National and regional gene banks -Access and Benefit Sharing and IP related issues

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Content

- The Nagoya Protocol: an introduction
- National implementation of the NP
- The NP and TRIPS agreement: a contradiction?
- Status of the NP discussion: global
- Status of the NP discussion: the EU
- Related processes and initiatives: FAO CGRFA
- Similarities / differences between AnGR and PGR gene banks
- NP and the operation of AnGR gene banks /PGR gene banks
- European gene banking strategy: Issues and Options

Objectives of the CBD: Article 1

- the conservation of biological diversity,
- the sustainable use of its components, and
- the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by <u>appropriate access</u> to genetic resources and by <u>appropriate transfer of relevant technologies</u>, taking into account all rights over those resources and to technologies, and by appropriate funding.

Why an International Regime?

The International Regime aims at providing a legal framework to articulate the *"quid pro quo"* that underpins the CBD



Timothy Hodges, 2010

Negotiations of the International Regime



Co-Chairs: Timothy Hodges (Canada) Fernando Casas (Colombia)

I. OBJECTIVE

Effectively implement the provisions [in Articles 15, 8(j), 1, 16 and 19.2] **of the Convention** [and its three objectives], specifically by:

- [[Facilitating] [regulating transparent] access to genetic resources, [their derivatives] [and products] [and associated traditional knowledge];]
- Ensuring [the conditions and measures for] the [effective,] fair and equitable sharing of benefits arising out of their utilization, [their derivatives] [and products] [and associated traditional knowledge] [and to prevent their misappropriation and misuse];
- [Securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country [of origin] providing those resources or of the Party that has acquired those resources in accordance with the Convention on Biological Diversity].

Adoption of the Nagoya Protocol

THE REAL PROPERTY OF THE PROPE

Plenary

EVENT HALL

President

UNEP/CBD/COP/DEC/X/1

NAGOYA PROTOCOL on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

TO THE CONVENTION ON BIOLOGICAL DIVERSITY

OBJECTIVE

The objective of this Protocol is **the fair and equitable sharing of the benefits** arising from the utilization of genetic resources,

including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies,

and by **appropriate funding**, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

- RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS
- 1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement...
- 2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized ABS agreements...
- 3. This Protocol shall be implemented in a **mutually supportive manner** with other international instruments ...
- 4. ...Where a specialized international ABS instrument applies ...this protocol does not apply ...in respect of the specific genetic resource covered...

SPECIAL CONSIDERATIONS

- (a) Create conditions **to promote and encourage research** which contributes to the conservation and sustainable use of biological diversity...
- (b) Pay due regard to **cases of present or imminent emergencies** that threaten or damage human, animal or plant health, as determined nationally or internationally...
- (c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the **need for** and **modalities of** a GMBSM 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 PIC.

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.

Implications of the Nagoya Protocol

National legislation

National level:

- All Parties will be users as well as providers of GR
- A number of Parties have access legislation in place (Brazil, Philipines, South Africa, France, Spain, Bulgaria)
- Few Parties have user compliance measures in place as required by the NP
- Implementing legislation to be adopted prior to ratification to ensure:
 - compliance with obligations
 - legal certainty for users

National level:

has to provide for legal certainty, clarity and transparency

Obligations to:

- Designate a National Focal Point on ABS
- Designate one or more competent national authorities on ABS
- Prepare and implement national legislation
- Make available to the ABS Clearing-House any information required by the Protocol
- Facilitate access to GR and TK
- Take measures to provide that GR utilized within its jurisdiction have been accessed in accordance with PIC and MAT
- Take measures to address situations of non-compliance
- Establish one or more checkpoints
- Encourage the development, update and use of sectoral and cross-sectoral model contractual clauses for MAT

and many more...

The Nagoya Protocol and the Intelectual Property Rights: PATENTS









Enola bean

Basmati rice

Kurkuma

Neem

"the illegal and unfair appropriation (patent claim) and exploitation of genetic and biological resources of specific regions by corporations".

(Biopiracy: Larousse dictionary, 2009 edition)

IPR: International organizations:

WIPO: World Intelectual Property Organization

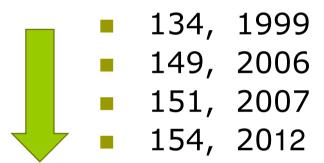
http://www.wipo.int/members/en/

- Genewa 1967/1974 171 members
 2012 185 members
- Provides administration of 24 international treaties
- since 1997: Global Intelectual Property Division
- in 2000: the WIPO Intergovernmental Committee
 on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

IPR: International organizations:

WTO: World Trade Organization 1.01.1995

Members



Brazil: 1995 **R**ussian Federation: an observer

Indie: 1995 China: 2001



USA: 1995 EU: 1995

TRIPs: Trade Related Aspects of Intelectual Property Rights

Annex to the WTO agreement

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm

Article 27 TRIPS

STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

SECTION 5: PATENTS
Article 27 Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents **shall be available for any inventions**, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, **patents shall be available** and patent rights enjoyable **without discrimination** as to the place of invention, the field of technology and whether products are imported or locally produced.

Article 27 TRIPS

 Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality,

including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Article 27 TRIPS

- 3. Members may also exclude from patentability:
- (a) **diagnostic, therapeutic and surgical methods** for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than nonbiological and microbiological processes.

However, Members shall provide for the protection of plant varieties either by patents or by an **effective** *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

UPOV: The International Union for the Protection of New Varieties of Plants

Established in 1961 Objective: to ensure rights of plant breeders from developed countries

Amendments in 1972, 1978 i 1991 New members: China, Brazil, Kenia

Status: 8.12.2011 – 70 Members http://www.upov.int/en/about/members/pdf/pub423.pdf

A plant variety to be registered by the UPOV has to be:

- novel
- distinct
- uniform
- stable

A clear contradiction:

Article 27 Patentable Subject Matter 27.1 – no obligation on the disclosure of origin of GR 27.3b – possibility to patent plants and animals



Third objective of the CBD (fair and equitable sharing of benefits)

Article 3 of the CBD (Principle: States have the sovereign right to exploit their own resources)

Article 15 of the CBD (Access to Genetic Resources: PIC and MAT) **NAGOYA PROTOCOL** to the CBD on ABS

STATUS of the Nagoya Protocol negotiation GLOBAL

A roadmap for the first COP/MOP adopted by decision UNEP/CBD/COP/DEC/X/1

The further decisions of the COP 10:

- Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol
 - the first meeting 6 to 10 June 2011 and
 - the second meeting 23 to 27 April 2012 (now 2-6 July);
- Co-Chairs:
 - Mr. Fernando Casas (Colombia)
 - Mr. Timothy Hodges (Canada)

A Special Voluntary Trust Fund for Additional Voluntary Contributions

http://www.iisd.ca/biodiv/icnp1/

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	Services and sustainable development		^
	News the ENB team About us Funders	Activities Links Search IISD.org 🗟 RSS 🛃 Share this page on Facebook	E
	Web Coverage/Summary IISD Reporting Services (IISD RS) has produced web coverage and a summary and analysis from the meeting. To download our report click below in the HTML or PDF icons. SUMMARY ENGLISH FRANÇAIS ESPAÑOL	First Meeting of the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ICNP-1)	
	REPORT htm pdf htm pdf 13 June 1 1 1 1 1	5-10 June 2011 Montréal, Canada	
	IISDRS IISDRS	Summary Highlights of the Meeting	
	IISDRS #CBD #SBSTTA 16 concludes discussion	DAILY WEB COVERAGE	
	of global strategy for plant conservation #biodiversity bit.ly/JMayO0 3 hours ago · reply · retweet · favorite	Sun. 05 Jun. Mon. 06 Jun. Tue. 07 Jun. Wed. 08 Jun. Thu. 09 Jun. Fri. 10 Jun.	
	IISDRS #CBD #SBSTTA 16 report and pictures of day 3 available now #biodiversity bit.ly/JMayO0 3 hours ago * reply * retweet * favorite		
	IISDRS #CBD #SBSTTA 16 convenes contact group on describing Ecol. and biol. significant marine areas beyond nat. jur. #biodiversity 21 hours ago ' reply ' retweet ' favorite		
	IISDRS ENB report and pictures of #CBD #SBSTTA 16 day 2 available now #biodiversity bit.ly/JMayO0 yesterday · reply · retweet · favorite		
	IISDRS #CBD #SBSTTA 16 discusses emerging 🚽		
	Luitter Join the conversation		
	Biodiversity Policy &	L-R: Ahmed Djoghlaf, CBD Executive Secretary; Co-Chair Janet Lowe, New Zealand; Co-Chair Eernando Casas, Colombia: and Valerie Normand, CBD	



Nagoya Protocol to the CBD

As for May 2012

Convention on Biological Diversity: 193 Parties (168 Signatures)

Cartagena Protocol on Biosafety: 162 Parties (103 Signatures)

Nagoya Protocol on Access and Benefit-sharing 5 Parties (92 Signatures) Gabon, Jordan, Rwanda, Seychelles, Mexico

STATUS of the Nagoya Protocol negotiation EUROPE/EU

Forum for EU:

European Council Working Party on Inernational Environent Issues (WPIEI)

Supported by EU ABS Expert group

<u>Ireland</u>	2012-02-01
<u>Ukraine</u>	2012-01-31
<u>Lithuania</u>	2011-12-29
<u>Slovenia</u>	2011-10-19
<u>Belgium</u>	2011-09-21
<u>France</u>	2011-09-20
<u>Greece</u>	2011-09-20
<u>Poland</u>	2011-09-20
<u>Portugal</u>	2011-09-20
<u>Romania</u>	2011-09-20
<u>Serbia</u>	2011-09-20
<u>Spain</u>	2011-07-28
<u>Austria</u>	2011-07-06
<u>Bulgaria</u>	2011-06-23
<u>Czech Republic</u>	2011-06-23
<u>Denmark</u>	2011-06-23
European Union	2011-06-23
<u>Finland</u>	2011-06-23
<u>Germany</u>	2011-06-23
<u>Hungary</u>	2011-06-23
<u>Italy</u>	2011-06-23
<u>Luxembourg</u>	2011-06-23
<u>Netherlands</u>	2011-06-23
<u>Sweden</u>	2011-06-23
<u>United Kingdom</u>	2011-06-23
<u>Norway</u>	2011-05-11
Switzerland	2011-05-11

European Commission, DG Environment

- A contracted study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union
- A web based public consultation to explore the possible effects of the Protocol and to gather concrete proposals on the practical challenges of implementation
- Meetings with stakeholders



Draft proposal for community legislation towards the end of third quarter of 2012

Structure of the impact assessment study

- 1. Baseline: Comparison of core provisions of the Nagoya Protocol and existing EU policies and legislation;
- 2. Identification of options for implementation of the Nagoya Protocol obligations at the EU level;
- 3. Analysis of potential impacts of options.

Public consultation

- **From 24.10.2011 to 30.12.2011**
- 43 responses are published
- The majority of responses provided by European or global federations and associations representing hundreds or even thousands of members
- □ A technical workshop in Brussels on 26 Jan 2012

http://ec.europa.eu/environment/consultations/abs_en.htm

AnGR sector in public consultation

- Animal breeding is an international activity. Extra regulation will hamper this and is therefore undesirable;
- International trade should be able to continue as usual;
- International trade of seed stock is the single most important factor to increase efficiency of animal production;
- Any regulation that blocks this trade will be a severe limitation on progress of animal production;
- We are afraid of misinterpretation of the Protocol would involve extra costs and practical trade barriers for animal breeding organisations.

European Forum of Farm Animal Breeders, 2011





Related processes and initaitives

FAO Commission on Genetic Resources for Food and Agriculture





FAO CGRFA

The FAO Conference, at its Thirty-first Session in Nov 2001, (Resolution 3/2001), approved the International Treaty on Plant Genetic Resources for Food and Agriculture

came into force on 29th June 2004, after 40th ratification

Multi Year Programme of Work of the CGRFA (MYPOW): covers ABS in the area of agricultural biological diversity



Ad Hoc Technical Working Group on Access and Benefit-sharing for Genetic Resources for Food and Agriculture







home Publications Information from ERFP bodies | TF Access and Benefit Sharing

Terms of Reference

Programme (MYPOW)

Organisational Structure

Meetings

Publications

Country Information

Project Information

Information from ERFP bodies

WG Ex situ Conservation

WG Documentation and Information

TF Access and Benefit Sharing

TF Risk Status and Indicators

TF Agri-environmental Measures

AnGR Publications

ERFP Task Force on Access and Benefit Sharing

Upcoming meetings:

- <u>European Workshop on Access and Benefit-sharing for Food and</u> <u>Agriculture, 27th to 28th June 2012 / ERG meeting 29th June 2012</u> Bonn, Germany
 - Draft Agenda
- <u>1st Session of the Ad Hoc Technical Working Group on Access and Benefit-Sharing</u> for Genetic Resources for Food and Agriculture Svalbard, Norway from 11th to 13th September 2012
 Draft Agenda

Further information:

- <u>Results</u> of public consultation of European stakeholder on the implemention of the Nagoyo Protocol on ABS (<u>EU Com</u>)
- · The Nagoya Protocol on Access and Benefit Sharing
- First Meeting of the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ICNP-1)
- <u>IISD summary report</u> of ICNP-1
- Information note from the EU Presidency and the Commission prepared for the meeting of the Council (Environment) on 21st June 2011

Genres-News RSS-Feed XML

suchen

- Contact
- Frank Begemann
- Sebastian Winkel
- <u>Babette Balzer</u>

Links

- EFABIS
- DAD-IS
- <u>FAO State of the</u> <u>World's Animal</u> <u>Genetic Resources</u>
- FAO Global Plan of Action
- ERFP Newsletter # 10
- <u>EU Genetic Resources</u> in Agriculture
- <u>EAAP</u>

Tasks for the Working Group

- identify relevant distinctive features of the different sectors and sub-sectors of GRFA requiring distinctive solutions;
- develop options to guide and assist countries, upon their request, in developing legislative, administrative and policy measures that accommodate these features; and
- analyze, as appropriate, possible modalities for addressing access and benefit-sharing for GRFA, taking into account the full range of options, including those presented in the Nagoya Protocol.

Other initiatives: IUCN

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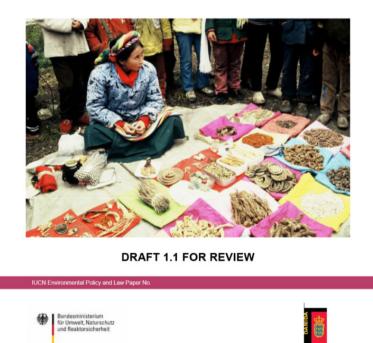
",the FAO Commission may decide

to develop further legally binding ABS instruments for specific components of biodiversity for food and agriculture in the future,

such as AnGR for food and agriculture, or others"

IUCN

An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing



Similarities and differences between AnGR and PGR genebanks

Nagoya Protocol and the operation of AnGR genebanks and PGR genebanks

Agro-biodiversity: sectoral differences

PGR AnGR		AnGR	
Breeding	initial crossbreeding	selection within population	
Inbreeding	used extensively	not desirable	
Testing costs	inexpensive	expensive	
GM	possible/efficient	difficult/not accepted	
Exchange	S→N	$N \rightarrow N$ and $N \rightarrow S$	
Centres of origin	well defined	multiple domestication	
Ownership	public genebanks	private	
Value of individual	low	high to very high	
Trading	breeders' / farmers' rights	bilateral agreements	
Patentability (TRIPS)	varieties	breeds not patentable	

Adapted from Hiemstra et al. 2006

Awassi sheep

Primitive fat tail sheep from Arabian Pennisula





(Galal, 2006)

(http://www.freeisraelphotos.com/photo/69)

Volcani Center, ARO

ASSAF: 5/8 Awassi 3/8 East Friesian



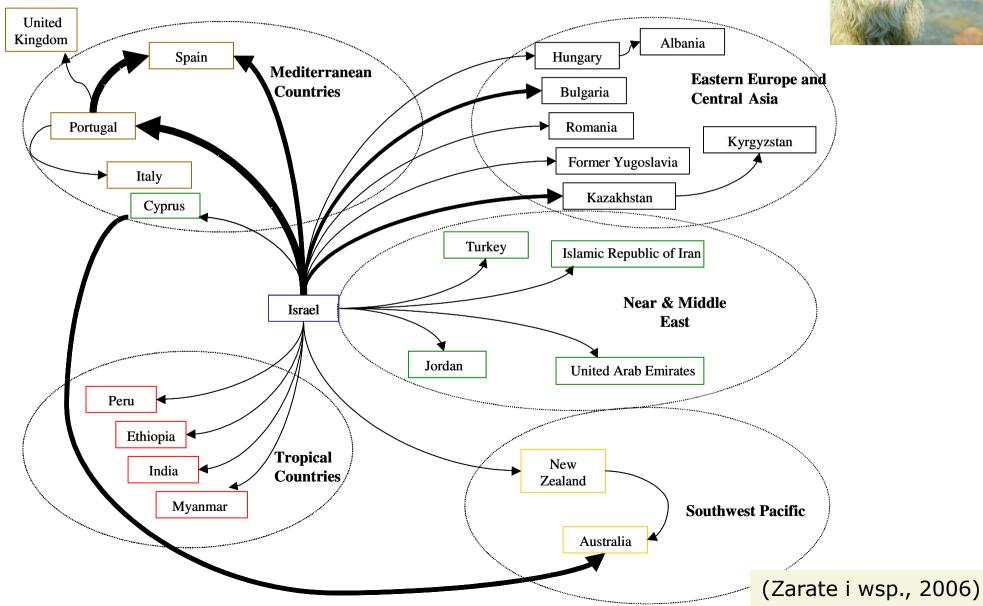








Gene flow of Awassi i Assaf





Success of Awassi and Assaf







breeding programme & selection

Claims on biopiracy?

Gootwine, 2008

Great sucess in Australia and USA





In1987 import to Australia frozen embryos

of Tuli (Zimbabwe) and Boran (Zambia)

(Tuli Breeders Society of South Africa , 2012 http://www.tulicattle.co.za/?p=24)

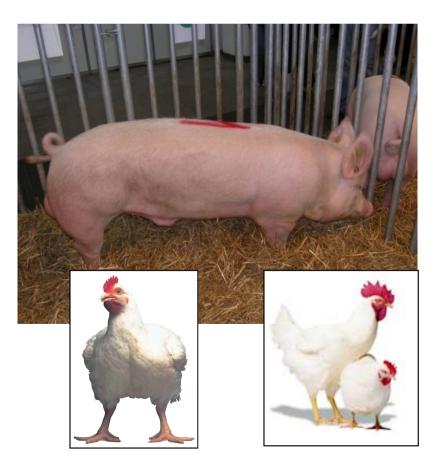
http://www.ars.usda.gov/is/graphics/photos/nov02/k10089-2.htm

AnGR Gene flow

- Rare examples on successful introgression of exotic genotypes to mainstream breeds (e.g. Meishan pig breed)
- Use of wild species almost negligible
- Gene flow: $N \rightarrow N \text{ and } N \rightarrow S$

Will further increase due to the Livestock revolution





AnGR Gene flow N > S

- Worldwide in 2011, the United States exported a record \$664 million worth of breeding stock and genetic material;
- About 14 percent of U.S. live animal exports, largely breeder chicks, were sent to China;
- Chinese companies bought \$41 million worth of live breeding animals and genetics, up nearly threefold from five years ago

China:

acquiring millions of live animals as breeding stock, capitalizes on decades of US investments in agricultural research

No expectations regarding sharing benefits!

Huffstutter and Niu Shuping, 2012: http://uk.reuters.com/article/2012/04/20/us-usa-china-food-idUKBRE83J05R20120420

Exchange of AnGR

Farm Animal Genetic resources are privately owned

Exchange of AnGR is beneficial and smoothly running

- Active international exchange by private-private transactions
- Contracts from very simple to very sophisticated
- Farmer owns AnGR after purchasing semen or animal
- Price according to the genetic value
- Models for best practices could further facilitate exchange

Standards for transfer set by:

- EU zootechnical legislation (pedigree, genetic value)
- Veterinary requirements

International regime on ABS

A system for exchange already in place

- Regime may offer supporting elements for transparency & uniformity
- Measures against those circumventing national legislation on GR
- Risk for over complications and expensive unambiguous regulations

Need for **sectoral approach** for ABS for GRFA, taking into account differences between PGR & AnGR

ABS for PGR FA

- For species included in the Annex 1
- For collections included in the Multilateral System of Access and Benefit-sharing
 - by Contracting Parties,

- the International Agriculture Research Centres of the CGIAR,
- other International Centres and
- natural and legal persons





International Treaty on Plant Genetic Resources for Food and Agriculture



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The Standard Material Transfer Agreement

- It is a mandatory model for parties wishing to provide and receive material under the Multilateral System;
- Result of a lengthy negotiation among the Parties to the Treaty;
- The STMA are private agreements between the particular providers and recipients;
- The Governing Body, through FAO as the Third Party Beneficiary, is recognized as having an interest in the agreements;
- The standard template has been developed to ensure that the provisions of the Treaty regarding the transfer of PGRFA under the Multilateral System are enforceable on users.

ABS PGR genebanks

Under the Treaty: SMTA and Multilateral System

- Article 5 Rights and Obligations of the Provider
- Article 6 Rights and Obligations of the Recipient
 - Material shall be used or conserved only for the purposes of research, breeding and training for food and agriculture.

(not include chemical, pharmaceutical and/or other nonfood/feed industrial uses)

ABS PGR genebanks

In the case that the Recipient commercializes a PGR Product and that incorporates Material referred to in Article 3:

- Product is not available without restriction the Recipient shall pay a fixed percentage of the Sales of the commercialized Product
- Product is available without restriction the Recipient is encouraged to make voluntary payments

□ PGR outside the Treaty ??????

PGR/AnGR gene banks

- Different type of genetic material stored
- Different management of the gene banks







Animal BioBank, Norway

IRI: http://science.howstuffworks.com/environmental/life/genetic/gene-bank.htm

AnGR gene banks

- Limited number of operational national genebanks (in public domain) to conserve AnGR
- Such genebanks are mainly in Europe, USA, Canada

Access to AnGR: regulated / not restricted

- No genebanks established under international organizations such as CGIAR
- Requests for access from other countries?
- Gradually developing private bio-banks, some with commercial interests

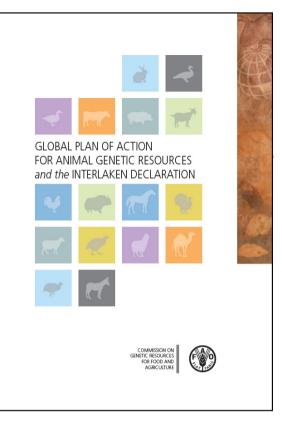
European gene banking strategy

Do we need one? Do we have one?

Do we need one?

Strategic Priority 10

Develop and implement regional and global long-term conservation strategies



Action 3

Establish **regional and global networks of gene banks** for animal genetic resources and harmonize approaches to conservation in gene banks and to facilitating exchange

Do we have one? First step already taken

- Gene bank management software
- FAO Guidelines for cryopreservation



17 partners, possibility to expand

Common standards



MUCH MORE IS REQUIRED

Flavia Pizzi, 2009 Option I: Virtual gene bank P 1 Cryower P 2 P 2 P 2 P 3 P 4

- Individual: collection and storage, management
- Common set of technical requirements
- Common software and database
- Exchange of information (transboudary breeds)
- Common set of ABS requirements (MTA)
- Facilitated access for members
- In lights of the Nagoya Protocol may require provisions in national ABS legislation

Option II: Physical gene bank

- Unlikely, although possible
 - More difficult to get agreement
 - Rather bilateral then regional
 - Require negotiation on SMTA
- Material Transfer Agreements used for research might provide an useful but not sufficient example
- Opens a question on potential benefit sharing

ABC of the Nagoya Protocol regarding AnGR gene banks

Access Realtively easy to regulate

Unclear:

Benefit sharing

Bilateral arrangements?

Mirrow Multilateral System for PGR with benefits directed towards the Funding Strategy of the GPA?

Use Article 10 of the Nagoya Protocol?

Compliance

Subject to national legislation, check points and monitoring

Global solutions for AnGR?



Important role of the Svalbard meeting...



http://www.thedailygreen.com/environmental-news/latest/svalbard-global-seed-vault-47022605

Biodiversity is life Biodiversity is our life





United Nations Decade on Biodiversity

Thank you for listening