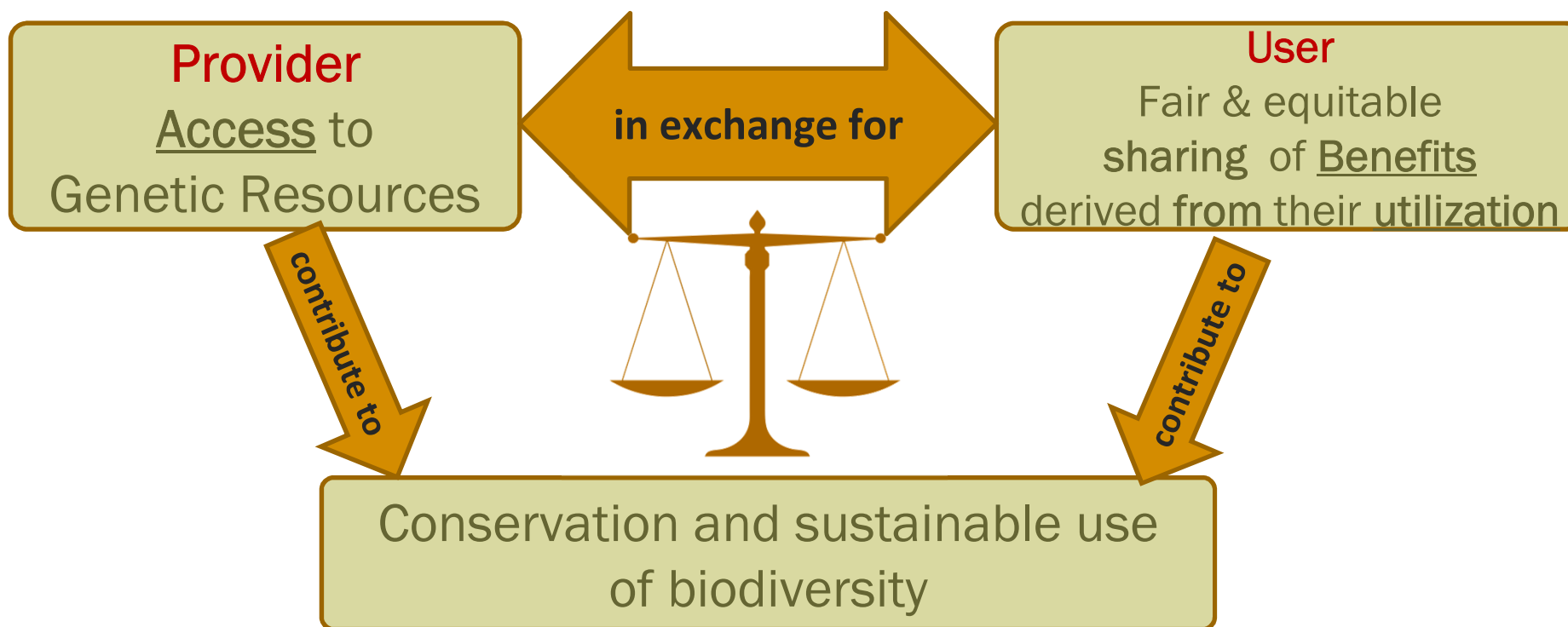
Equity relationship between Access and Benefit-Sharing



The Convention on Biological Diversity

Basic idea:

Equity relationship between Access and Benefit-Sharing



Definitions to Understand ABS

Genetic Resources = any material of plant, animal, microbial or other origin **containing functional units of heredity** and **of actual or potential value**

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The term “**Genetic Resources**” comprises:

- Everything that contains DNA
- Living or dead plant material
- Wild species as well as breeding varieties
- material from *in situ* and *ex situ* sources

Definitions to Understand ABS

- **Access** = Acquisition of a genetic resource
(no matter whether from *in situ* or *ex situ* sources)
- **Utilization** = Research and development on the genetic and/or biochemical composition of genetic resources

Definitions to Understand ABS

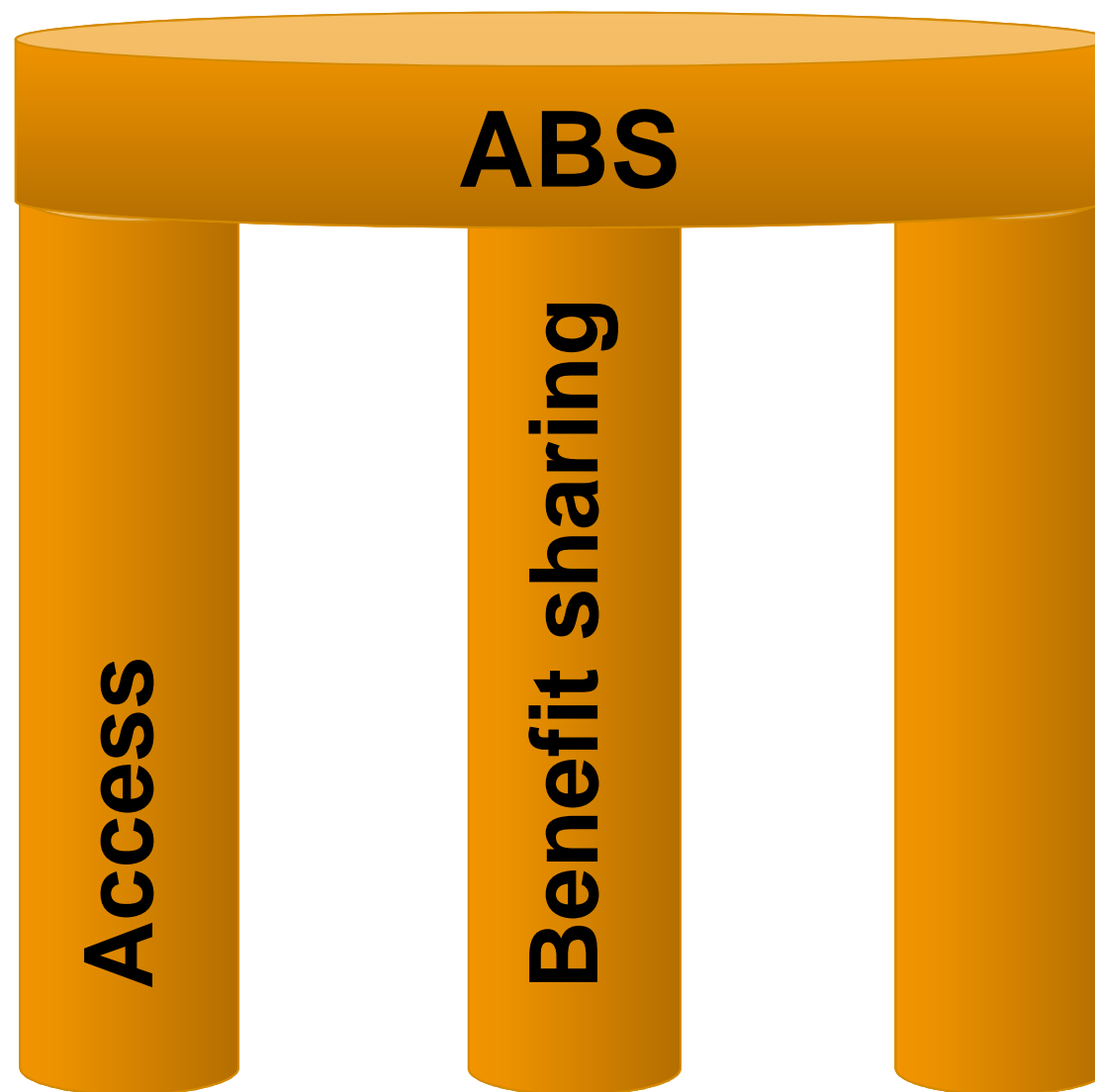
- **Access** = Acquisition of a genetic resource
(no matter whether from *in situ* or *ex situ* sources)
- **Utilization** = Research and development on the genetic and/or biochemical composition of genetic resources

- The definition of “**utilization**” might be interpreted differently from country to country
- No differentiation between commercial and non-commercial (ABS provisions **applicable also to basic research**)

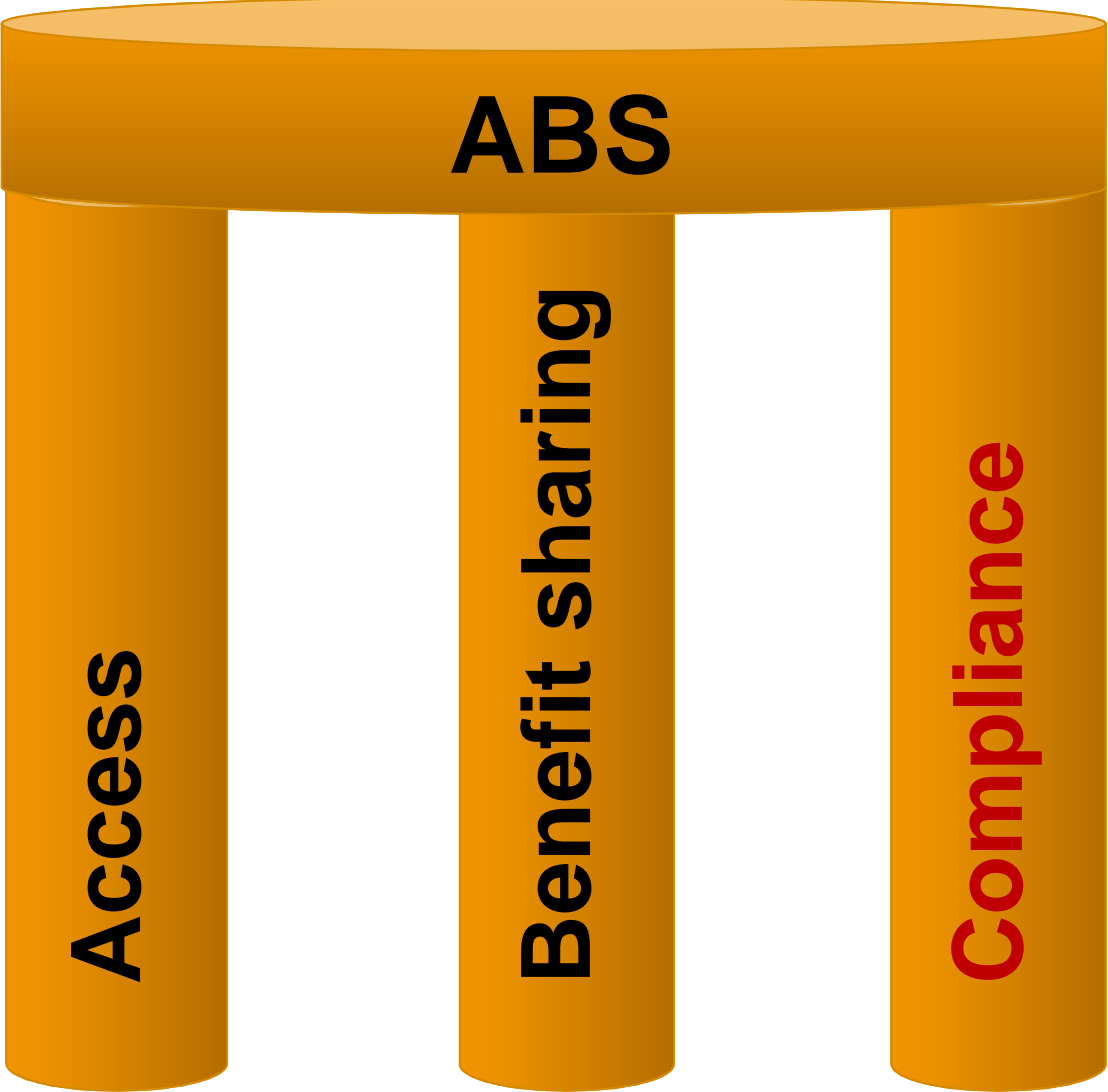
... and some abbreviations & important Terms

- CBD = Convention on Biological Diversity
- NP = Nagoya Protocol
- ABS = Access & Benefit Sharing
- GR = Genetic Resources
- TKaGR = Traditional Knowledge associated with genetic resources
- USER = natural or legal person that utilises GR or TKaGR
- PROVIDER=supplier of GR or TKaGR
- PROVIDING COUNTRY= the country supplying GR
- *IN SITU* SOURCES OF GR=includes populations of both wild and domesticated species. It determines the country of origin of the GR
- *EX SITU* SOURCES OF GR= GR kept outside their natural habitat which may or may not be allocated in the same country of origin of that GR

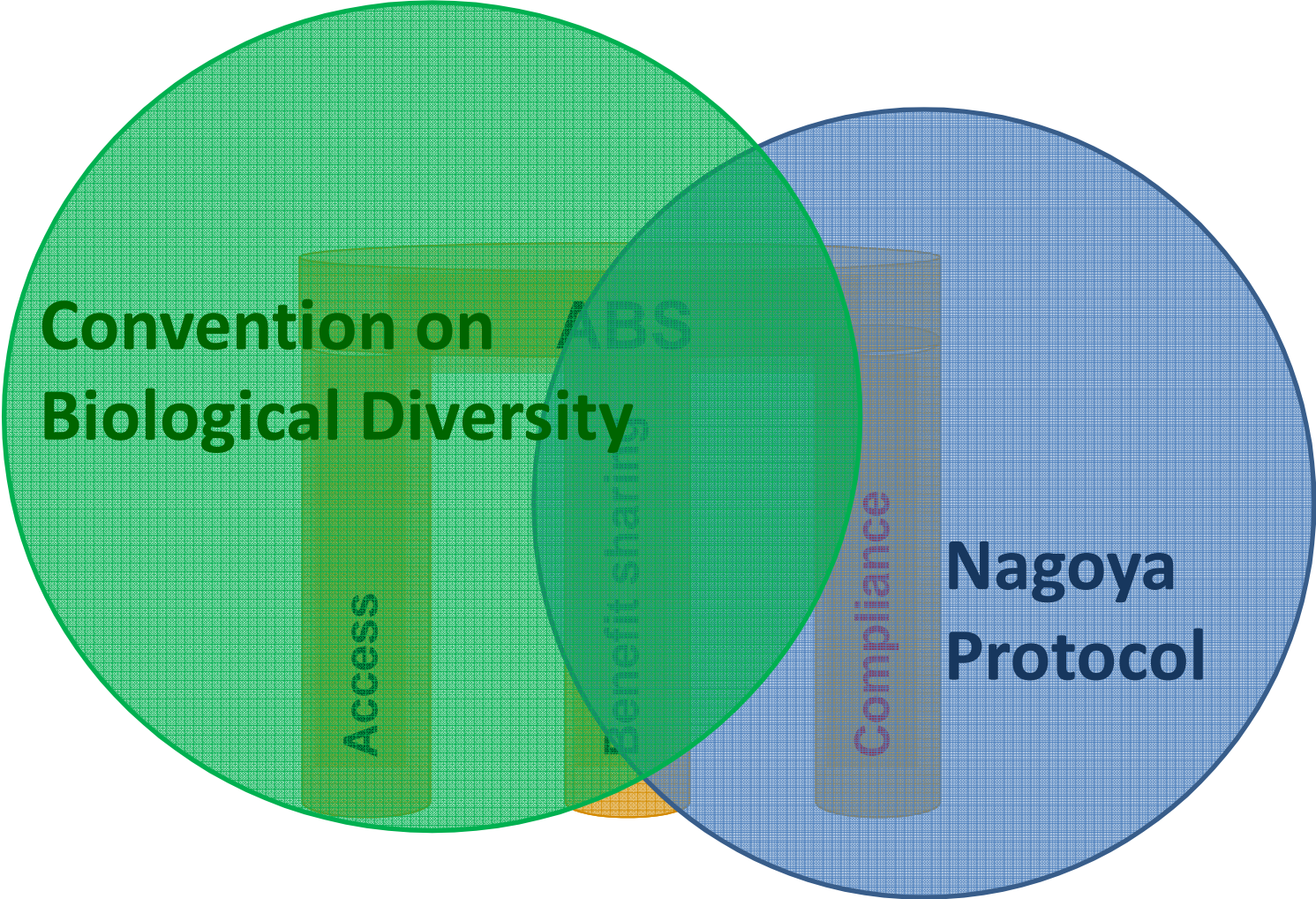
Three Pillars of ABS – the need to add a legal framework



Three Pillars of ABS – the need to add a legal framework



Three Pillars of ABS – the need to add a legal framework



Examples why there is a need for compliance measures

Rooibos Tea (*Asphalatus linearis*)

Nestlé filed a patent for the anti-inflammatory, pro-biotic and health supportive nature of rooibos tea, traded

An NGOs claims that this violates the principles of the CBD and is against South African law.

*The NGO claimed that "If they're exporting rooibos to make tea, they don't need a permit. But if they were going to be used for **research**, the suppliers would have needed an export permit including a bioprospecting application from Nestlé."*

<http://www.ictsd.org/bridges-news/biores/news/food-giant-nestl%C3%A9-accused-of-biopiracy>

Examples why there is a need for compliance measures

Hoodia goordonii

The indigenous Khoi-San people in Southern Africa have used this plant as an appetite suppressant for long time, knowing its medicinal properties

In 1997, CSIR patented the use of the extracted ingredient

In 2002 after international outcry, CSIR officially recognized the rights of the Khoi-San people over hoodia

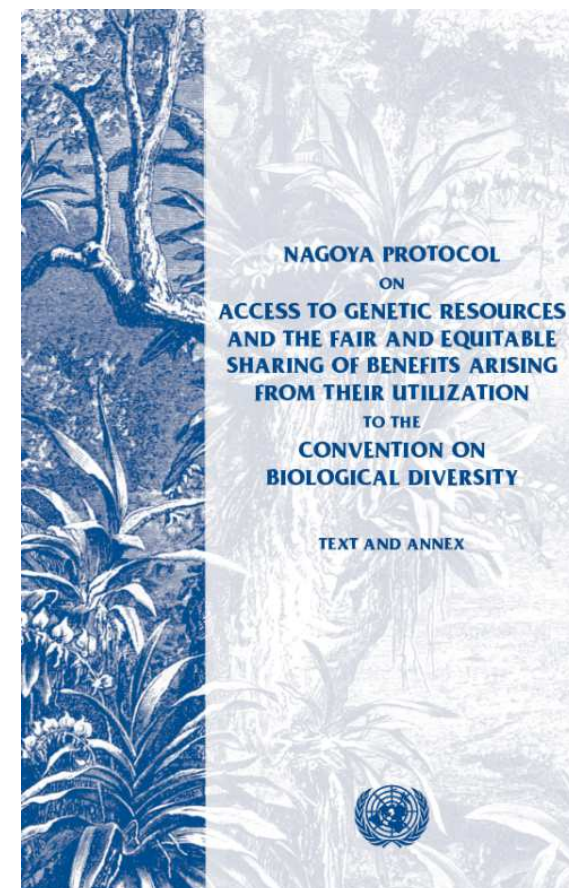
<http://www.kew.org/science-conservation/plants-fungi/hoodia-gordonii>

A Further Step for Compliance - the Nagoya Protocol

2010 (CBD COP10): Nagoya Protocol on Access and Benefit Sharing adopted (www.cbd.int/abs)

Supplementary agreement to CBD, providing a legally binding framework for the implementation of its objective 3

- **12 October 2014:** Nagoya Protocol came into force
- 69 parties (updated 16 Mar 2016)



The concept of the Nagoya Protocol

The **Nagoya Protocol** further specifies Article 15 of the Convention on access to genetic resources (GR)

It should provide:

legal certainty

transparency for both providers and users of GR and TKaGR

The key elements of the NP are

- to establish **predictable conditions** for access to GR in the Providing Country
- to ensure that **only legally acquired GR are used**
- that **potential benefits** arising from utilisation of GR **are shared**
- to establish **compliance measures** (Check points)

The Nagoya Protocol

Parties of the Protocol should:

- establish a **national Focal Point** (NFP) providing information and facilitating cooperation
- establish one or more **Competent National Authorities** regulating access
- take measures to **raise awareness**
- cooperate in **capacity building**
- **cooperate in research**
- **promote technology transfer**

The Nagoya Protocol

Parties of the Protocol should also:

- give special considerations to:
 - Create conditions with **simplified measures** for non-commercial research
 - Pay due regard to **emergencies affecting human, animal or plant health**
 - Consider the importance of **GR for food and agriculture**
- Encourage development and use of
 - **model contractual clauses** for Mutually Agreed Terms (MAT)
 - **codes of conduct**
 - **guidelines**
 - **best practices and standards**

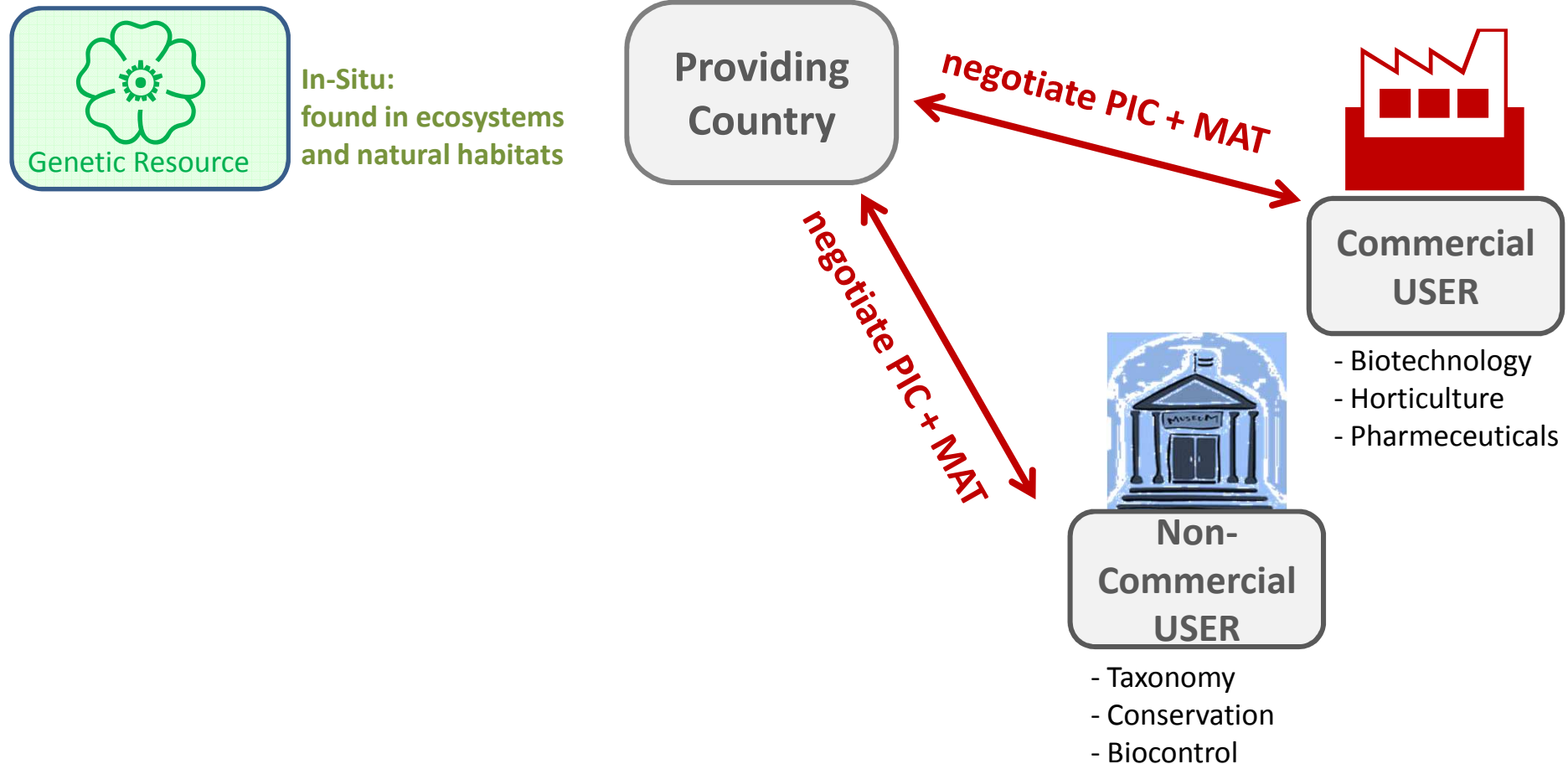
The Scope of the Nagoya Protocol

- **The scope of what exactly will be covered is being negotiated at national level**
- **The NP does not apply to :**
 - **human genetic resources**
 - But it **does** cover human pathogens, parasites and other associated organisms carrying genetic material
 - **areas beyond national jurisdiction** (e.g. Open Sea or Antarctica)
 - to exchange of raw materials and traded commodities

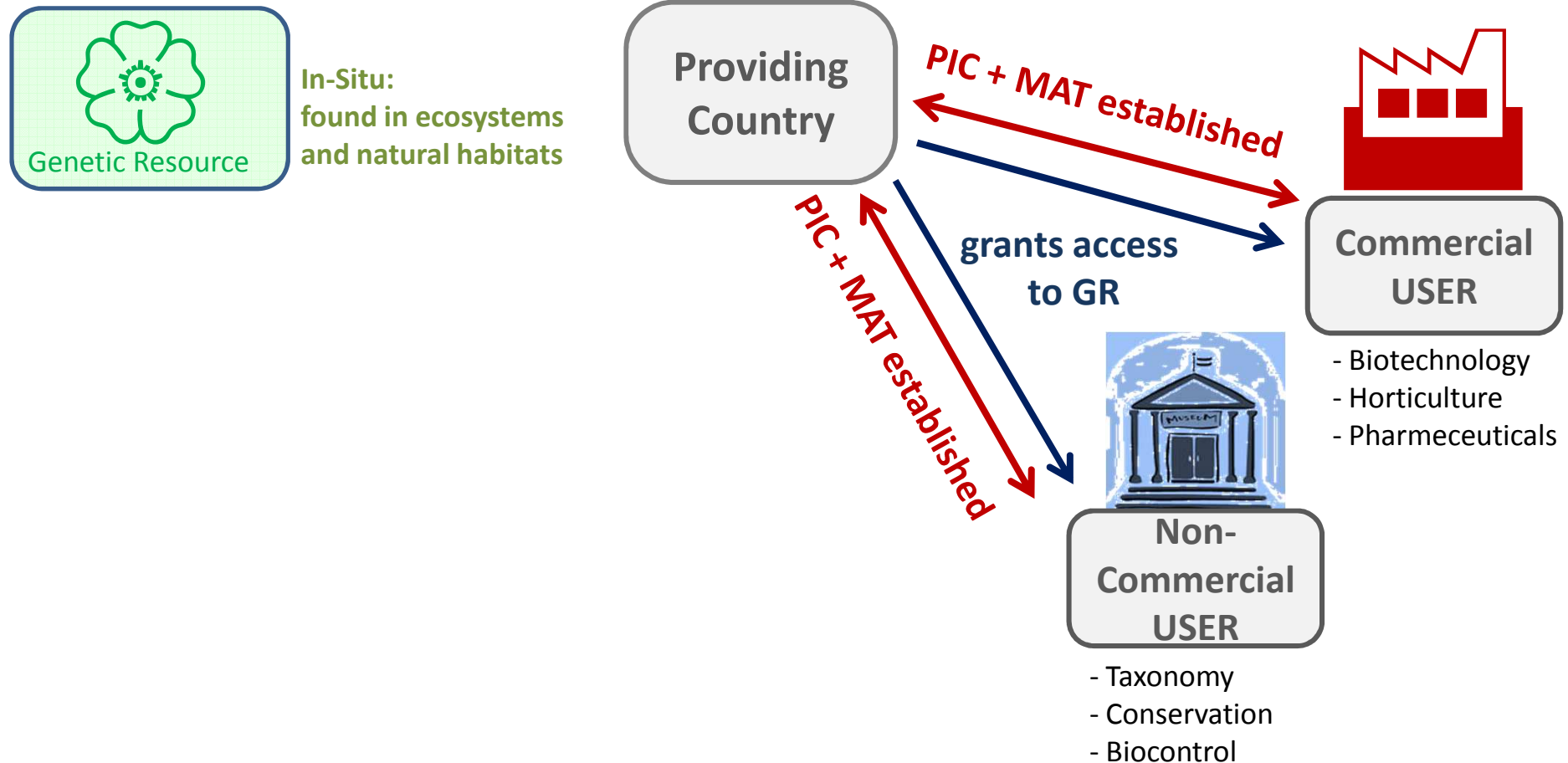
The Scope of the Nagoya Protocol

- **It should be carefully checked if it applies to GR covered by other international agreements such as**
- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), e.g. if used for research and development
- Pathogens, e.g. those covered under the WHO PIP-Pandemic influenza preparedness Framework (WHO-World Health Organization)

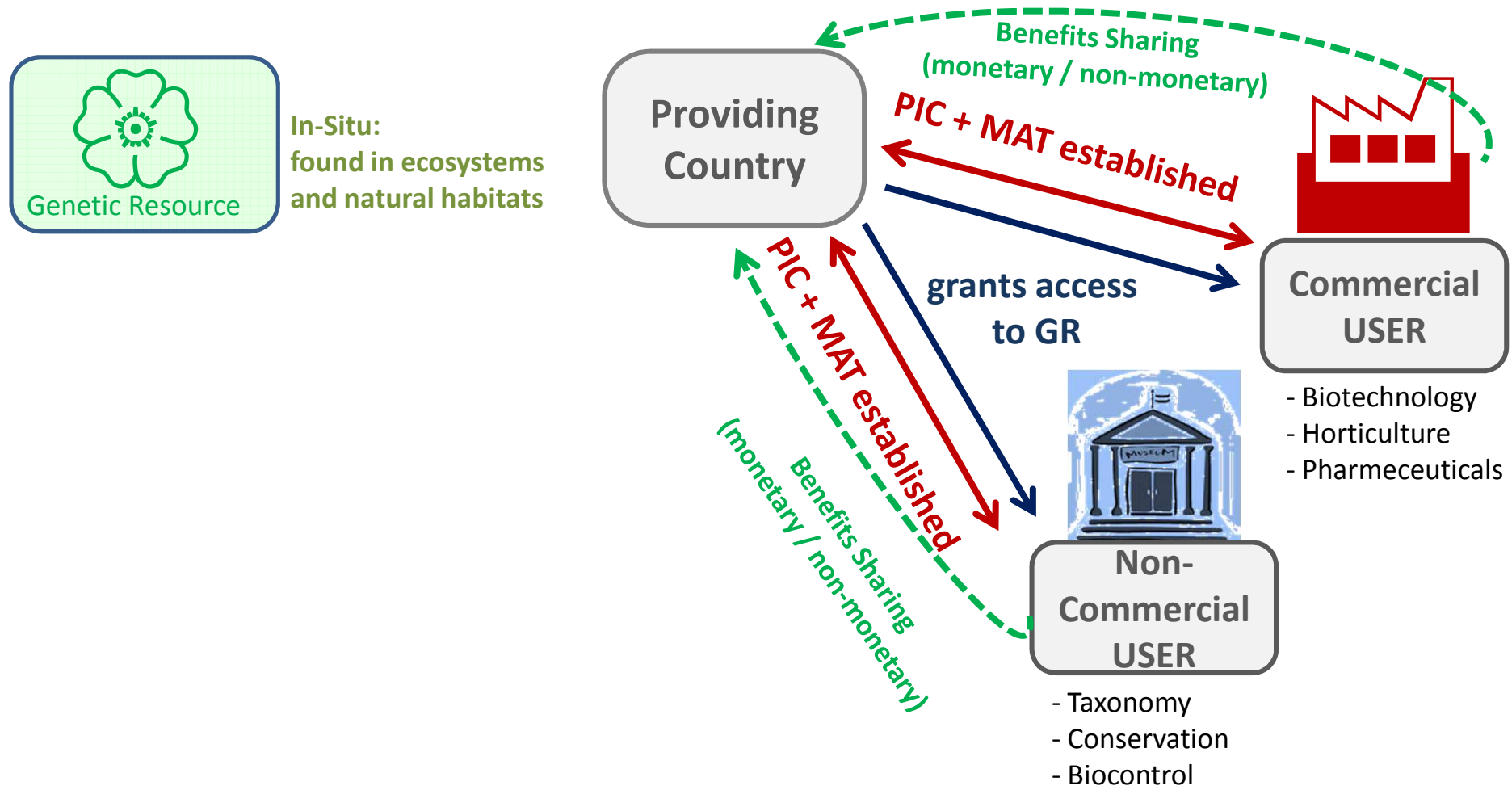
ABS – how it works in principle



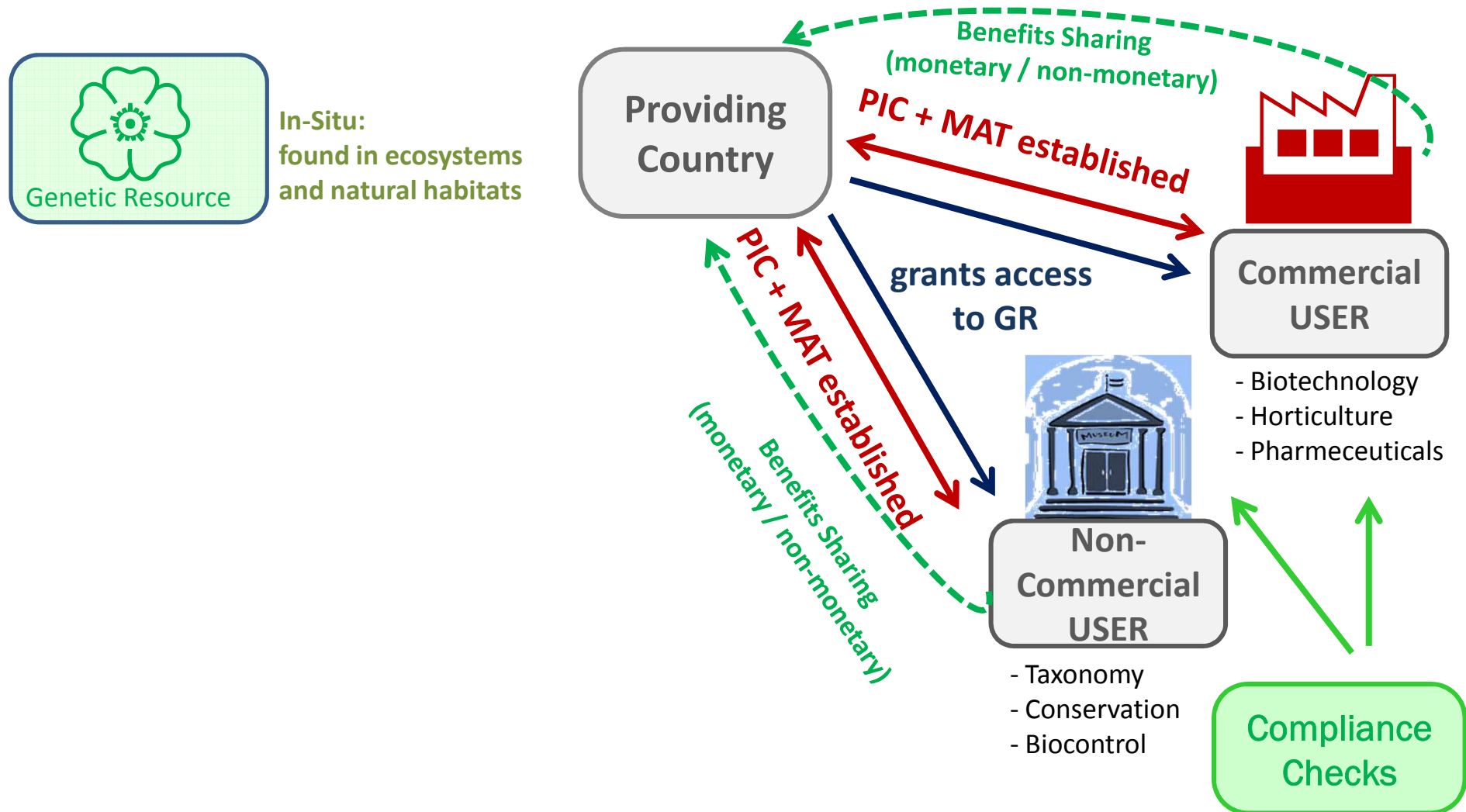
ABS – how it works in principle



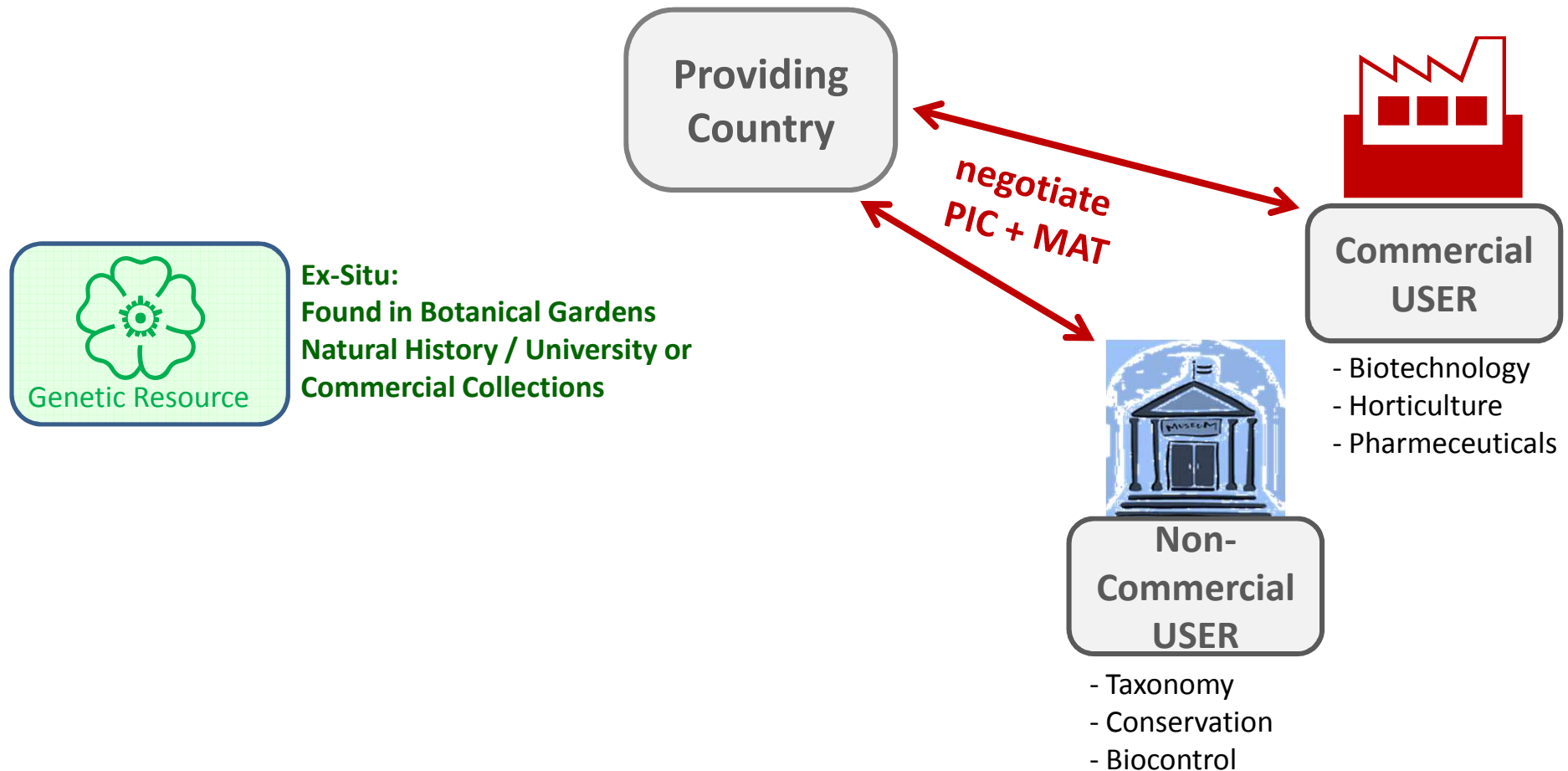
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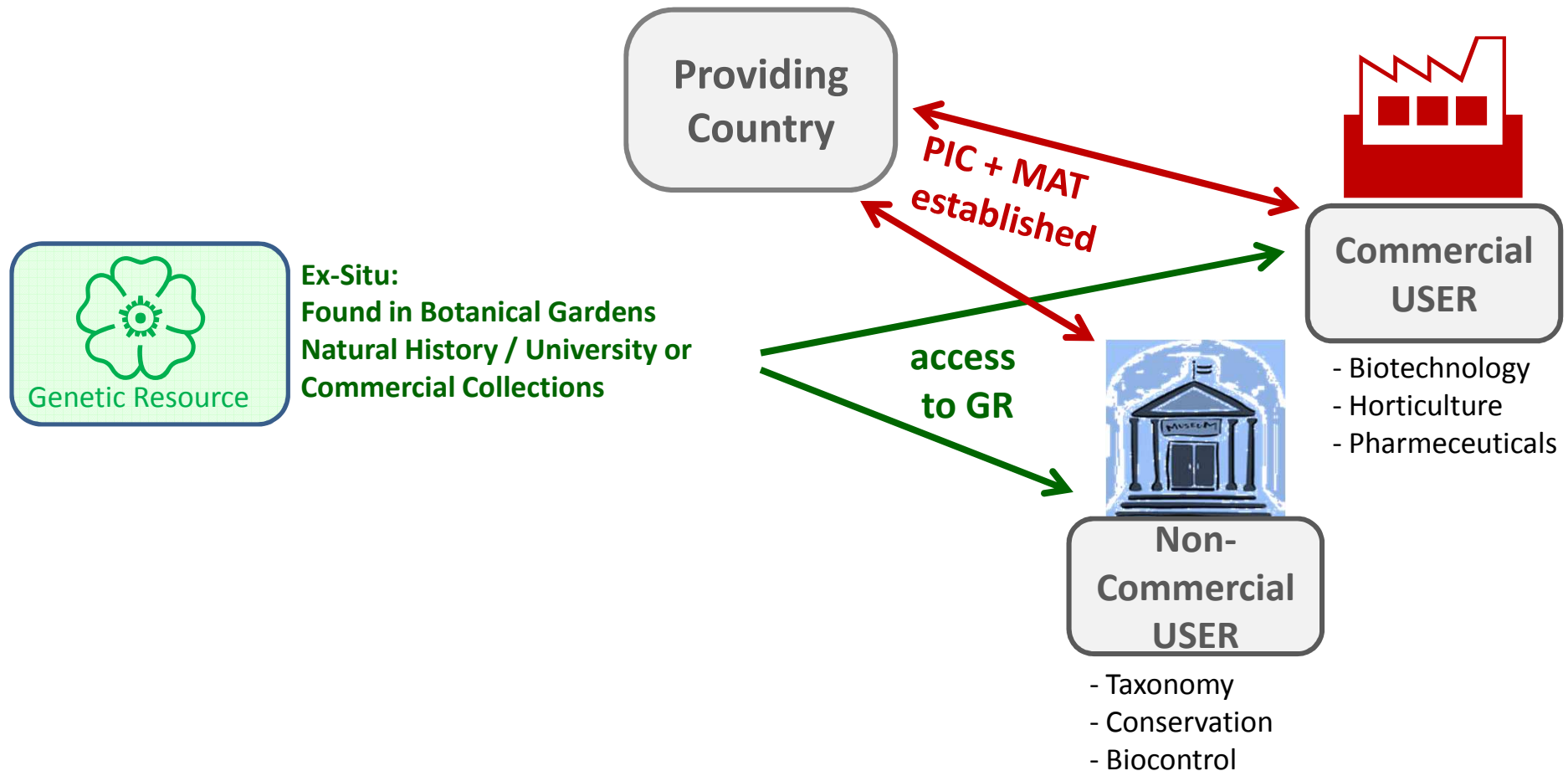
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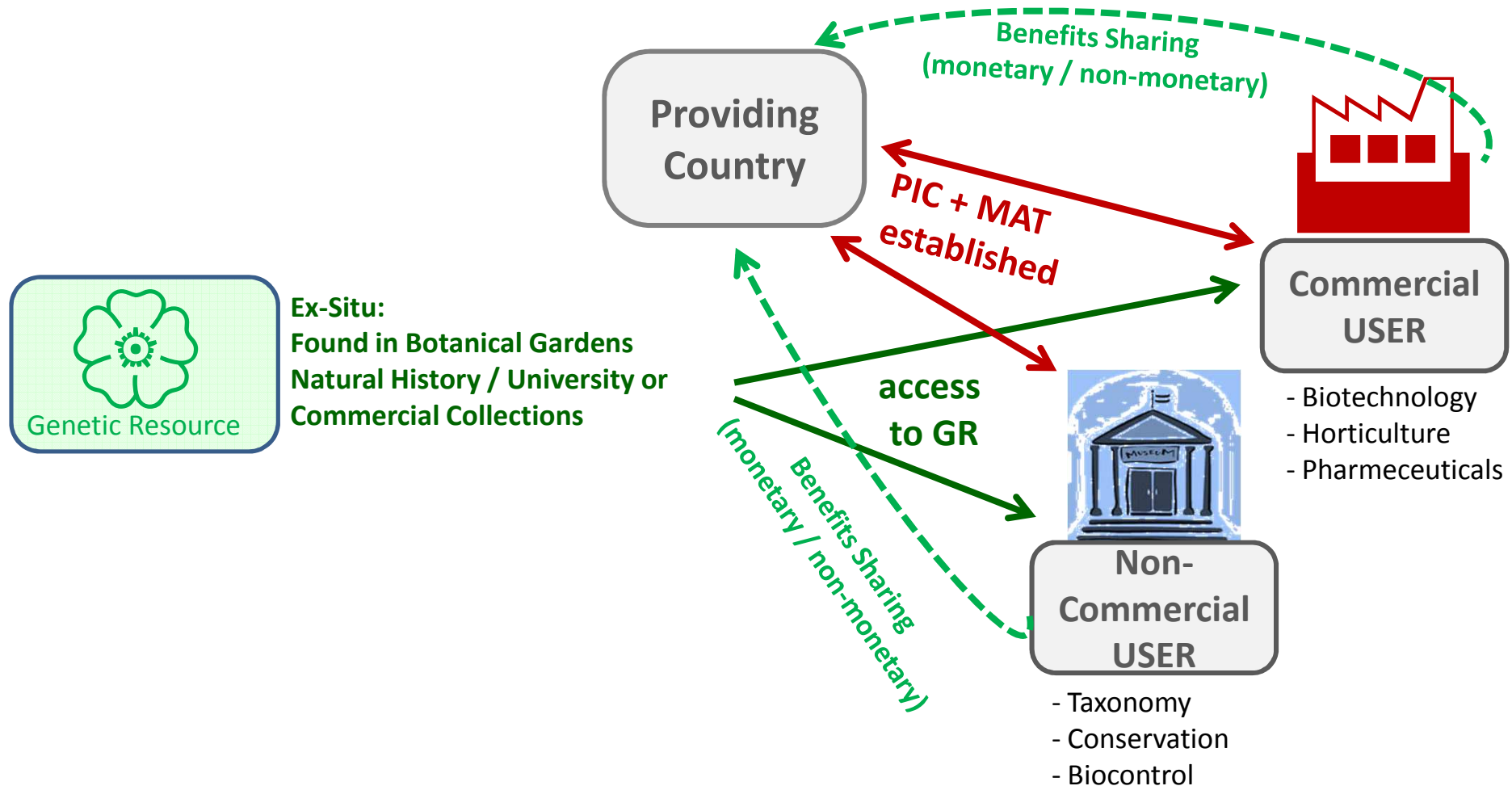
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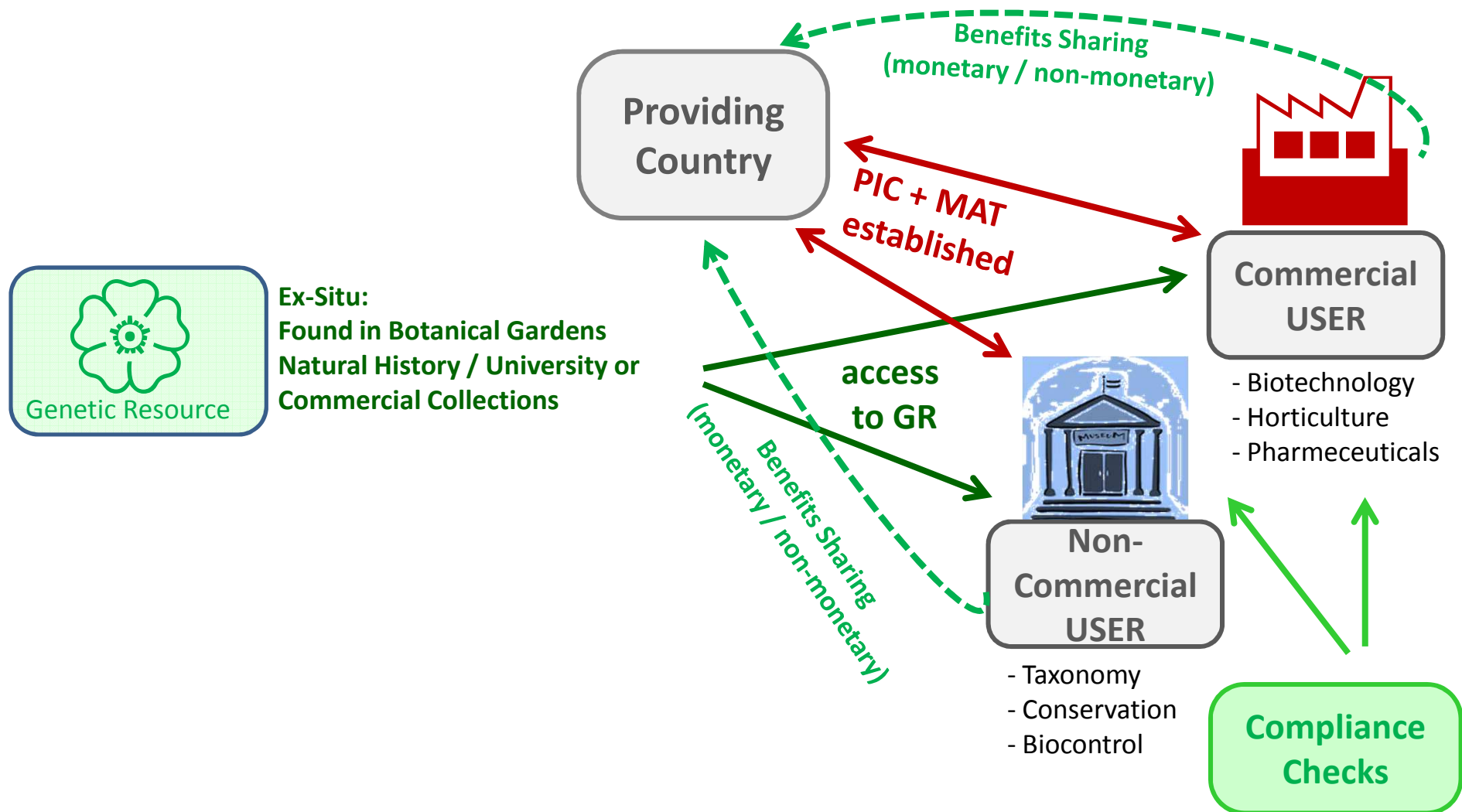
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Nagoya Protocol: THE ABC OF ABS

Access



States (also within EU)
may regulate access to
their genetic resources

→ *National Legislation*

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Get permission (PIC,
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Benefit-Sharing



Users must agree
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→ *Mutually agreed
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Compliance



States must ensure that users comply with the Nagoya Protocol

→ *EU Regulation*

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→ *EU Regulation*



Fulfill obligations of
the EU Regulation
(e.g. reporting)



ABS – workflow

- **Negotiate PIC:**
 - ✓ **Prior Informed Consent** = permission of the Providing Country to a user to access GR
- **Negotiate MAT:**
 - ✓ **Mutually Agreed Terms** = agreement between *provider* and *user* of GR on conditions of access, use and (monetary / non-monetary) benefit sharing between both parties

Important:

Do not confuse MAT with **MTA (Material Transfer Agreement)**: an agreement between two institutions stipulating the terms and conditions for transferring specimens or samples, including genetic material, on voluntary basis to ease procedures

Has been good practice anyway

- 1. Legal compliance.** You have comply with all legal requirements (as per current legislation).
- 2. Contractual agreements.** You already negotiate access with providing countries. Now, you need to follow the documentation requirements.
- 3. Reputational conditions.** The benefit sharing has been done for decades; it is already an implemented practice for researchers (on non-monetary basis).



ABS working group

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