

International Governance of Pathogen Genomics Data



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Outline

- 1. Sovereignty over genetic resources**
- 2. Genetic resource digital sequence information**
- 3. Multilateral ABS for pandemic pathogens & sequences**



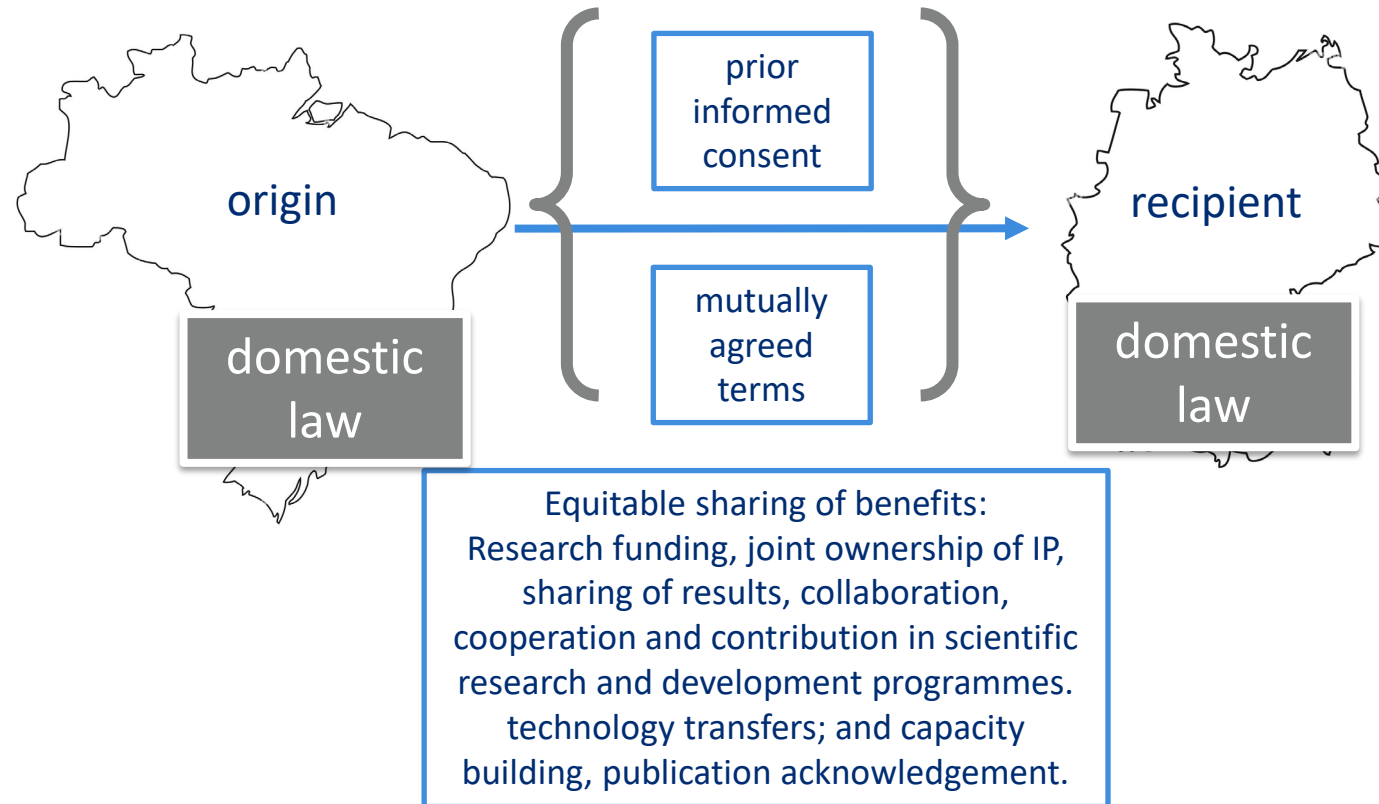
1. Sovereignty over genetic resources

- Sovereignty
 - founding principle of international law
 - inc. right of a state to rule itself, develop its own laws, govern its own territory
 - Extraction of resources as a feature of colonialism
- Convention on Biological Diversity (1992) recognizes:
 - States' sovereign rights over genetic resources within their territory
 - Genetic resources defined to include any material of microbial origin containing functional units of heredity
- Nagoya Protocol governs:
 - **Access** to Genetic Resources; and
 - Fair and Equitable **Sharing of Benefits** Arising from their Utilization → **ABS**



1. Sovereignty over genetic resources

Bilateral – “I give, I get”



Multilateral (for specific genetic resources) – Access decoupled from Benefits Sharing – “We give, we get”

- Pandemic influenza: WHO Pandemic Influenza Preparedness Framework
- Other pathogens: N/A at present time

2. Genetic resource digital sequence information

Expansion of GSD sharing has potential to “unravel” the core bargain of ABS.

- Bilateral:
 - Captured in existing domestic ABS laws
- Multilateral:

Under CBD COP Decision 15/19 (Dec 2022) States Parties:

- *Agree* that the benefits from the use of digital sequence information on genetic resources should be shared fairly and equitably
- Efficient, feasible, certainty, open access, not hinder research & innovation
- Requires distinctive approach but not necessarily legal binding
- Ongoing work (e.g. fund for commercial use, not-for-profit use, voluntary or triggered benefit sharing)



3. Multilateral ABS for Pandemic Pathogens & Sequences

- Negotiations for a Pandemic Agreement
 - Dec 2021, WHO Member States
- **Pathogen Access and Benefits Sharing (PABS) System**

Agreed (as of 22 Jul 2024)

 - Recognition of sovereign rights
 - Public health need for rapid and timely sharing of **pathogens with pandemic potential and sequence information**
 - Rapid, timely, fair and equitable sharing of benefits from pandemic pathogens & sequences
 - PABS System (and definition) to be governed by a new PABS Instrument
 - Importance of legal certainty, and research and innovation



3. Multilateral ABS for Pandemic Pathogens & Sequences

- **Pathogen Access and Benefits Sharing (PABS) System**

Still to be determined (as of 22 Jul 2024)

- Definition of pathogen with pandemic potential
 - Process for access to samples (eg WHO lab networks) and sequences (eg types of databases)
 - Benefits to be shared (eg 10-15% vaccines, diagnostics, therapeutics during a PHEIC, 20% during a pandemic emergency on public health risk and need)
 - Use of legally binding contracts
 - Annual monetary contributions
- Next negotiation sessions: 9-20 Sept, 4-15 Nov
 - Adoption: 15 Dec 2024 or May 2025



Summary

1. Sovereignty over genetic resources

- ABS regimes exist under international law for genetic resources
- Pathogens fall within their scope genetic resources

2. Genetic resource digital sequence information

- There are current efforts to include genetic resource sequence information in a multilateral ABS instrument

3. Multilateral ABS for pandemic pathogens & sequences

- Current negotiations for a Pandemic Agreement include a new PABS instrument specifically for pandemic pathogens and sequences

