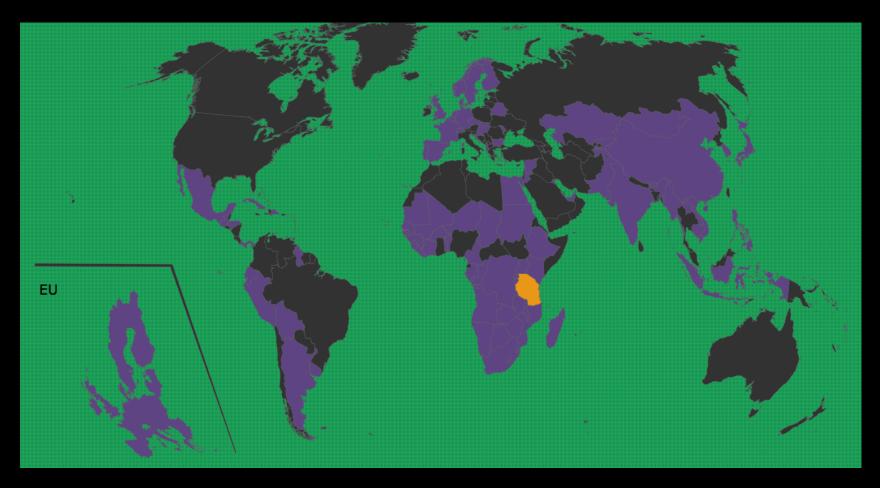
#### New Horizons for Research and Collections: The Nagoya Protocol on Access and Benefit-Sharing



Breda M. Zimkus

Museum of Comparative Zoology, Harvard University

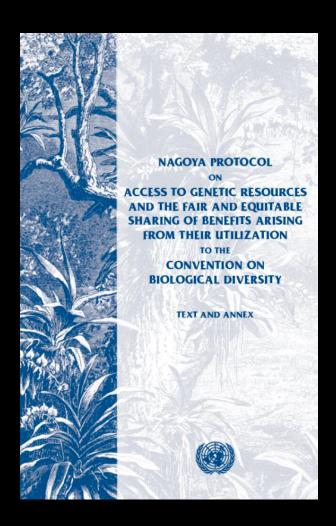
### Access & Benefit-Sharing: History

- Convention on Biological Diversity (CBD, <a href="https://www.cbd.int">https://www.cbd.int</a>)
  - Established in 1992 (in force since 1993) with 3 objectives:
    - 1. Conservation of biological diversity
    - 2. Sustainable use of its components
    - 3. Fair and equitable sharing of benefits arising from the use of genetic resources



- Paradigm shift due to biopiracy
  - Genetic resources no longer common heritage
  - States have sovereign rights over genetic resources

### Access & Benefit-Sharing: History

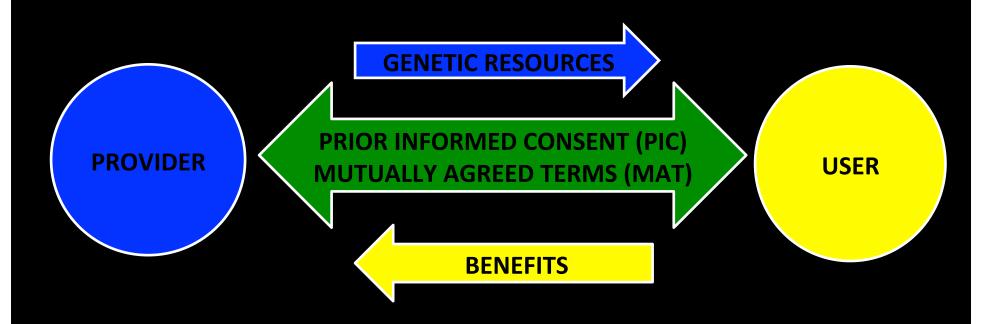


- Nagoya Protocol
- Legally binding supplementary agreement to CBD
- Adopted in 2010; came into force on 12 October 2014
- Outlines obligations for genetic resources and associated traditional knowledge (ABCs of ABS):
  - Access regulated
  - Benefits from utilization shared
  - Compliance measures required

#### Access & Benefit-Sharing: Terms

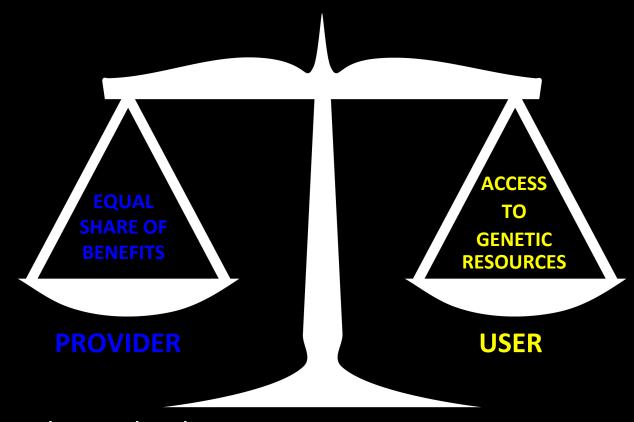
- Genetic Resources (defined in CBD)= any material of plant, animal, microbial or other origin containing functional units of heredity and is of actual or potential value, including:
  - Everything that contains DNA (living or dead material)
  - Wild species as well as breeding varieties
  - Material from in situ and ex situ sources
- <u>Traditional Knowledge</u> associated with genetic resources (included in Nagoya but not defined)
  - "Knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity." (WIPO 2010, http://www.wipo.int/tk/en/tk/)

### Access & Benefit-Sharing: Terms



- Prior Informed Consent (PIC) required before access
- Mutually Agreed Terms (MAT) must be established (if required), including terms for sharing benefits

### Access & Benefit-Sharing: Principles



- Equity relationship between access to genetic resources and benefits that arise from their use
- Users and providers both contribute to the conservation and sustainable use of biodiversity

### Access & Benefit-Sharing: Principles

- Benefit-sharing is subject to Mutually Agreed Terms (MAT)
- Benefits may be monetary or non-monetary, for example:



- Monetary Benefits
  - Access fee(s) per sample
  - Commercial products
  - Intellectual property ownership Education or training
  - Milestone payments
  - Licensing fees
  - Royalties
  - Salaries
  - Up-front payments

- Non-monetary Benefits
  - Access to information for conservation
  - Collaborative activities/research

  - Intellectual property ownership
  - Knowledge or technology transfer
  - Research partnerships
  - Research exchange
  - Resources for capacity-building

### Access & Benefit-Sharing: Principles

- Parties must develop and enforce compliance measures with domestic legislation or regulatory requirements
  - Provide evidence that genetic resources have been accessed in accordance with applicable laws
  - Cooperate in cases of alleged violations
  - Monitor utilization of genetic resources, including designation of checkpoints within value-chain:

Research Development Innovation Commercialization

#### Access & Benefit-Sharing: Compliance

- Applies to genetic resources and acquired from a Party since 12 Oct 2014 or later (when country became Party and established ABS measures)
- Some countries established access legislation before Nagoya Protocol (in response to the CBD) and use that date
  - National ABS laws that pre-date NP are legally-binding (even though compliance may not be enforced outside country)



### Access & Benefit-Sharing: Challenges



- Increased scrutiny on international biological research
- No uniformity regarding ABS among signatory countries
  - Different interpretations of Nagoya Protocol
  - Different stages of development of relevant laws
  - Different dates used for compliance
- Confusion about application of Nagoya
  - ABS legislation/regulations must be followed (e.g., PIC, MAT)
     even if researcher is from a non-signatory country
  - Nagoya still applies even if research is non-commercial

## Access & Benefit-Sharing: Implications for Collecting/Research

- Obtain PIC and establish MAT before collecting specimens
  - All must comply with domestic ABS legislation (even if from nonsignatory country)
  - Ensure agreements reviewed and signed by designated institutional representative
  - Change in utilization (e.g., noncommercial to commercial) requires renegotiation of PIC/MAT



# Access & Benefit-Sharing: Implications for Collections

- Track all compliance documentation (e.g., permits, certificates, agreements)
- Implement procedures to share benefits as negotiated with providing country (if not done so already)
- Keep records of all instances of material use
  - Temporary use (e.g., loans) or permanent transfer can only take place if permitted by PIC/MAT
  - Any restrictions/requirements arising from MAT should be communicated to third-parties



Harvard Museum of Natural History and Museum of Comparative Zoology

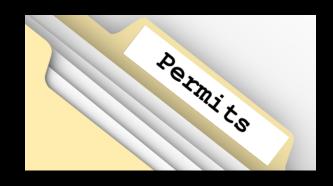
# Implications for Collections: Acquisition & Accession

- Acquisition and accessioning policies should be reviewed in regards to ABS
  - Originals (preferred) or copies of all compliance documentation must be obtained:
    - 1) Collecting permit(s) from country of origin
    - 2) Benefit-sharing agreements
    - 3) Export permit(s) from country of origin
    - 4) Import permit(s) into the U.S



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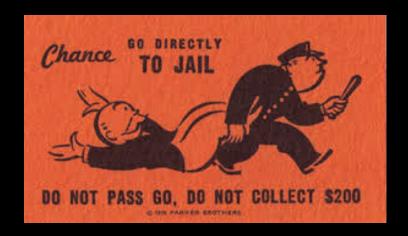


# Implications for Collections: Tracking Compliance Documentation



- Policies and procedures should be developed to increase transparency and access to "permits":
  - Scanning and uploading "permits" to database
  - Tracking core information regarding "permits" (e.g., identifying number, issued by, issued to, dates) in database
  - Using controlled vocabulary to categorize "permit" types
  - Linking "permits" to transactions (e.g., accessions, loans) within database

### Access & Benefit-Sharing: Implications



- Researchers and institutions may risk research programs and reputations if they don't obtain PIC, negotiate MAT, and follow through with obligations
- The Lacey Act, regulating interstate commerce in illegally taken fish, wildlife, and plants, may force U.S. institutions to implement ABS measures on a voluntary basis
- Individuals and institutions could be held responsible for violations of the Lacey Act (although this has not yet occurred)

# Ways to Adapt to the New Landscape for Collecting/Research



- Determine country-specific permitting requirements (ABS-CH)
- Apply for permits as far in advance as possible
- Apply for permits for broadest scope possible
- Collaborate with in-country partners (may be required)
- Articulate how research can benefit providing countries in permit applications and benefit-sharing agreements

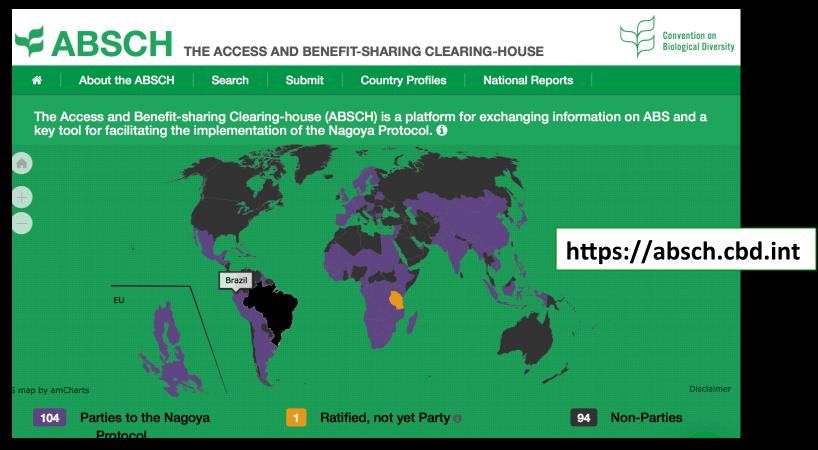
B. M. Zimkus (MCZ)

## Ways to Adapt to the New Landscape for Collections



- Review collection acquisition and accessioning policies in regards to ABS
- Develop policies and procedures to increase transparency and access to compliance documentation by tracking digitally

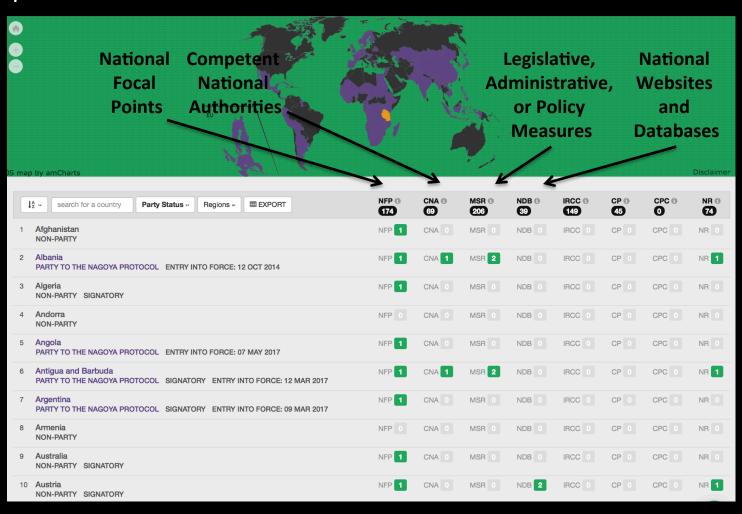
#### Resources



- Web-based platform for information exchange associated with implementation of Nagoya Protocol
- Most relevant resource when institutions/researchers plan to access genetic resources or want to find country specific information

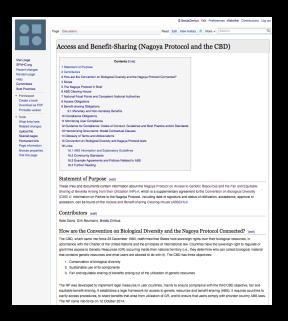
### ABS Clearing-House (ABSCH)

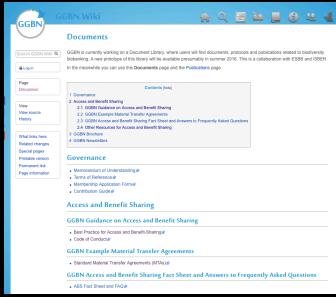
 Many parties do not have complete profiles BUT most parties and even non-parties have ABS National Focal Points that can be contacted

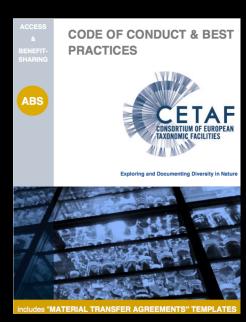


#### Additional ABS Resources

- SPNHC Wiki Page http://spnhc.biowikifarm.net
- GGBN ABS Guidance, MTAs, ABS Fact Sheet & FAQs http://wiki.ggbn.org/ggbn/Documents#
- CETAF Codes of Conduct, Best Practice, MTAs
   http://cetaf.org/sites/default/files/final\_cetaf\_abs\_coc.pdf



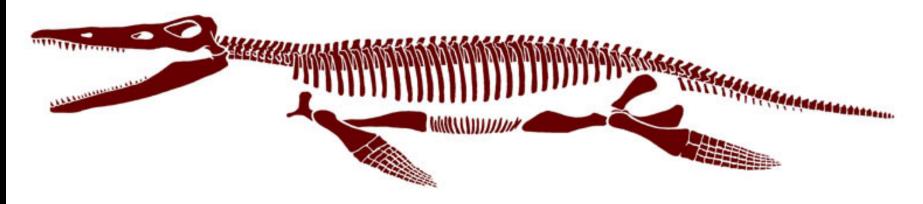




## 7 Stages of Grief

Shock Initial paralysis at hearing the bad news Denial Trying to avoid the inevitable Anger Frustrated outpouring of bottled up emotion Bargaining • Seeking in vain for a way out Depression Final realisation of the inevitable **Testing**  Seeking realistic solutions Acceptance Finally finding the way forward

#### MUSEUM OF COMPARATIVE ZOOLOGY



HARVARD UNIVERSITY