# TRUST & The Nagoya Protocol: Creating Legal Certainty and Comparative Advantage

## Challenges & Opportunities For Collections

# Presentation Objectives

To show how the Nagoya Protocol requires all governments to:

- Facilitate access to resources
- Provide legal certainty
- Ensure permit and contractual compliance

- Introduce collections as the bridge between providers and users of microbials
- Identify challenges opportunities and comparative advantages of ex-situ collections

# The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization

- Signed by 92 Countries, – 50 ratifications & commences 90 days after the 50th ratification (16 so far)
- Applies to In-situ and Ex-situ biological material and associated traditional knowledge (TK)
- Applies only to material within national jurisdiction

# The Nagoya Protocol

- Expected to come into operation as new international law by end of 2014
- All ex-situ collection managers will need to understand how this new system affects them
- Changes the way business is done in their institutions and creates opportunities

# Institutions Involved in ABS:

- Companies undertaking R & D on genetic resources
- Universities undertaking R & D on genetic resources
- Public and private research Institutes undertaking R & D on genetic resources
- National and Private ex-situ Taxonomic collections
- University and research Institutes' biological collections

# Nagoya Protocol- A reminder:

- Creates first **global** research and investment system in the use of genetic resources and traditional knowledge
- 6 years in Negotiation – not perfect
- Applies to material taken for research on its genetic and biochemical make-up
- Purpose - ensure countries with natural resources can reliably get a share in value created from those resources
- Has no retrospective effect

# Nagoya Protocol

**Remember: Does not cover**,

- Commodity trade - ie excludes fishing, crops, lumber, grains, essences, wild harvest, e.t.c. & **Includes**:
- Provides for simplified procedures for non-commercial research & health emergencies (Art 8)

# Nagoya Protocol

Valuable research products derived from Genetic Resources include different expense, timelines, likelihood & profitability:

- Pharmaceuticals
- Industrial Enzymes
- Biofuels
- Cosmeceuticals
- Nutraceuticals
- Climate adaptive organisms drought, salt, temp etc
- Limited only by imagination

# The Nagoya Protocol: Principles

## Principles of ABS

- States **must** provide access to genetic resources by their prior informed consent (PIC) and Contracts for sharing of benefits (Mutually Agreed terms – MAT)
- Legal certainty, clarity & transparency

# 3 Core elements: 1. Access

**National access systems must provide:**

- Fair and non-arbitrary rules & procedures.
- Clear rules & procedures for PIC and MAT.
- Issuance of a permit or equivalent is evidence that PIC was obtained and MAT were established.

# 3 Core elements: 2 Compliance

## National Compliance obligations:

- ensure imported genetic resources are lawfully obtained
- ensure Benefit-sharing Agreements (contracts) are honoured
- establish ‘checkpoints’ where information about utilisation of genetic resources is obtained, and
- Support establishment of model contract clauses, standards and best practices

# 3 Core elements: 3. The Internationally Recognised Certificates of Compliance

- Permit issuing country lodges a copy (or certain minimum information) with the ABS Clearing House Mechanism
- This then becomes an ***Internationally Recognised Certificate of Compliance***
- The information on the ABS CHM is public & **allows for electronic verification of Permits and provenance**
- Certificates verify imported material lawfully obtained

# 3 Core elements: 3. Certificates of Compliance:

- Establish legal certainty and reduce risk for collection managers, research partners and investors
  - Eliminate counterfeit Permits
  - Make **Biopiracy** unprofitable: the more valuable the resource, the greater the value of a Certificate
  - Free provenance and resource use information for BRCs

# Certificates of Compliance

- Reduce admin costs (free)
- Create a permanent ‘Insurance-copies’
- Are the basis for monitoring and securing compliance
- Simple way of disclosing source and PIC and MAT in Patent applications
- Creates a unique identifier that goes along the research and development chain
- Can be linked to deposits lodged with International Barcode of Life Reference Library and BRCs

# NP Article 8-Special Considerations ie simplified procedures

- Inserted at request of research and the Taxonomic community
- 8(a) Obligation to enable simplified access procedures for non-commercial research
- 8(b) Pay due regard to health emergencies, consider rapid access to both GR and benefit-sharing including access to treatments

# Non-Commercial Research

Simplified system 6 Common elements:

1. Intent is non-commercial R & D on GRS (ie not intended to make a profit)
2. Permission of provider
3. Duplicate sample lodged with public Taxonomic institution
4. Research results provided or published
5. No 3rd party transfer without provider permission
6. Obligation to negotiate MAT if **intent** changes eg serendipitous discovery

# **Nagoya Protocol - 8** Operational Steps

1. Responsible country issues Research Permit
2. Permit contains reference to obligation to share in benefits (as agreed)
3. Permit registered in SCBD Montreal and creates an ***internationally recognized certificate of compliance***
4. All countries are required to ensure Permit material imported is utilized in accordance with original Permit

# **Nagoya Protocol-** Operational Steps

5. User complies with permit and contract
6. Benefits flow in accordance with contract
7. Government checks compliance with permit and contract terms
8. International Certificates are proof of lawful access

# Culture Collection Challenges:

- Align best practice and procedure with NP
- Align with CC existing IP system role
- Consider outcomes of WIPO IGC on TK GR & Folklore
- Consider growing national disclosure of source rules (18 Countries)
- Integrate physical and digital transfer of organisms or parts
- Make best use use of Compliance Certificates

# Culture Collection Challenges:

- Align culture collection practices with other best practice codes eg AUTM MTA Industry codes and MTAs
- Take advantage of simplified procedures article (Art 8),
- Get national governments to nominate Culture Collection standards and rules for international recognition under Art 19 & 20
- Obtain support from stakeholders eg researchers, industry, governments and environment groups

# Ex-Situ Collection Opportunities

- Impact of Bayhe–Dole Business Model favors ex-situ collections under the NP
- BRCs now central to R & D on GR
- NP ratification creates comparative advantages for BRCs
- Ex-situ collections already have IT infrastructure system & MTA experience
- Increased profile with governments and industry
- Obtain improved public funding
- Make BRC model central to NP

# Ex-Situ Collection Opportunities

- Reduce transaction costs further through IT
- Reduce regulatory burden by using *NP International Certificate* infrastructure
- Create comparative advantage over private, non-NP compliant ex-situ collections
- Obtain early adopter  advantage by building on existing culture collection and BRC infrastructure

# Ex-Situ Collection Opportunities EU Draft regulation

- Presented to European Parliament in 2012
- Committee Report  1 May 2013
- Legal obligation on users to to undertake ‘due diligence’ to determine that they have obtained GR and Associated TK in accord with provider country requirements.
- Penalties apply for failure to do so
- Will form basis of international standard for developed countries.
- Final Step: goes to EU Council

# Ex-Situ Collection Opportunities EU Draft regulation

EU Register of Trusted Collections

- Extend concept so that all World Federation of Culture Collections could be registered
- consider using the revised  best practice standard to seek EU registration & CBD-NP endorsement of its Standards and Best Practices

# NP Implications

- Culture Collection managers must be aware that countries implementing the Protocol will introduce or amend existing ABS Laws and policies - including their own countries’
- All countries will introduce compliance measures - including their own countries’
- Internationally recognised standards for the movement of samples will become a key element of facilitated research

# NP Implications

- Culture Collection Managers must check that post-Protocol material deposited is lawfully obtained & used
- Ensure researchers honor permit conditions and agreement terms through the MTA
- Where possible, sight *International Certificates* and quote identifier in MTA
- Users quote identifier in IP applications and publications - as required

# Thank you!

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