Global regimes on genetic resources: the food and agriculture, and health sectors

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The FAO Treaty is more than access and benefit sharing

Objectives: conservation and sustainable use of PGRFA, fair and equitable benefit sharing, for sustainable agriculture and food security

Scope: all PGRFA

Recognizes Farmers' Rights

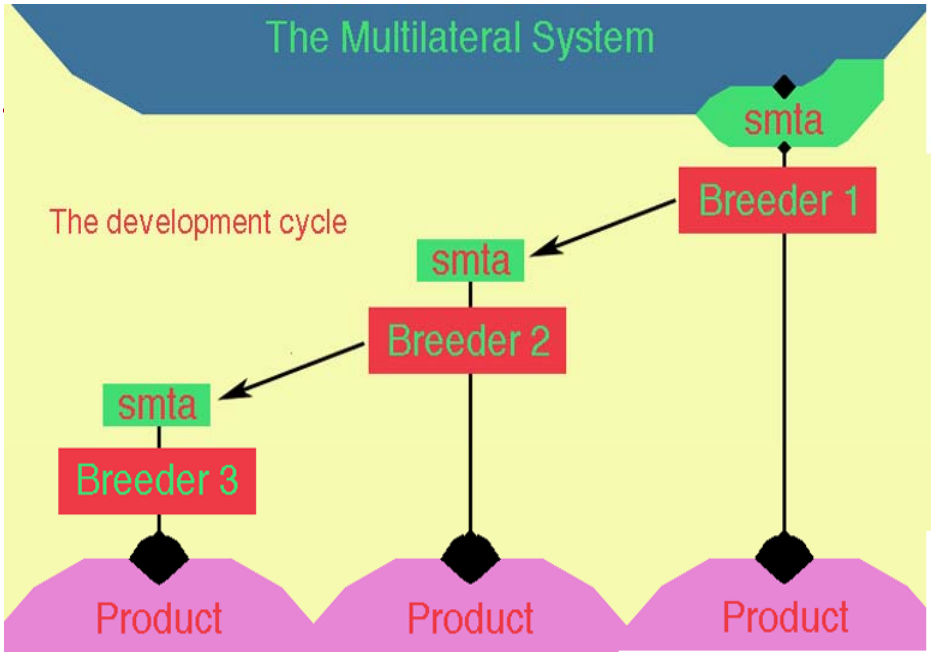
Funding Strategy for developing countries

The Multilateral System (MLS)

- 64 crops and forages => important for food security and interdependence
- provide 80% of our food from plants

PGRFA are shared in the MLS by:

- Governments
- Private institutions and companies
- The CGIAR and other international institutions



Challenges and innovative solutions

⇒ Uniform enforcement of contracts across jurisdictions through binding international arbitration

=> Contractual recognition of a 'third party beneficiary' to act on behalf of the Treaty in the context of dispute settlement

Benefits

- Facilitated access to PGRFA
- Low transaction costs
- Overcomes market failure
- Contributes to food security
- Provides the industry with a clear framework in which to plan investment

WHO Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (WHO PIP Framework)

- Use of ABS principles to push for an outcome that works in the interest of public health
- Adopted in 2011 - non-legally binding agreement that provides for a multilateral benefit sharing arrangement
- **Objective**: to improve PIP and response by strengthening the WHO global influenza surveillance and response system ("WHO GISRS"), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing:

(i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and

(ii) access to vaccines and sharing of other benefits.

The PIP Framework makes use of two different SMTAs:

- **SMTA 1** => the exchange of viruses between institutions that operate within the WHO GISRS – i.e. designated by WHO and have accepted to work under agreed WHO terms of reference.
- **SMTA 2** => exchange of samples between the WHO (on behalf of relevant WHO laboratories) and third parties, which operate outside the WHO-GISRS – i.e. all entities that receive "PIP Biological Materials" from the WHO-GISRS, such as **influenza vaccine, diagnostic and pharmaceutical manufacturers**, as well as biotechnology firms, research institutions and academic institutions.

Partnership Contributions as Benefit Sharing

- Manufacturers, using the WHO GISRS (past (15Y) and/or current), make an annual **partnership contribution** to WHO for improving global PIP and response
- Annual contributions shall be equivalent to 50% of the running costs of WHO GISRS - in 2012, approximately **USD 28 million**
- Distribution between companies based on transparency and equity, their nature and capacities (formula: average annual influenza product sales per manufacturer for 3 past years + 2009)

Benefit sharing as a contractual obligation

- **SMTA 1** prohibits parties to obtain any IPRs on the received materials; no monetary benefit-sharing obligations.
- **SMTA 2** does not limit the possibility to obtain IPRs; it provides for specific **compulsory benefit-sharing obligations** - negotiated between the WHO and the recipient in accordance with a list of options.
- **Third party transfers** of PIP materials allowed only if the prospective recipient has already concluded an SMTA with the WHO - the transfer shall be reported.

Benefit Sharing Options under SMTA 2

Manufacturers of vaccines and/or antivirals shall commit to at least **two** of the following BS options:

- **Donate** at least 10% of **pandemic vaccine production to WHO**.
- **Reserve** at least 10% of pandemic vaccine production **at affordable** prices.
- **Donate** at least X treatment courses of needed **antiviral medicine**.
- **Reserve** at least X treatment courses of needed **antiviral medicine** for the pandemic at affordable prices.
- **Grant** to manufacturers in developing countries **licenses** that should be **fair and reasonable** including in respect of affordable royalties **on technology, know-how, products and processes** for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.
- **Grant royalty-free licenses** to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics.

Comparative analysis of types of benefits and their triggers

Systemic benefits ⇩ ⇨ **Triggers:**

"use of the system" type of triggers

Ex situ collections / research infrastructure (for outside institutions)

Compulsory benefits ⇨ **access to GR**

⇨ **utilization of GR** (specific use-dependent triggers)

Lessons learned

- Material and Information sharing requirements: data / information / knowledge / sample sharing policies to facilitate universal access to research products - major BS component
- Prohibitions / limitations on exclusive rights; respect for preexisting rights
- Relationship between IP protection and benefits sharing
- Monitoring and notification requirements: third party transfers of materials / information / IPR
- Dispute resolution and third party beneficiary's rights
- "Interoperability" between instruments under the international ABS regime – e.g. SMTAs used as an internationally recognized certificate of compliance, but administering a large number of contracts may prove challenging

Thank you!

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