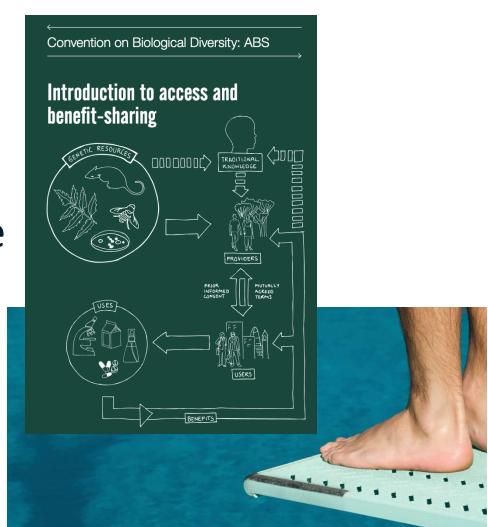
Standing on the edge: ABS/NP considerations for a regional reference laboratory

Dr. Scarlett Sett CSIRO - Australian Centre for Disease Preparedness

Asia Pacific Quadripartite Webinar Series 2: Nagoya Protocol from One Health Perspective December 6th, 2024





Who are we and what do we do?



industries, as well as people, from emerging infectious disease threats

- Laboratory diagnostics (ISO 17025) and research
 - Animal studies



ACDP's Reference Laboratory Role

WOAH

WOAH Collaborating Centres

- Laboratory Capacity Building
- New and Emerging Diseases
- Diagnostic Test Validation Science in the Asia-Pacific Region

WOAH Reference Laboratory

- Bluetongue
- Hendra and Nipah virus diseases
- Highly pathogenic & low pathogenic avian influenza
- Newcastle disease
- · African swine fever
- · Classical swine fever
- Abalone herpesvirus
- Ranavirus
- Yellow head disease
- Epizootic haematopoietic necrosis virus

ACDP helps protect Australia's multi-billion agriculture industries, and the nation, from emerging infectious and emergency animal disease threats.



National Reference Laboratory

Terrestrial animals

- 27 diseases of multiple species
- 2 cattle diseases
- 5 sheep & goat diseases
- 11 equine diseases
- 16 swine diseases
- 10 avian diseases
- 4 diseases of other species

Aquatic species

- 24 fish diseases
- 13 mollusc diseases
- 15 crustacean diseases
- 3 amphibian diseases

UN/FAO

- FAO Reference Centre for Animal Influenza & Newcastle Disease
- FAO Reference Centre for Biorisk Management
- UNSGM Designated Laboratory for Biological Weapons

Innocuity testing

 Representation on WHO SARS-CoV-2 Expert Group

WHO

 Global Outbreak & Response Network (GOARN) partner



ACDP Reference Laboratory services

- Primary and confirmatory lab diagnostics and characterisation of viruses (ISO 17025)
- Technical advice, eg diagnostics, surveillance, sample collection
- Training
 - Laboratory and field diagnostics
 - Biosafety and biorisk management
 - Quality Assurance
- Supply quality assured reagents and reference materials
- Provider of Proficiency Testing (ISO 17043)
- Disease surveillance national programs and overseas
- Research in Australia and in collaborating country



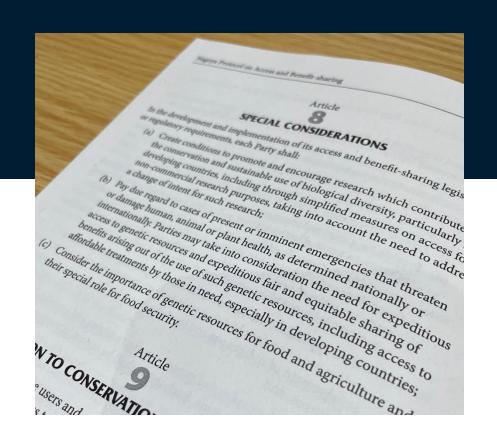


Why should we have ABS/NP considerations for our reference lab activities?



Relevance to WOAH ref labs

- Reference lab services
 might not fall under the
 scope of the NP
 - Article 8(b) special consideration
 - Activities might not fit the "utilization"





What is covered under the NP?



MATERIAL SCOPE

"genetic material of actual or potential value"

"any material of plant, animal, microbial or other **(non human)** origin containing functional units of heredity i.e. genes."

Biological material that contains DNA/RNA (dead or alive)*

UTILIZATION SCOPE

.."to conduct research and/or development on the genetic and/or biochemical composition of the genetic resource, including through the application of biotechnology."

R&D on **derivatives** (proteins and enyzmes, secondary metabolites)

*excludes: human DNA ≠ human pathogens & microbiome, any material covered by another framework would be out of scope of the NP (for example: material under the Pandemic Influenza Preparedness framework)



Relevance to WOAH ref labs....

- Reference lab services *might* not fall under the scope of the NP
 - Article 8(b) special consideration
 - Activities might not fit the "utilization" definition
- If material is only to for identification *might* be out of scope, however, if material is to be used for research purposes *might* require ABS permits
- National reference labs ≠ NP CNA nor NFP

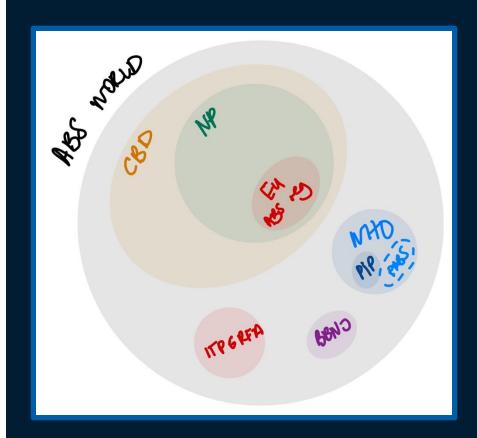




Challenges AND opportunities



 ABS is complex and goes beyond the NP





National implementation is key but also a challenge

- Differences in interpretation
 - access ≠ collection
 - Limited GR under scope of national legislation
 - exemptions
- Each country can decide IF and HOW they regulate their resoures
 - Party with ABS measures
 - Party without ABS measures
 - Non–Party with ABS
 - Non-Party without ABS





System is not perfect but it is established law! legal consequences if found non-compliant

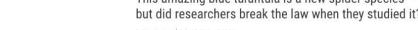


A new centipede beguiled taxonomists-but the specimens had murky origins. © MAGNOLIA PRESS, C. DOMENECH ET AL. ZOOTAXA, 4483(3), 401 (2018): REPRODUCED WITH PERMISSION

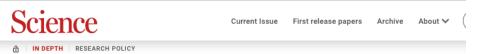
Illicit centipede raises thorny question: Should journals have refused to publish a paper about it?

By Yao-Hua Law | Feb. 10, 2021, 12:20 PM





By Yao-Hua Law | Feb. 27, 2019, 12:00 PM



Indonesia gets tough on foreign scientists

Strict new rules and prison sentences for biopiracy could stifle international research.



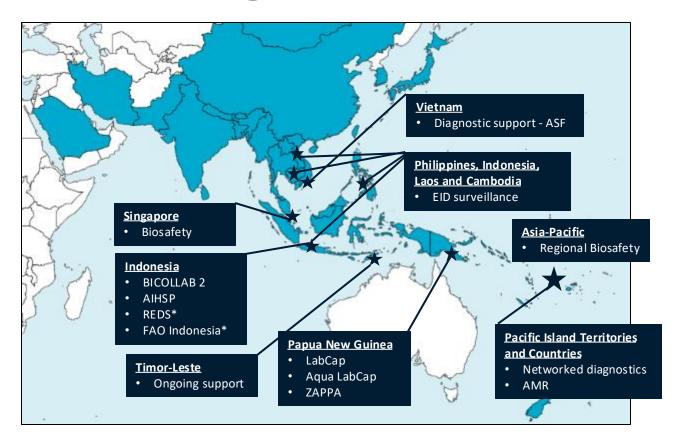


- Principles, values and objectives of frameworks are upheld by compliance
- Opportunities for scientific collaboration and to increase benefit-sharing
 - Non-monetary benefits often overlooked
 - Capacity building
 - WOAH reference lab diagnostic testing (for free)



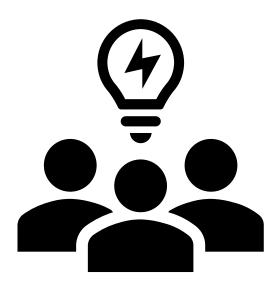


Internation Program: 2024





- Policy makers and practitioners need to communicate and engage with each other
 - Established relationships in the region need to connect with the correct authorities







Thank you for your attention!

Comments, questions, concerns?

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Useful resources and links

- ABS clearing house website (www.absch.cbd.int)
- ABS kit (https://www.cbd.int/abs/information-kit-en), for printing material, created by the secretariat for awareness raising on specific topics
- German Nagoya Protocol HuB (<u>www.nagoyaprotocol-hub.de</u>), project for awareness raising on ABS for the academic sector in Germany
- Dutch Nagoya toolkit website (https://www.absfocalpoint.nl/en/absfocalpoint/Help-tool.htm)
- An introduction to ABS (1 hr presentation) https://youtu.be/LYGsyXbku1Y?si=EGiGF8VqUON0fVcz
- Digital Sequence Information and the CBD (1 hr presentation) https://youtu.be/hgwGQXk8SM0?si=Qo3LgAzBSCZVOQ9R

Abbreviations

CBD = Convention on Biological Diversity

ABS = Access and Benefit Sharing

GR = genetic resources

BS = benefit sharing

IRCC = Internationally Recognized Certificate of Compliance

PIC = Prior Informed Consent

MAT = Mutually Agreed Terms

MTA = Material Transfer Agreement

DSI = Digital Sequence Information

ITPGRFA = International Treaty on Plant Genetic Resources for Food and Agriculture

PIP framework = Pandemic Influenza Preparedness

NFP/CNA = National Focal Point / Competent National Authority

What about sequence data?

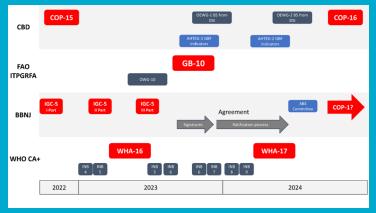




Digital sequence information (DSI)

- Sequences deposited in databases
- Use of sequences ≠ use of GR
- COP16 outcomes
 - OA remains key
 - Research does not contribute to the fund
 - Databases not ABS police
 - Opportunities for hormonization with other UN fora
 - Funding for capacity building missing in text







ABCs of ABS – the pillars of the NP

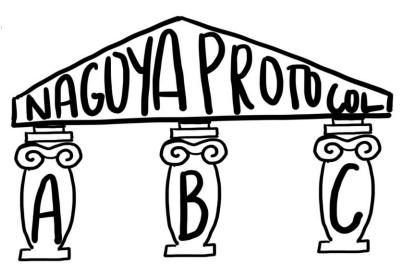
A is for access

 prior informed consent (PIC) – it means askin for permission first

- B is for benefit-sharing

- it's about giving something back
- Based on mutually agreed terms (MAT)
 between the providing country and the user
- benefit-sharing should contribute to conservation and sustainable use of biodiversity
- Monetary and non-monetary



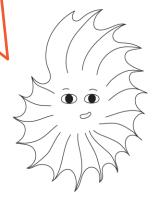




What kind of benefits could I share? Some examples:

Monetary benefits:

- Access fees
- Payment of royalties
- Licence fees in case of commercialization
- Salaries and preferential terms where mutually agreed
 - Joint ventures
 - Joint ownership of relevant intellectual property rights.



Non-monetary benefits:

- Sharing of research and development results, including relevant ones to conservation and sustainable use
 - Education and training
- Collaboration in scientific research and development programmes
- Research directed towards local priorities, including biodiversity management, health and food security
- Admittance to ex situ collections and to databases
- · Institutional capacity-building