

MULTILATERAL BENEFIT-SHARING APPROACHES POSSIBILITIES AND CHALLENGES UNDER THE NAGOYA PROTOCOL

***Third ABS Dialogue
24-25th May 2018, Mexico City***



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OUTLINE

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- **CONCEPT**
 - Benefit Sharing (in the Multilateral Context)
- **LANDSCAPE**
 - Approaches to Benefit-sharing in International Instruments
- **ARTICLE 10**
 - Perspectives and Processes
- **PROSPECTS**
 - For progress

CONCEPT

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THE GRAND BARGAIN OF THE CBD

Access to genetic resources

*From Common Heritage of Mankind
to
National Sovereignty*



Fair and equitable share of the
benefits derived from their
utilization

CONCEPT

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“HYPEROWNERSHIP”

“As more patents issue for synthesized genes, more raw genes are legally enclosed by developing nations.

Increased enclosure, or hyperownership, results in the suboptimal utilization, conservation, and improvement of vital genetic material.

It generates tensions between nations and threatens individuals and indigenous communities. The global commons is being subjected to a global tug of war over genetic material at the expense of the global common good.”

Sabrina Safrin (2004), “Hyperownership in a Time of Biotechnological Promise”

CONCEPT

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IRONIES

- NP bilateral approach advocated and embraced but final deal contingent on entrenching consideration of multilateral approach
- Post-NP adoption and implementation pushing researchers away from in-country/in-situ access and towards ex-situ access
- In-turn, strengthening arguments/rationale advocating need for multilateral benefit-sharing mechanism
- Concurrently, DSI and ARK issues bolstering arguments for multilateral BS approaches

CONCEPT

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BENEFITS

Annex. Monetary and Non-monetary Benefits

1. Monetary benefits may include, but not be limited to:

- (a) Access fees/fee per sample collected or otherwise acquired;
- (b) Up-front payments;
- (c) Milestone payments;
- (d) Payment of royalties;
- (e) Licence fees in case of commercialization;
- (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- (g) Salaries and preferential terms where mutually agreed;
- (h) Research funding;
- (i) Joint ventures;
- (j) Joint ownership of relevant intellectual property rights.

CONCEPT

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BENEFITS

Annex. Monetary and Non-monetary Benefits

2. Non-monetary benefits may include, but not be limited to:

- (a) Sharing of research and development results;
- (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
- (c) Participation in product development;
- (d) Collaboration, cooperation and contribution in education and training;
- (e) Admittance to ex situ facilities of genetic resources and to databases;
- (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
- (g) Strengthening capacities for technology transfer;
- (h) Institutional capacity-building;

CONCEPT

2. Non-monetary benefits may include, but not be limited to:

(Continued)

- (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
- (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- (l) Contributions to the local economy;
- (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
- (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- (o) Food and livelihood security benefits;
- (p) Social recognition;
- (q) Joint ownership of relevant intellectual property rights.

LANDSCAPE

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- FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- World Health Organization (WHO) PIP Framework
- Genetic Resources Beyond National Jurisdiction (BNJ)
 - High Seas
 - Seabed
 - Antarctica
- Intellectual Property Rights
 - WIPO
 - TRIPS
 - UPOV

LANDSCAPE

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Some Reflections on Approaches to Benefit-sharing in Other International Instruments

- Instructive but limited utility re Mechanism
- Specific approaches taken for given “specialized” instruments
- Development takes time
- Iterative processes appear to work
- Sustainability of systems/approaches a question
- Technical issues challenging but surmountable
- Mutual interest required to go forward
- Cost-Benefit should not be ignored
- Benefits to stakeholders (e.g., IPLCs, farmers) re conservation limited

	CBD/NP	ITPGRFA	PIP framework
Parties	CBD: 195+EU – no USA or Vatican NP: 105	144 - no China, Russia, South Africa, Mexico...	194 WHO member states
Scope (resources covered)	All biological resources except human and in areas outside national jurisdiction (& GR covered by particular CBD-supportive ABS instruments)	Of treaty: all PGRFA Of MLS: 35 genera of food crops, 29 forage species And IARC collections For F&A purposes only	Influenza viruses with human pandemic potential
Objectives	Conservation of biological diversity; sustainable use; benefit-sharing	Conservation of PGRFA; sustainable use; benefit-sharing; for sustainable agriculture and food security	Preparedness and response Global influenza surveillance and response system (GISRS) Sharing of pandemic influenza viruses Access to vaccines and sharing of other benefits
Access procedure	Varies by country PIC, MAT CBD: 'facilitated for environmentally sound purposes' NP: 'simplified access procedures for non-commercial research'	Multilateral system SMTA Annex 1 & certain collections 'expeditious'	National labs provide material to WHO labs; SMTA1 between GISRS labs SMTA2 to outside entities
Benefit-sharing	Bilateral Multilateral system is being discussed	Multilateral system, with 4 mechanisms, including the Benefit Sharing Fund	Partnership contributions; SMTA2 terms (company-WHO); Share vaccines, reagents, test kits, antiviral stockpiles, etc.

ARTICLE 10

Article 10. Global Multilateral Benefit-sharing Mechanism

“Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.”

ARTICLE 10

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NEGOTIATING CONTEXT

- Underlying issues (e.g., transboundary) raised over course of talks, but limited discussion
- Global multilateral benefit-sharing mechanism introduced late in game
- Subject to neither substantive discussion nor negotiation
- In effect, a late-hour demand – reflected in final text
- Expedient ‘solution’ to negotiating impasse?

ARTICLE 10

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ISSUE EVOLUTION: PRE-ENTRY

ICNP-2 (July 2012)

- Recommendation to COP11 (NB: Indicative list of questions)

COP-11 (October 2012)

- ES to conduct consultations
- Experts to be convened

Expert meeting (September 2013), Online Discussions

- Mechanism should not undermine State sovereignty
- Mechanism not intended to replace the bilateral nature of Protocol but to supplement it
- Article 11 of the Protocol relevant and helpful in some cases

ICNP-3 (February 2014)

- Considered experts' report, drafted decision

ARTICLE 10

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ISSUE EVOLUTION: POST-ENTRY

COP-MOP 1 (October 2014)

- ES to prepare synthesis of views, commission study, convene experts meeting

Study on experiences gained with the development and implementation of the NP and other multilateral mechanisms

- Experiences gained with the development and implementation of NP and other multilateral mechanisms
- Potential relevance of ongoing work undertaken by other processes, including case studies re ex situ and in situ GRs, ATK and transboundary situations

ARTICLE 10

ISSUE EVOLUTION: POST-ENTRY

EXPERT MEETING

- Recalled sovereign right of States over their genetic resources
- Noted insufficient information and experience to determine need for Mechanism
- Noted relevant developments under internationally (e.g., UNGA, FAO CGRFA, WIPO IGC, WHO, ATS)
- Recognized limited information on implementation on NP provisions re ATK
- Requested ES commission study on ABS practices/experiences in ex situ collections (e.g. national and international, public and private)
- Recognized many situations in which it is not possible to grant or obtain PIC may be addressed through capacity-building for Parties and ILCs

ARTICLE 10

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ISSUE EVOLUTION: POST-ENTRY

COP-MOP 2 (December 2016)

- Invites submissions of information on different aspects re Article 10
- Invites views on the way forward
- Feeding into SBI -- to explore need for a Mechanism and to make recommendations for consideration by COP-MOP 3

PROSPECTS

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SUBMISSIONS

Parties to the Nagoya Protocol and other Governments

- Argentina
- India
- Japan
- Mexico
- Oman

Organizations and stakeholders

- Botanical Gardens and International Plant Exchange Network
- Deutsche Sammlung von Mikroorganismen und Zellkulturen
- Gothenburg Botanical Garden
- International Chamber of Commerce
- Japan Bioindustry Association
- Joseph Henry Vogel - Submission in English, Submission in Spanish
- United Nations Division for Ocean Affairs and the Law of the Sea
- World Federation for Culture Collection, World Data Centre for Microorganisms, Transparent User-friendly System of Transfer programme
- Zoologisches Forschungsmuseum Alexander Koenig

PROSPECTS

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SUBMISSIONS: RANGE OF VIEWS (SELECTED)

PARTIES

- Need for GMBSM must be established before further discussions on modalities etc. takes place
- Only where countries of origin cannot be identified and PIC obtained can GMBSM be supported

- NP Article 11 covers transboundary issues
- Where capacity lacking to grant PIC capacity should be provided (i.e., not relevant to GMBSM)
- Need for GMBSM only be considered after above is examined

- Analyses could be conducted on whether or not GMBSM needed and if it could be used:
 - in absence of ABS legislation/regulation
 - for DSI
 - for enforcement

PROSPECTS

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SUBMISSIONS: RANGE OF VIEWS (SELECTED)

PARTIES

- Situations exist where it is not possible to grant/obtain PIC re in situ or ex situ GRs and ATK
- Technical challenges recognised, as are the political commitments made
- Experts should be convened
- GMBSM could:
 - establish technical assistance and international cooperation schemes
 - incorporate information exchange schemes re GRs and ATK in cross-border elements
 - incorporate tech transfer schemes to facilitate the access of such tools to all in GMBSM
 - promote research and development partnerships, including the private sector

PROSPECTS

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SUBMISSIONS: RANGE OF VIEWS (SELECTED)

STAKEHOLDERS

- Difficulties related to obtaining PIC encountered due to lack of action by authorities
- “We haven’t received a valid Nagoya PIC / MAT from a depositor yet”
- “Many countries are lacking elaborated legal frameworks for collecting, PIC, ABS, etc. It is not possible to demand permits in a specific format when they do not exist from the beginning”
- Not aware of any cases where it is fundamentally not possible to grant or obtain PIC
- “National examples of incomplete or inadequate implementation of the NP do not serve as relevant examples of cases where it is not possible to grant or obtain PIC”
- Premature to negotiate an additional ABS tool such as a GMBSM because:
 - the present bilateral ABS system is not running well
 - full attention of policy makers required to address the implementation challenges

PROSPECTS

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SUBMISSIONS: RANGE OF VIEWS (SELECTED)

STAKEHOLDERS

- Unable to identify concrete situations in which it is not possible to grant/obtain PIC re GRs and ATK
- NP not retroactive
- COP-MOP has not yet identified the need for a GMBSM
- “NP...[prevents doing] biodiversity research in some countries (e.g., India, Indonesia), in which it seems to be impossible to get a PIC/MAT without visiting them personally”
- PIC/MAT unattainable a priori for specimens from unknown countries of origin
- PIC/MAT may be unattainable when in situ sampling occurred before the entry into force of NP but no documentation is available except the fact that the microorganism was deposited before this date
- Other such situations occur when a third party wants to deposit material in a culture collection but has no documentation concerning the date and place of sampling (a “regularising procedure” can be employed in this case)

PROSPECTS

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SUBMISSIONS: RANGE OF VIEWS (SELECTED)

STAKEHOLDERS

- “Bounded Openness for Genetic Resources and Bounded Openness for Traditional Knowledge”
- Modalities for above re GRs:
 - Genetic resources flow unencumbered for R&D
 - Disclosure of utilization occurs through applications for intellect property protection over the value added
 - GMBSM acquires or outsources the capability to determine the diffusion of natural information across taxa and the corresponding geographic distributions across jurisdictions
 - Royalty rates are negotiated through the COP and will vary according to the combination of characteristics in utilization
 - The royalty is levied only when utilization has become sufficiently successful to cover the costs of determining the diffusion across taxa and determining the apportionment of revenues according to geographic distribution
 - Should the estimates of the aforementioned costs still exceed the revenues collected by the date of expiry of the IP then the revenues collected are dedicated to the infrastructure of the GMBSM, thereby making the GMBSM self-financing

PROSPECTS

SUBSIDIARY BODY ON IMPLEMENTATION (9-14 JULY 2018)

“The Subsidiary Body on Implementation will have before it a note by the Executive Secretary developed in accordance with paragraphs 3 to 6 of the decision.

The Subsidiary Body on Implementation is invited to consider this matter and make recommendations for consideration by the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its third meeting.”

PROSPECTS

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PRAGMATIC AND STRATEGIC “REALITIES”

- Magnitude of problem in question
- Range of views on purpose and modalities (middle ground?)
- Clarity on specific policy gap the GMBSM meant to fill is required
- Political issue? Technical solution?
- Deep suspicion among some Parties and stakeholders (users)
- Should no-go zones be established?
- Panacea or Trojan Horse?
- Could fall under its own weight!
- Look forward, anticipatory approach
- Identify incentives

PROSPECTS

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PRAGMATIC AND STRATEGIC “REALITIES”

- Link with DSI? Link with ATK?
 - Good or bad for respective issues?
 - Tactical questions??
- Bilateral not ideal for DSI PIC/MAT
- Will Mechanism improve ability of Parties to use DSI?
- Need to address non-monetary benefits, distribution
- Investment vs. outcome, vs. other priority challenges?
- Limited resources/attention spans
- Bilateral approach yet to be fully implemented
- Cynicism exists, momentum time-limited

PROSPECTS

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PRAGMATIC AND STRATEGIC CONSIDERATIONS

Strategies and Process Going Forward: The Art of the Possible

- Refine core questions
- Define goals (e.g., conservation? sustainable use?)
- Public good argument
- Clarity on benefits Mechanism will provide and to whom (e.g., IPLCs)--
 Conceptualize benefit sharing in its broadest terms
- Build on intersection of views
- Dialogue with researchers
- Identify intermediate steps and aim for concrete process
- Cross-forum synergies could be explored but potential has limits (political

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FAO INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (ITPGRFA)

PGRFA ARE DIFFERENT

- Vital for food security
- Countries are interdependent on PGRFA – all countries depend on crops that originated elsewhere
- Human intervention – farmers have adapted crops to different climates and needs, and shared
- Intra-specific variety

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ITPGRFA

MULTILATERAL SYSTEM OF ABS:

- ▣ Facilitated exchange of a common pool of genetic resources
- ▣ Multilateral benefit sharing (vs. CBD bilateral approach):
benefits go to the Multilateral System
- ▣ Standard MTA – no case-by-case negotiations

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ITPGRFA

MULTILATERAL SYSTEM (art. 11):

- Scope:
 - ▣ Plant genetic resources *for food and agriculture*
 - ▣ Annex I
 - ▣ “Under the management and control of the Contracting Parties and in the public domain”
 - ▣ Genetic resources from the CGIAR (some exceptions)
 - ▣ Private collections (voluntary)

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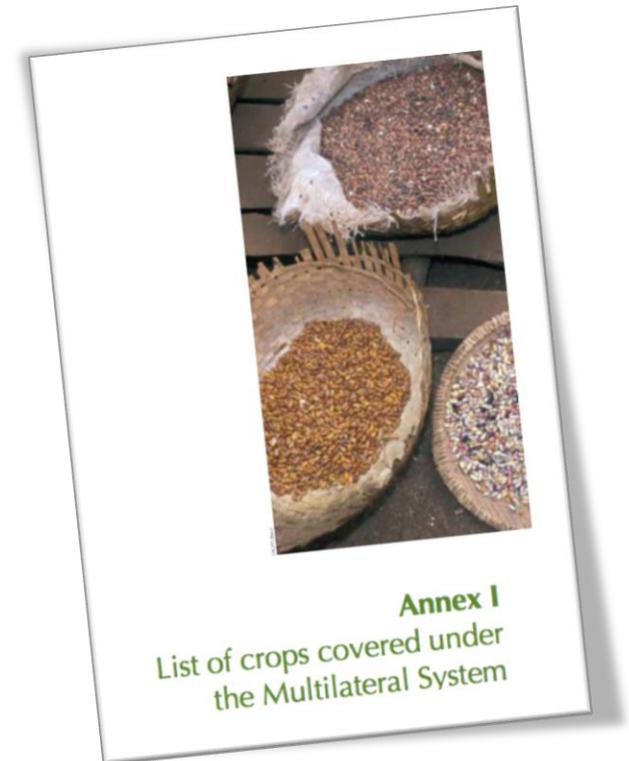
ITPGRFA

ANNEX 1 CROPS

- 35 genera of food crops and 29 forage species, including all major 'international crops' except:
 - groundnut
 - soybean
 - tropical forages

- Also not yet included: *Phaseolus polyanthus*, *Solanum phureja*, *Musa textilis*, *Zea perennis* / *Zea diploperennis* / *Zea luxurians*, minor millets, *Aegelops*

- In the case of cassava, only *Manihot esculenta* is included



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ITPGRFA

BENEFIT SHARING

- Facilitated access - itself a major benefit
- Exchange of information
- Access to and transfer of technology
- Capacity building
- Sharing of monetary and other benefits of commercialization

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ITPGRFA

7TH GOVERNING BODY (2017)

- Benefit-sharing: improve the flow of monetary benefits
 - ▣ possible move to a Subscription System for regular users and a mechanism for occasional users, instead of voluntary payments
 - ▣ SMTA to be revised
 - ▣ Annex 1 may be amended (more crops would attract more subscriptions to the MLS and so more monetary benefits)
 - *all this will take time!*
- Considering how to manage and monitor the use of digital sequence data in the Global Information System

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GENETIC RESOURCES BNJ: ANTARCTIC

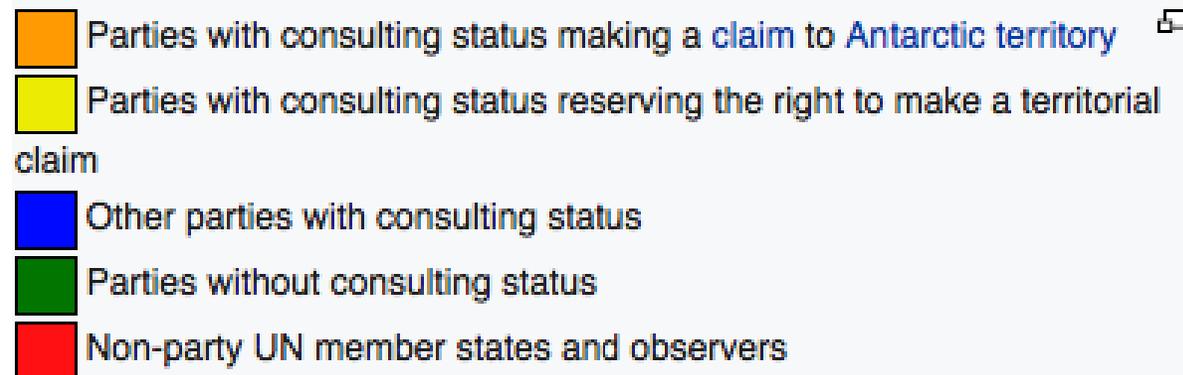
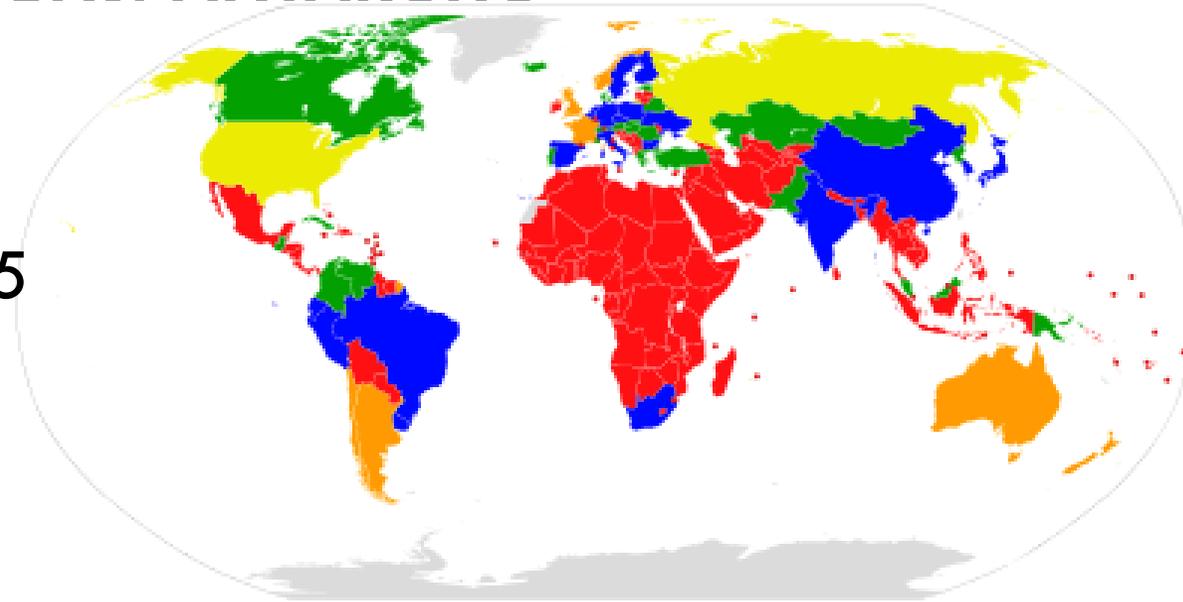
Antarctic Treaty System:

- Antarctica and the Southern Ocean: 10% of the planet's surface south of 60th parallel south
- Antarctic Treaty (entered into force 1961, 63 Parties)
 - ▣ covers land and ice shelves, not high seas
 - ▣ sets aside Antarctica as a scientific preserve, establishes **freedom of scientific investigation (with advance notice), results exchanged and freely available**, bans military activity

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GENETIC RESOURCES BNJ: ANTARCTIC

Antarctic Treaty
53 Parties as of 2015
29 with voting status



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INTELLECTUAL PROPERTY RIGHTS (IPRs)

Major IPR Issues for ABS

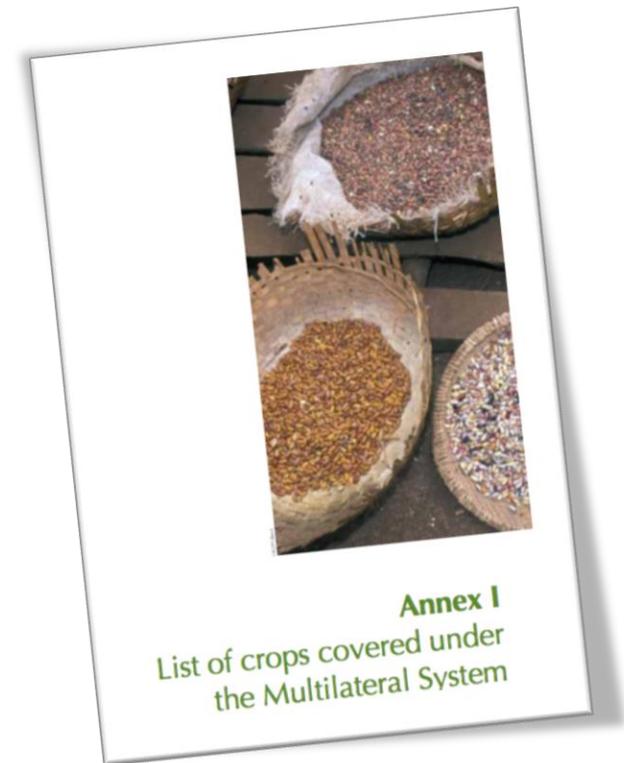
- Disclosure of origin of genetic resources and traditional knowledge to prevent misappropriation
- Sui generis protection of traditional knowledge to reflect its special characteristics

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ITPGRFA

Challenges

- Low number of notifications of PGRFA in the Multilateral System
- Projects have been funded under benefit-sharing Fund -- through government donations, as commercial benefits from GR use the use in the Multilateral System yet to be to appear
- Drop in Annex 1 crop innovation, rise in non-Annex 1 crop innovation
- Move to a Subscription System for regular users and mechanism for occasional users, instead of voluntary payments under consideration
- Do farmers benefit from Fund?



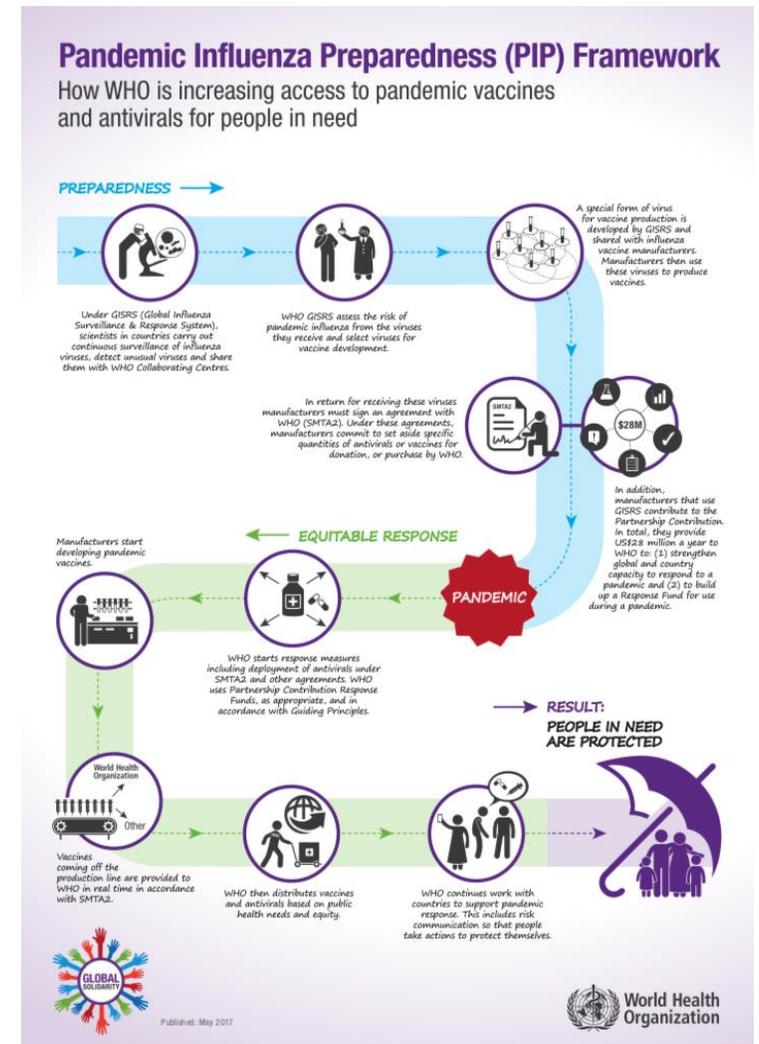
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WORLD HEALTH ORGANIZATION (WHO)

PIP FRAMEWORK

- Coordinated response to the 2006 H5N1 influenza outbreak
- **Pandemic Influenza Preparedness Framework** for the sharing of influenza viruses and access to vaccines and other benefits (PIP framework) (effective on 24 May 2011)
 - to improve and strengthen the sharing of **influenza viruses with human pandemic potential**
 - to increase the access of developing countries to vaccines and other pandemic related supplies
- Another specialized international ABS instrument...

- National influenza centres share viruses with with GISRS, WHO-coordinated network
- Traceability: Virus transfers are monitored
- SMTA-2 between WHO and companies, individually negotiated – guarantees access to vaccines for quick response
- Benefit-sharing system
 - Access to vaccines and information, capacity-building
 - Vaccine manufacturers make annual cash Partnership Contribution

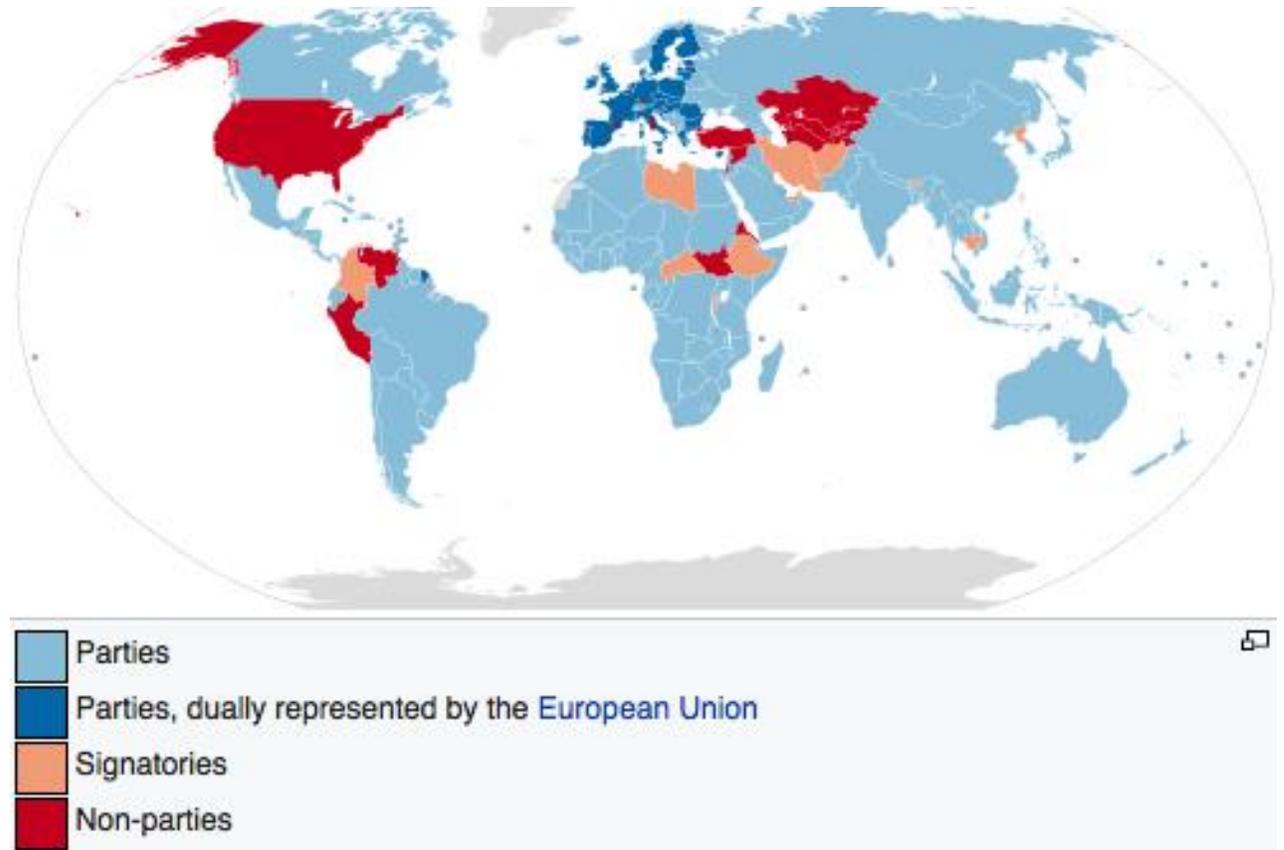


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GENETIC RESOURCES BNJ: MARINE

UNCLOS

- Came into force 1994, 168 Parties
- Establishes the different spatial divisions and the rights of the States over those spaces
- General reference to the conservation of the marine environment
- Article 82



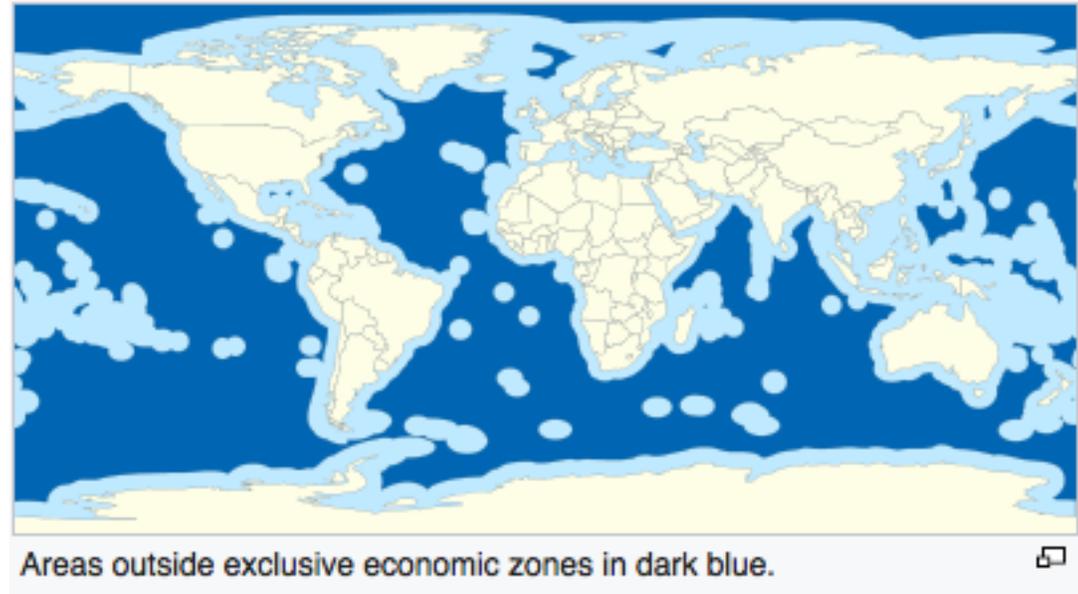
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GENETIC RESOURCES BNJ: MARINE

Areas outside national jurisdiction (Common Heritage of Mankind)

- High Seas: International waters surface, international waters
- Deep Sea Bed: International seabed surface and underground



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GENETIC RESOURCES BNJ: MARINE

Issues

- Proposals for benefit-sharing include:
 - Mechanisms for data-sharing (open-access gene pools)
 - Codes of conduct
 - Co-operation and info-sharing on research
 - Facilitating access to samples
 - Fostering developing country participation in public-private partnerships
 - Establishing public trusteeship to distribute royalties and benefits MGRs
- Process has long way to go

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GENETIC RESOURCES BNJ: MARINE

International Seabed Authority (ISA)

- Regulates mineral resources in deep seabed (common heritage of mankind)
- ISA to “provide for the equitable sharing of financial and other economic benefits derived from activities in the Area...” and other benefits are distributed (e.g., transfer of S&T knowledge)
- Contractors to provide training/capacity-building activities to assist developing countries to States to participate in activities in the Area by drawing up “practical programmes for the training of personnel
- Authority has created an endowment fund for marine scientific research in the Area

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GENETIC RESOURCES BNJ: MARINE

International Seabed Authority (ISA)

Issues

- Mineral exploitation yet to occur
- Endowment fund relies on voluntary donations (a sustainable approach?)

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GENETIC RESOURCES BNJ: ANTARCTIC

- Bioprospecting in Antarctica?
- Interesting extremophiles, but uncertainty over use and ownership of samples and information exchange
- **Views differ** over whether Antarctica lies outside scope of national territories
 - CBD bilateral model not readily applicable
 - But CBD and ATS both stress cooperation!
- Different resolutions of the governing body identify the relevance of Antarctic GR and the need to adopt measures (Resolution 9/2009: Collection and use of Antarctic biological material)

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GENETIC RESOURCES BNJ: ANTARCTIC

Issues

- Views differ over whether Antarctica lies outside scope of national territories
 - CBD bilateral model not readily applicable
 - But CBD and ATS both stress cooperation!
- No reference to benefit sharing per se, but ATS provides for:
 - exchange information regarding plans for scientific programs in Antarctica
 - exchange scientific personnel in the Antarctica between expeditions and stations
 - exchange and make available for free the scientific observations and results from Antarctica
- No reference to benefit sharing per se, but ATS provides for:
 - Exchange of info on bioprospecting and specimen through Electronic Information Exchange System (EIES) limited at best



LANDSCAPE

INTELLECTUAL PROPERTY RIGHTS (IPRs)

Selected Relevant Forums

- World Intellectual Property Organization (WIPO)
Intergovernmental Committee (IGC)
- WTO Trade-related Aspects of Intellectual Property Rights (TRIPS)
Agreement
- UPOV: Union for the Protection of Plant Varieties