United Nations
Educational, Scientific and
Cultural Organization

UNESCO Chair in
Environmental Studies

Universidad
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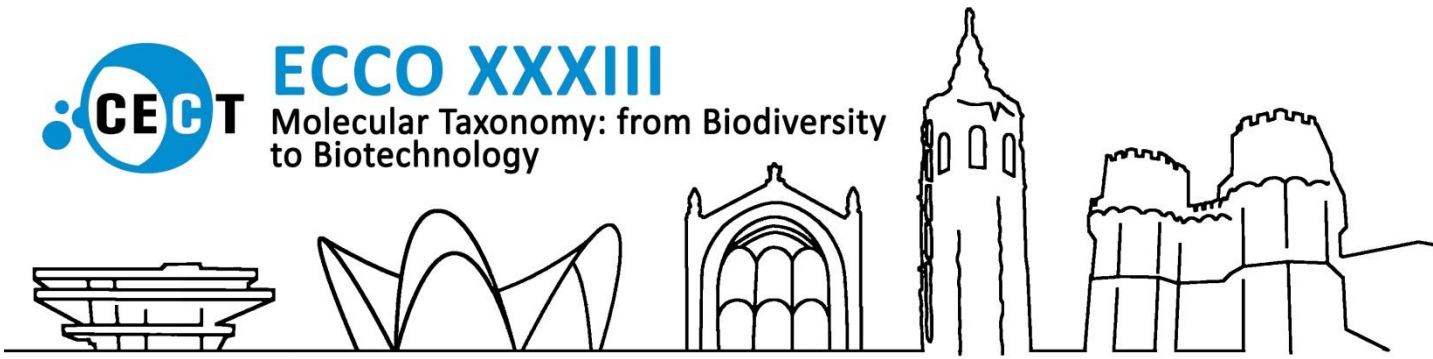
NAGOYA PROTOCOL ON ACCESS TO GR AND BENEFIT SHARING (**ABS**): CHALLENGES AND OPPORTUNITIES FOR MICROBIOLOGY



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Outline

1. About Access to genetic resources and Benefit-Sharing (ABS)
2. Main instruments and features
    1. Convention on Biological Diversity
    2. Nagoya Protocol
    3. European Regulation 511/2014
3. Opportunities and Challenges (for microbiology research institutions)

1. About ABS

- ABS:
  - "Access to genetic resources (GR) and the fair and equitable sharing of Benefits arising from their utilization";
  - Also covers access to Traditional Knowledge (TK) held by Indigenous and Local Communities (ILCs) associated with GR and its benefit-sharing
- Historically free access to GR (common heritage) (research conducted by public institutions)

1. About ABS

- Since the decade 1970s
  - Raw material for the elaboration of products of high added value of the new economies: Biotechnology, pharmaceutical, agroindustrial, phytosanitary, cosmetic
  - Common characteristic of the biotech sector: Added value never paid back the access
  - Bigger gap between modified GR (Intellectual Property Rights) and raw GR (common heritage- in favour of science and knowledge)

2.1 Convention on Biological Diversity

- Three objectives (art. 1):
  1. Conservation of biological diversity;
  2. Sustainable use of its components; and
  3. The fair and equitable sharing of the benefits arising out of the utilization of GR
- Limited scope: biodiversity under national jurisdiction; exclusion of human GR (Decision II/11)
- Changes the paradigm- **sovereignty of States over GR**

2.1 Convention on Biological Diversity

- ABS (art. 15):
  - Delicate balance: sovereign rights of States over their GR, access is subject to national legislation (art. 15.1) vs. facilitate access to GR by other Parties (art. 15.2)
  - Basic access instruments: **Prior Informed Consent** (PIC) and **Mutually Agreed Terms** (MAT) (arts. 15.4-5)
  - Develop and carry out scientific research based on GR provided by other Parties with the full participation of, and where possible in, such Parties (art. 15.6)
  - Each Party shall take measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the utilization of GR (art. 15.7)

2.1 Convention on Biological Diversity

- CBD- Other relevant articles:
  - Art. 16.3 and 4 access and transfer of technology that uses GR
  - Art. 16.5 consistency of the patent system with the CBD system and support of the objectives of the Convention
  - Art. 19.1 participation in biotech research that uses GR
  - Art. 19.2 access to the results and benefits of biotechnology
    - Art. 8j) **Traditional knowledge** (TK) of **indigenous and local communities** (ILCs)

2.1 Convention on Biological Diversity

- Bonn Guidelines (2002):
  - Reference for the establishment of:
    - PIC system (Basic principles, elements, competent authorities, procedures, …)
    - MAT
  - Suggestion of possible economic and non economic benefits (annex)
  - Voluntary

2.2 Nagoya Protocol

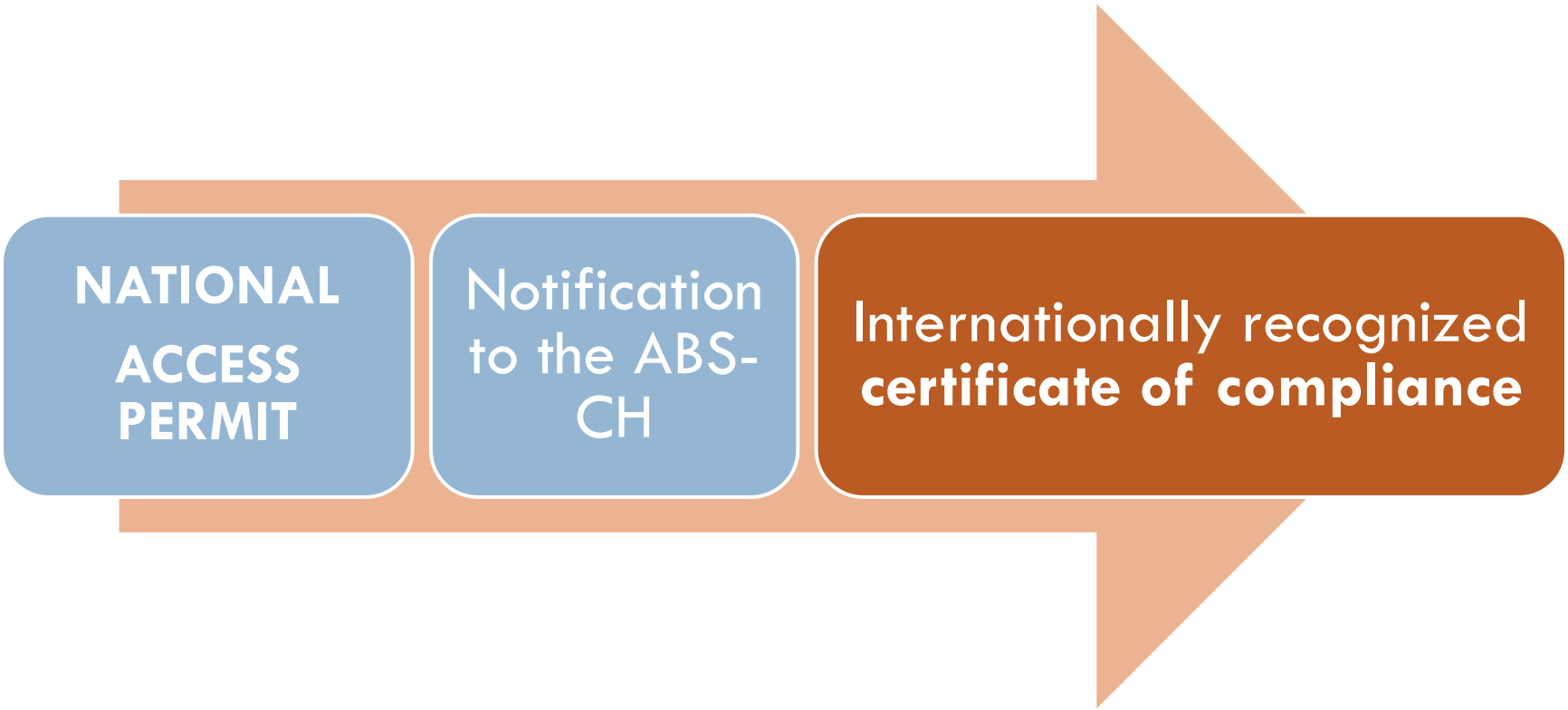
- Adopted at COP-10 (Nagoya, Oct 2010) not yet into force)
- Definition of "utilization of GR"
- Same scope as CBD

- Specialized agreements prevail:
  - International Treaty on Plant GR for Food and Agriculture (FAO) (2001)
  - Pandemic Influenza Preparedness (PIP) Framework WHO (2011)

2.2 Nagoya Protocol

- Main Novelties(ACCESS):
  - More transparent, clear and certain national systems to obtain PIC and MAT
  - **+ NATIONAL PERMIT**(once notified to the ABS-CH-**internationally recognized certificate of compliance**)
  - Respect the rights of ILCs over their GR
  - Simplified access for non commercial research and emergency situations
- ACCESS to TK of ILCs:
  - New international obligation: PIC and MAT from ILCs over their TK
  - Respect ILCs customary laws and community protocols

2.2 Nagoya Protocol



2.2 Nagoya Protocol

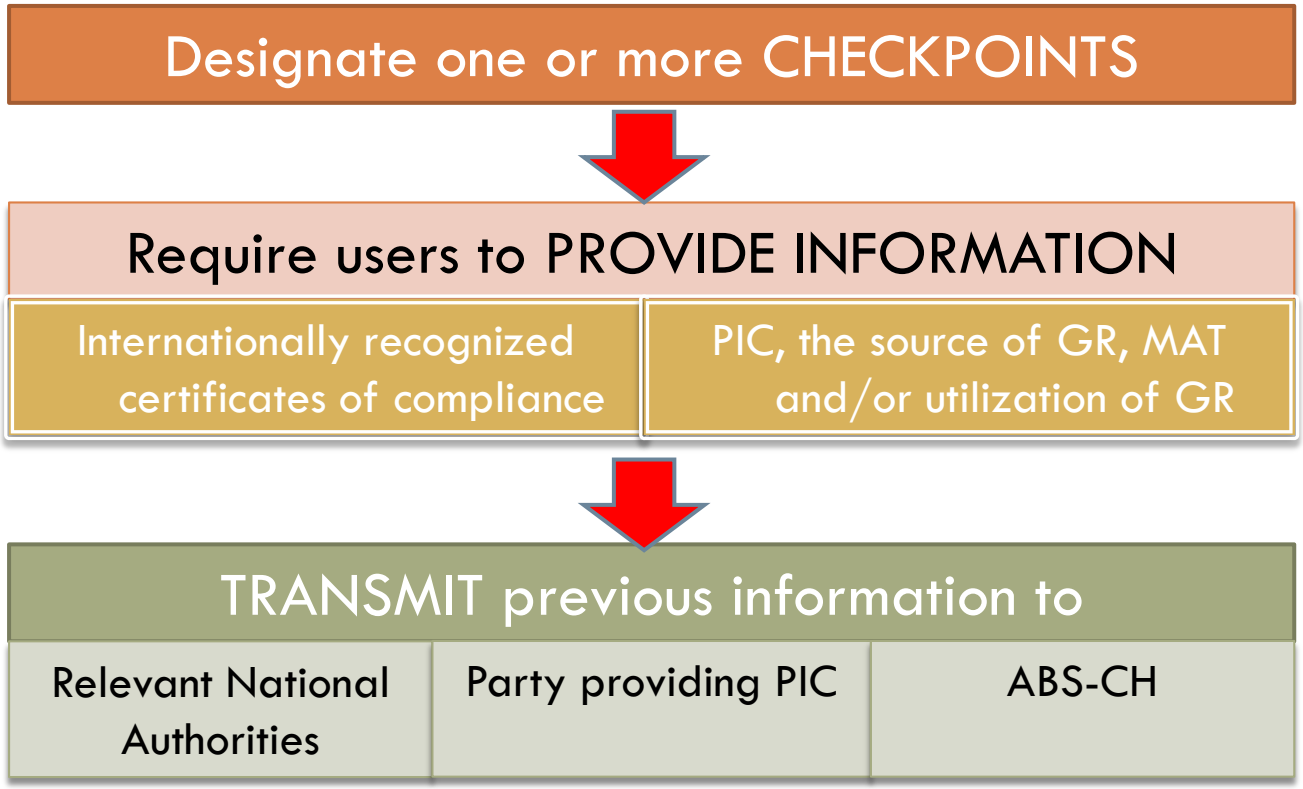
- Nagoya Protocol and research:
  - Facilitated access for non commercial research (art. 8a):

"Each Party shall create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;"

2.2 Nagoya Protocol

Main Novelties (COMPLIANCE):

Monitoring the utilization of GR (art. 17):



2.2 Nagoya Protocol

- Main Novelties (COMPLIANCE):
  - New obligations of Parties in regard to COMPLIANCE:
    - Provide that GR and TK utilized in their jurisdictions have been accessed **in compliance with the ABS legal framework of the provider country**
    - Measures to address situations of non compliance
    - Cooperation between Parties in cases of alleged violation of ABS national frameworks

2.2 Nagoya Protocol

What is the NP going to bring at the international level?

- **FLEXIBILITY** to adapt at the national level to the local circumstances
- **LEGAL CERTAINTY** through the implementation of:
  - More transparent ABS national systems
  - Certificate of compliance
  - Compliance measures in user countries
- **CONTROL OVER GR** (through the monitoring that user and provider countries will have to exercise)
- **VISIBILITY TO ILCS,** in particular on TK issues

2.3 EU REGULATION 511/2014

- EU deposited its accession instrument to the NP on 16th May 2014 (Hungary, Denmark and Spain have already ratified it)
- Published 20/05/2014- will enter into force on the same date as the NP [+ one year of deferred or transition period for the main obligations (arts. 4, 7, 9)]
- Scope:
  - Compliance measures [**Access measures are excluded**- exclusive competence of Member States]
  - GR over which States exercise sovereign rights and to traditional knowledge associated with GR **that are accessed after the entry into force of the Nagoya Protocol for the Union**

2.3 EU REGULATION 511/2014

- GR and TK associated with GR shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements
- Main obligations of European users of GR- **DUE DILIGENCE** (art. 4): seek, keep and transfer to subsequent users the internationally-recognised certificate of compliance and/or PIC and MAT
- When the information in their possession is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or discontinue utilisation

2.3 EU REGULATION 511/2014

- Automatic compliance with due diligence:
  - PGRFA acquired from a Party to the ITPGRFA subject to the SMTA (art. 4.4)
  - GR acquired from a COLLECTION included in the register of collections within the Union (art. 4.7) (Collections, art. 5)
- Special conditions for pathogens (art. 4.8)

2.3 EU REGULATION 511/2014

- Registered collections in the Union (art. 5):
  - Register- European Commission
  - Proposals- Member States
  - A collection shall demonstrate its capacity to:

(a) **apply standardised procedures** for exchanging samples of GR and related information with other collections, and for supplying samples of GR to third persons in line with the CBD and the NP;

(b) supply GR and related information to third persons for their utilisation only **with documentation** providing evidence that were accessed in accordance with applicable ABS legislation;

(c) **keep records** of all samples of GR and related information supplied;

(d) establish or use unique identifiers, where possible, for samples of GR supplied;

(e) use appropriate **tracking and monitoring tools** for exchanging samples of GR and related information with other collections.

2.3 EU REGULATION 511/2014

- Monitoring user compliance (research funding, final development of a product (!?): user self-declaration to the national competent authority (decouple from the substantive authority)
- Authorities (Member States): Plan checks (reduced if BEST PRACTICES) and sanctions
- Some issues will have to be further developed by the European Commission and the Member States (unequal implementation and divergent sanctions in different Member States)

3. Opportunities and Challenges

- Ensure that your institution/collection does not have illegal material
- Lack of clear rules (both access and compliance) in different countries
  - Try to be involved in the development of clear rules and standards for research institutions
  - Research in countries with clear and good records
  - Help those countries to have clear access rules and procedures (promote in your projects the integration of legal and technical capacity)

4. Practical steps ABS policy (CC)

The basic principle

GET MATERIAL/ INFORMATION LEGALLY …
CERTIFICATE OF COMPLIANCE (OR PIC & MAT)

INSTITUTION
USE IN LINE WITH TERMS OF ACQUISITION

SUPPLY IN LINE WITH TERMS OF ACQUISITION

Share benefits

DOCUMENTED

CULTURE COLLECTIONS

INTEGRATE ABS IN YOUR ACTIVITIES

1. RESPECT NATIONAL ACCESS LEGISLATIONS
2. DOCUMENT YOUR STEPS (CERTIFICATE OF COMPLIANCE, PIC & MAT, SOURCE, ..)
3. SHARE BENEFITS
4. RESPECT THE TERMS OF YOUR AGREEMENTS
5. TRANSMIT TO THIRD PARTIES THOSE OBLIGATIONS

+ **REGISTER AS UNION COLLECTIONS**

Thank you for your kind attention

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