

Can we keep it? Dealing with the Nagoya Protocol and its implications for collections

Chris Lyal

The Convention on Biological Diversity

“States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources...”

Convention on Biological Diversity, Article 3

From 29 December 1993:

- The biodiversity of a country belongs to that country
- The country determines who can collect that biodiversity, and what they can do with it.



The Convention on Biological Diversity

Parties to the CBD agreed three objectives:

conservation of biological diversity

the sustainable use of its components

*the fair and equitable sharing of the benefits arising
out of the utilization of genetic resources*

The last is 'Access and Benefit-sharing' (ABS)

Access & Benefit-Sharing (ABS): the 3rd objective of the CBD

Access – obtaining the Genetic Resources (GR) from the Providing Country

the fair and equitable sharing of the

Benefits – monetary or non-monetary

arising out of the

Utilization - conduct research and development on the genetic and/or biochemical composition of GR, including through the application of biotechnology.

of

Genetic resources - any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value.

Access & Benefit-Sharing

Has led to a wide requirement for collecting permits

These are effectively bilateral contracts:

The researcher can collect material for agreed purposes

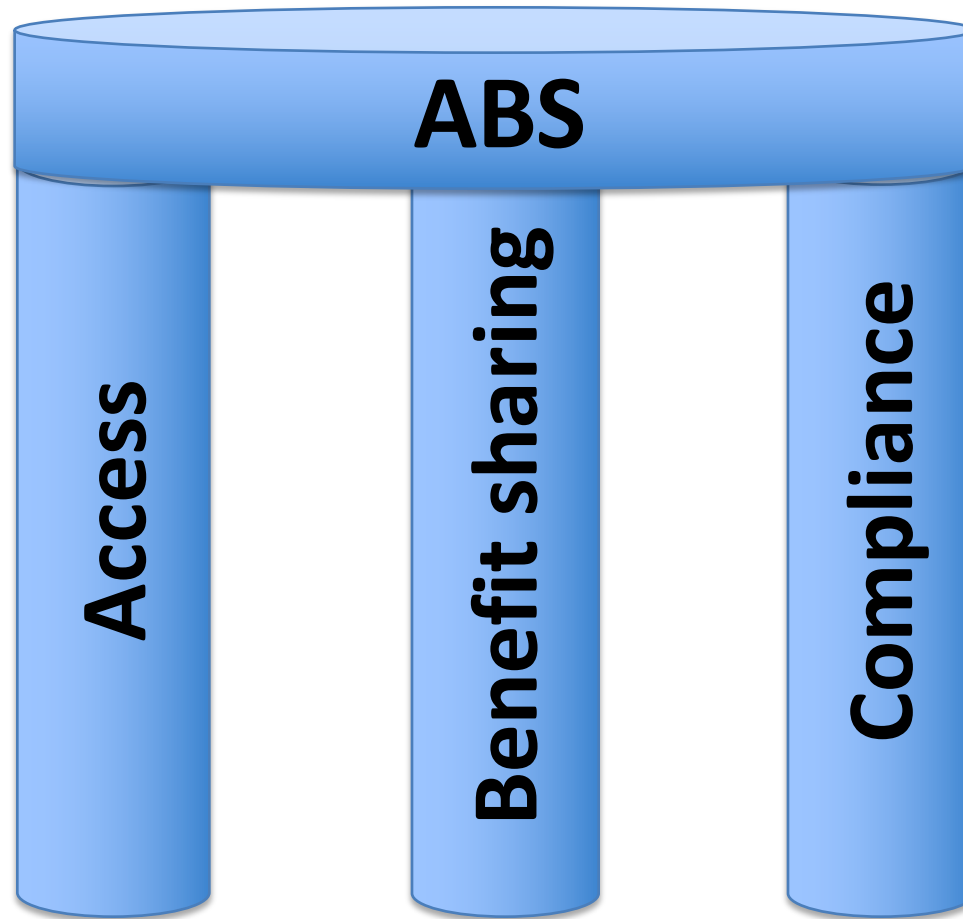
(*'Prior Informed Consent'*)

Under agreed conditions

(*'Mutually Agreed Terms'*)



The ABC of ABS



Nagoya Protocol

The legally-binding Nagoya Protocol on Access and Benefit-Sharing came into force on 12th October 2014

It applies to:

- Genetic resources within the scope of Article 15 of the CBD
- Traditional knowledge associated with those genetic resources



Nagoya Protocol

Does not apply to:

- Human genetic resources
 - But **does** cover human pathogens, parasites and other associated organisms carrying genetic material
- Genetic resources obtained from areas beyond national jurisdiction (ABNJ)
 - e.g. high seas (see UNCLOS) or areas covered by the Antarctic Treaty

ABS REGIME
(CBD, BILATERAL CONTRACTS, PROVIDING COUNTRY
NATIONAL LAW)

NAGOYA PROTOCOL

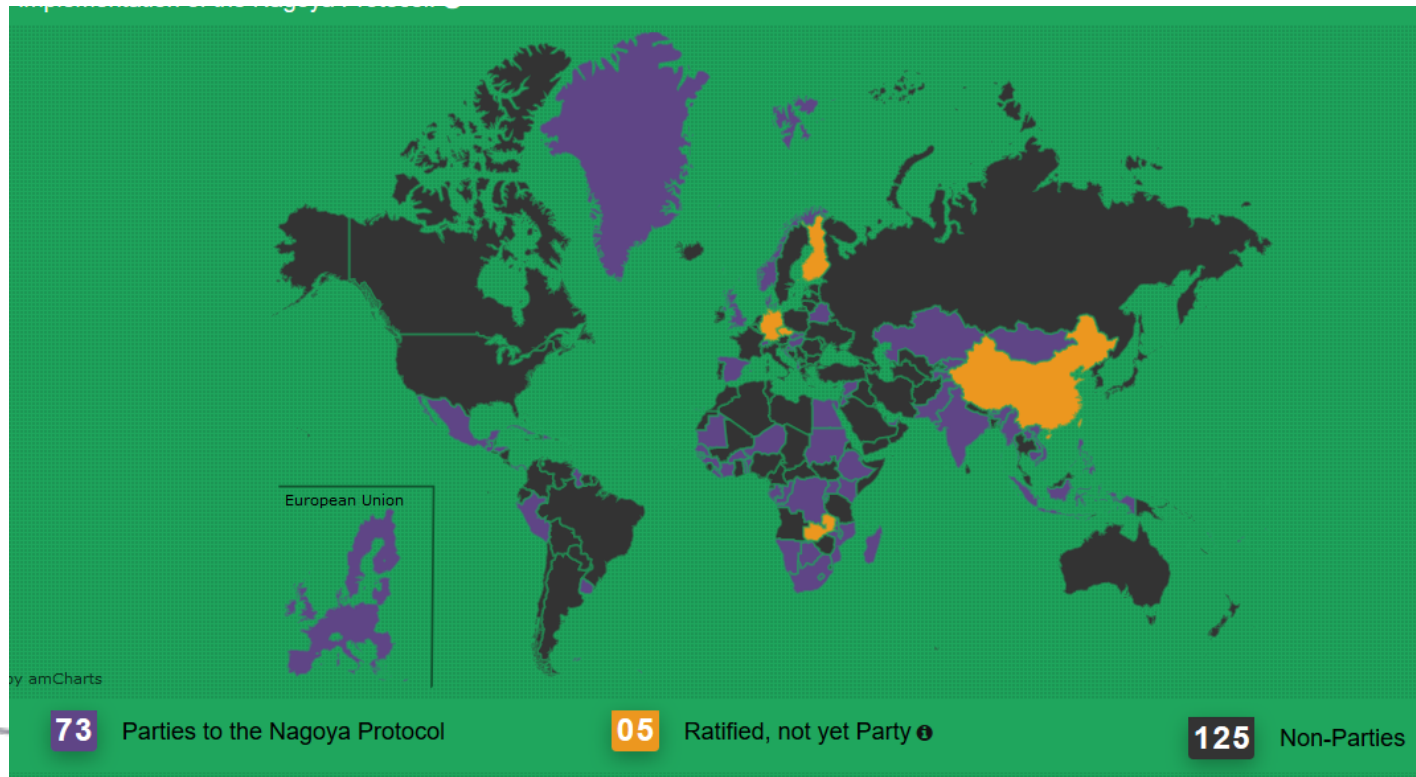
EUROPEAN
REGULATION

MS
NATIONAL
LAWS

ITPGRFA

Nagoya Protocol: Ratifications

- 73 countries Party to the Protocol so far
- EU Ratified in 16 May 2014
- UK Ratified 22 February 2016



Relevant (domestic) legislation

- EU Regulations
 - ABS Regulation (No. 511/2014) (12 Oct 2014)
 - Commission Implementing regulation (No. 2015/1866) (9 Nov 2015)
 - Covers Articles 5, 7 and 8 (register of collections, monitoring user compliance and best practices) which did not apply before then
 - applicable to all Member States:
- UK:
 - The The Nagoya Protocol (Compliance) Regulations 2015 Statutory Instrument 2015 No. 821 (Mar 2015).

Relevant (domestic) legislation

- UK Checkpoint / Competent National Authority
 - *Regulatory Delivery* (National Measurement and Regulation Office)
 - Key contact: Katie Beckett, ABS Project Manager
katie.beckett@nmro.gov.uk
 - See
<https://www.gov.uk/government/organisations/regulatory-delivery>
and
 - <https://www.gov.uk/guidance/abs>
- Responsible for compliance in the UK

EU Regulation: Temporal Scope

The EU ABS Regulation:

- applies to GR / aTK accessed after entry into force of the Nagoya Protocol for the European Union (12 Oct. 2014)
- No retro-active effect of EU legislation
- Time of access (not utilisation) determines applicability
- Provider-country legislation may diverge
 - (but does not affect temporal scope of EU Regulation)

EU Regulation: Geographical Scope

The EU ABS Regulation applies to:

- GR / TKaGR from Parties to the Protocol
 - Non-Party access legislation to be respected (but not covered by EU Regulation)
- With access legislation in place – info from:
 - ABS Clearing-House <https://absch.cbd.int/>
 - Provider country's National Focal Point
 - Users' partners in country

EU Regulation: compliance

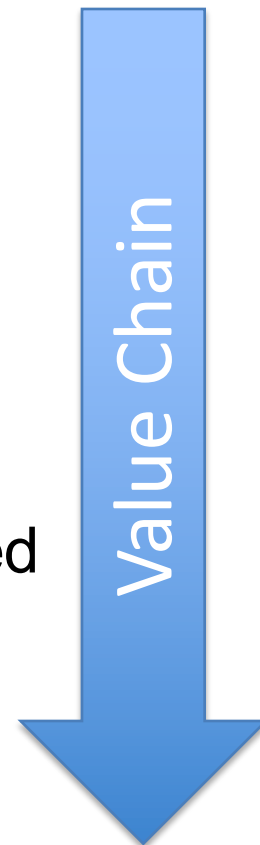
For GR accessed from Parties to the Nagoya Protocol users should:

Exercise Due Diligence when GR are acquired / accessed

Transmit specified information when GR transferred to a 3rd Party

Report due diligence when GR are utilized

Report due diligence when results of utilization are placed on the EU market



EU Regulation: Monitoring

Due diligence declaration at the stage of research funding

- MS, EC to request the declaration from all recipients of research funding (public or private)
 - Research funding defined as grant
- *Multiple recipients of funding*
 - Declaration may be done only once
 - Project co-ordinator reports on all utilisation of project, even if taking place in more than one MS

EU Regulation: Monitoring

Due diligence declaration at the stage of research funding

- Declarations to be made to the competent authorities of MS
- Declarations to be made when 1st payment received and genetic resources obtained, but not later than final report
- MS may define further timeline



EU Regulation: Monitoring

Due diligence declaration at the point of commercialisation

- Events triggering the obligation to declare
 - a) When market approval is sought
 - b) When notification is required
 - c) When placing product on a market (developed via utilisation of GR)
 - d) When result of utilisation sold or transferred for the purpose of (a), (b) or (c)
 - e) When utilisation ended in EU and its outcome sold or transferred outside of EU
- But not on publication of scientific paper

EU Regulation: Registered Collections

“Registered Collections”

- Option set up under the Regulation to facilitate compliance
- Users obtaining GR from a Registered Collection are considered to have exercised due diligence with regard to seeking of information under Article 4(3) of the Regulation (legality of access)
- Effectively collection doing the work for the user
- May be only part of an institution's collections
- Institution can apply for registration to National Competent Authority

EU Regulation: Best Practices

Best practices

- "Combination of "procedures, tools and mechanisms" enabling users to comply with due diligence obligations"
- Implementing Regulation specifies procedures:
 - Application process
 - Recognition of best practices by EC
 - Dealing with deficiencies, withdrawing recognition
- Implementation of recognised best practice to be taken into account in MS checks on users



Wellcome Images

Risks associated with ABS

Three areas of risk that may impact biodiversity collections and research:

- Legal risks of non-compliance
- Civil risks from failure to manage contractual agreements (clauses in permits)
- Reputational risks arising from the above, and failing to share benefits appropriately
 - But apply to all countries whether Parties to the NP or not, and whenever collections were made

What does it mean to us?

Collections need to

- Comply with National Regulations and Legislation when staff collect
- Be sure they can legally receive material
- Be sure they can carry out our research legally
- Be compliant with conditions of access
- Share any benefits as agreed (contracts / permits)
- Report to domestic national authorities as required

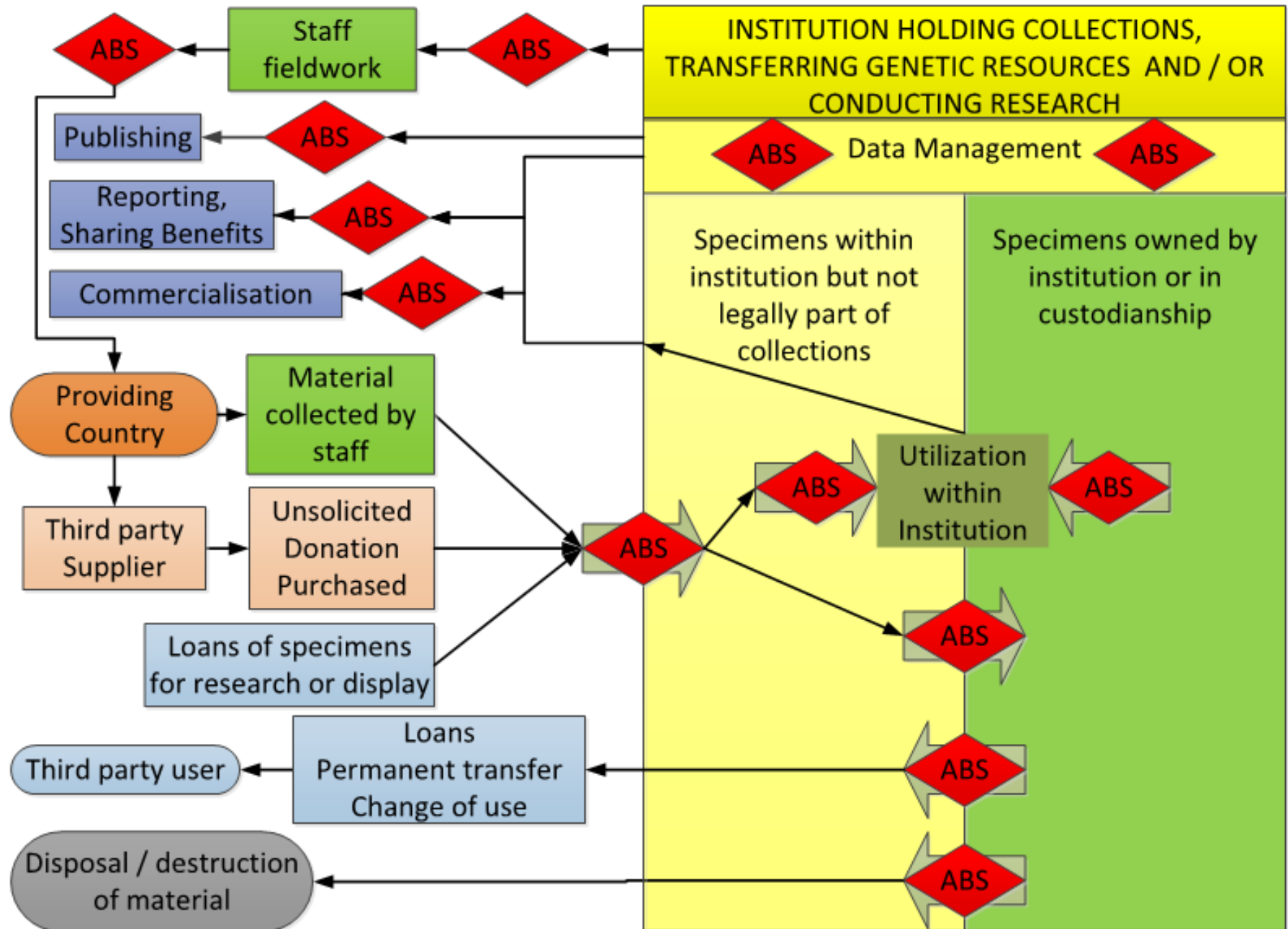
Risk management

- Clarity on responsibilities at individual and institutional levels
- Management to ensure compliance by staff
- Data management:
 - To meet EU Regulation Requirements
 - To meet National regulatory requirements where different
 - To manage contract compliance
- Develop / Adopt Best Practices



Courtesy of Ben Beal

ABS Decision Points in a Museum Workflow



Managing ABS Decision Points in a Workflow

- At each decision point staff need to know:
 - That a decision point is reached
 - How to take a decision
 - What to do
- This is important to the Institution:
 - To ensure that it is consistent in its activities
 - To ensure that it and its staff are legally compliant
 - To manage legal and reputational risk
 - To ensure it can and does meet contractual requirements (MAT)
 - To protect its staff

Nagoya Protocol Responses: Code of Conduct and Best Practice

- Called for in Nagoya Protocol Article 20 & EU Regulation Article 8
- Assists institutions develop their internal policies and processes
- Facilitates:
 - trust by national Checkpoints (EU Regulation has ‘risk-based’ approach to monitoring compliance)
 - trust by Provider Countries
 - exchange of specimens
 - non-commercial research and delivery of benefits

Nagoya Protocol Responses: Code of Conduct and Best Practice

- Build on existing Codes and Practices, e.g.
 - Botanic Gardens Principles
 - Swiss Academy of Sciences guidelines
 - International Plant Exchange network (IPEN)
- Recently developed by a number of relevant initiatives:
 - Consortium of European Taxonomic Facilities
 - Global Genome Biodiversity Network
 - Microbial Resource Research Infrastructure (MIRRI)
- CETAF has submitted CoC to EU seeking its recognition



CETAF Code of Conduct

- Sets out basic principles
 - Abiding by CBD, NP, national laws etc
 - Acquisition of Biological Material
 - Curation and Data management
 - Utilization of Genetic Resources
 - Transfer to third parties
 - Benefit-sharing
 - Institutional Policies
 - Staff training



http://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf

CETAF and GGBN Best Practices

- Give detail on how to implement the Codes of Conduct
- Different organisations have:
 - different systems in place
 - different database systems
 - different overarching policies and legal requirements
 - so cannot be prescriptive as to policies and procedures
 - Also assists users have 'ownership'
- Can set out:
 - Required outcomes of implementation
 - Policy areas that should be addressed
 - The outcomes procedures should achieve
 - Issues that need to be addressed

Access / Acquisition

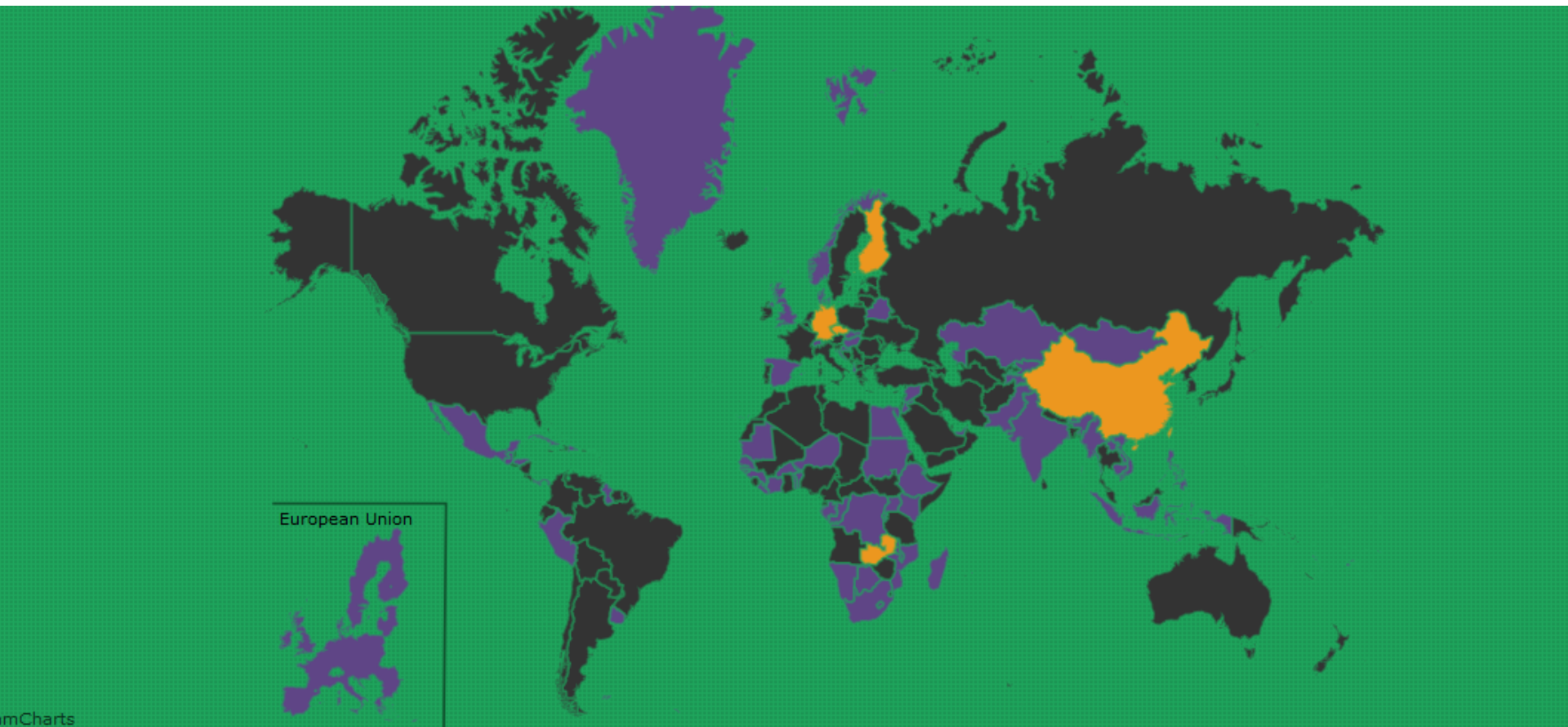
- **Access** (collecting) is often managed under same regulations for taxonomic (non-commercial) research and commercial research.
- Nagoya Protocol Parties are asked to
*“Create conditions to promote and encourage **research which contributes to the conservation and sustainable use of biological diversity**, particularly in developing countries, including through simplified measures on access for non-commercial research purposes....”*



Access / Acquisition

- Seek PIC with a full explanation of the purposes for which biological material will be used and how genetic resources will be utilized.
- in situ:
 - (i) obtain information on the Country's access laws and procedures for obtaining permits, and for agreeing MAT
 - (ii) obtain PIC and relevant permits from Government and other relevant stakeholders as required under national law;
 - (iii) agree terms, according to applicable law and best practice.
- ex situ collections, commercial sources or individuals:
 - agree terms of use with the body governing the collection.
 - evaluate available documentation and take appropriate steps to ensure, as far as is reasonably possible, that the material was acquired in accordance with applicable law.

Nagoya Protocol: Gaining Access



imCharts

73

Parties to the Nagoya Protocol

05

Ratified, not yet Party ⓘ

125

Non-Parties

United Kingdom of Great Britain and Northern Ireland

Party Status: Party to the Nagoya Protocol
Entered into force on: 22 May 2016
Ratification on: 22 Feb 2016
Signatory: Signed on 23 Jun 2011
CBD Country Profile: www.cbd.int/countries/?country=gb

- + ABS National Focal Points (NFP) 1
- + Competent National Authorities (CNA) 0
- + Legislative, administrative or policy measures on access and benefit-sharing (MSR) 3
- + National Databases and Websites (NDB) 0
- + Checkpoints (CP) 0
- + Internationally Recognized Certificates of Compliance (IRCC) 0
- + Checkpoint Communiqués (CPC) 0
- + Interim National Report on the Implementation of the Nagoya Protocol (NR) 0

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Access: data use statement

- For use when seeking PIC, and can be appended to it
- Details what user might do with material
- Helps give legal certainty
- Can be edited in consultation



Consortium of European Taxonomic Facilities (CETAF)

ANNEXES 1 to 4 to the Code of Conduct on ABS

ANNEX 1: Statement of Use of Biological Material

This document sets out the typical ways in which biological material, accessioned into the collections of [institution name] ("[institution acronym]"), may be used and genetic resources may be utilized.

This includes use both in facilities managed or owned by the legal body and in facilities owned or

Code of Conduct: use

- Retain and manage BR/GR unless otherwise stipulated in MAT
- Safeguard TK
- Maintain records:
 - to record PIC and MAT / MTAs
 - to track utilization and benefits
 - to record supply to third parties (loans etc)
- Share benefits fairly and equitably
- Supply material to 3rd parties only in compliance with PIC and MAT, and use written MTAs to set out conditions

Other Tools: model MTAs

Material Transfer Agreements:

- Carry information and documents to ensure:
- Legal certainty of custody
- Information to enable reporting under national legislation
- Information to enable compliance with PIC and MAT
- Conditions of use, including disposal and 3rd party transfer



Consortium of European Taxonomic Facilities (CETAF)

Standard MATERIAL TRANSFER AGREEMENT (MTA 3)
for RECEIPT OF MATERIAL with change in ownership

Preamble

1. This AGREEMENT is for permanent transfer of MATERIAL containing GENETIC RESOURCES for non-

Other Tools: model MTAs

Material Transfer Agreements:

- May include identifiers of permits etc
- Will list specimens / samples covered
- Includes dispute resolution clauses, applicable jurisdiction etc
- For use in:
 - Receipt of material (= MAA)
 - Temporary transfer of custody with no change in ownership
 - Change of ownership

Data Management

Data management system should enable:

- Rapid discovery of all legal documents, requirements and restrictions associated with a specimen
 - efficient transfer of this information to a user in another institution;
- Rapid discovery of all records on the use of a specimen or sample (including 'utilization' or transfer to Third Parties)
- Association of data and information obtained from the use of specimens or samples to original specimen or sample;
- Retention of all relevant records and legal information covering utilization an appropriate period
- Discovery of how and when contractual agreements met (MAT)

Data management

- User databases must be able to hold and report key information

	Item	ABSCH Checkpoint Communiqué	EU Regulation (Checkpoint – Art 7(1))	EU Regulation (Checkpoint – Art 7(2))	EU Regulation (Transfer to 3rd party – Art 4)	For internal use
SUBJECT MATTER						
1	Subject-matter or genetic resources relevant to the information collected or received (CPC – free text). = Description of the genetic resources and/or traditional knowledge utilised or unique identifier(s), where available (EU IA; EU Reg)	Required if no IRCC (Optional additions of URLs to specimen data, name, georeference)	Required if no IRCC*	Required if no IRCC*	Required if no IRCC	+
PERMIT / ACCESS INFORMATION						
2	Reference number(s) of Internationally-Recognised Certificate of Compliance (IRCC)	Required if issued	Required if issued**	Required if issued	Required if issued	+
4	Date of Access of GR [unclear if this refers to the individual GR or the date of the permit]		**	Required*	Required if no IRCC	+
5	Source from which GR (or TKaGR) were directly obtained [likely to be a finer detail than Country but required detail needs clarification]			Required – not to be placed on ABSCH	Required if no IRCC	+

Data management

- ABS-CH can support Application Programming Interface (API)
 - So elements (e.g. IRCC) can be linked to individual databases
- GGBN has developed elements of Darwin Core to support permit information

Concept definitions in GGBN Permit Vocabulary

Concept Name:	ggbn:permitStatus
Normative URI	http://rs.tdwg.org/dwc/terms/disposition
Label	Permit Status
Definition	Information about the presence, absence or other basic status of permits associated with the sample(s).
Defined By	
	Required: Yes — Repeatable: Yes
Examples	Permit available , Permit not required , Permit not available , Unknown Material collected after 2014-10-12 cannot be in "Unknown" permit status!
Notes:	Predefined vocabulary, See permitStatus vocabulary ; entry of data is mandatory

Data Management

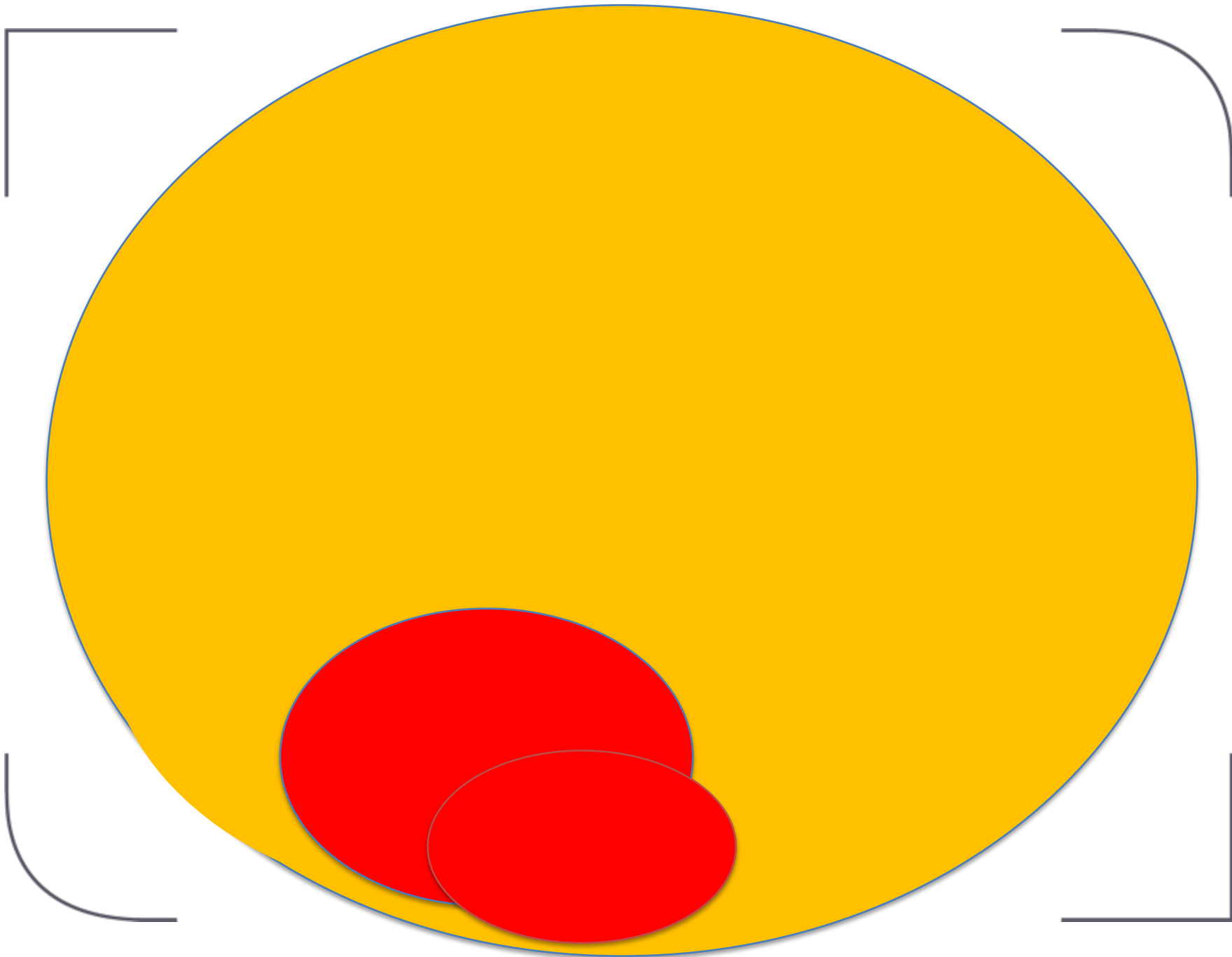
- Streamline processes
- Fit to workflows where possible
- Consider cost-benefits (e.g. retrospective documentation)
- Automatic report generation
- Develop tools (e.g. MTAs, electronic forms)

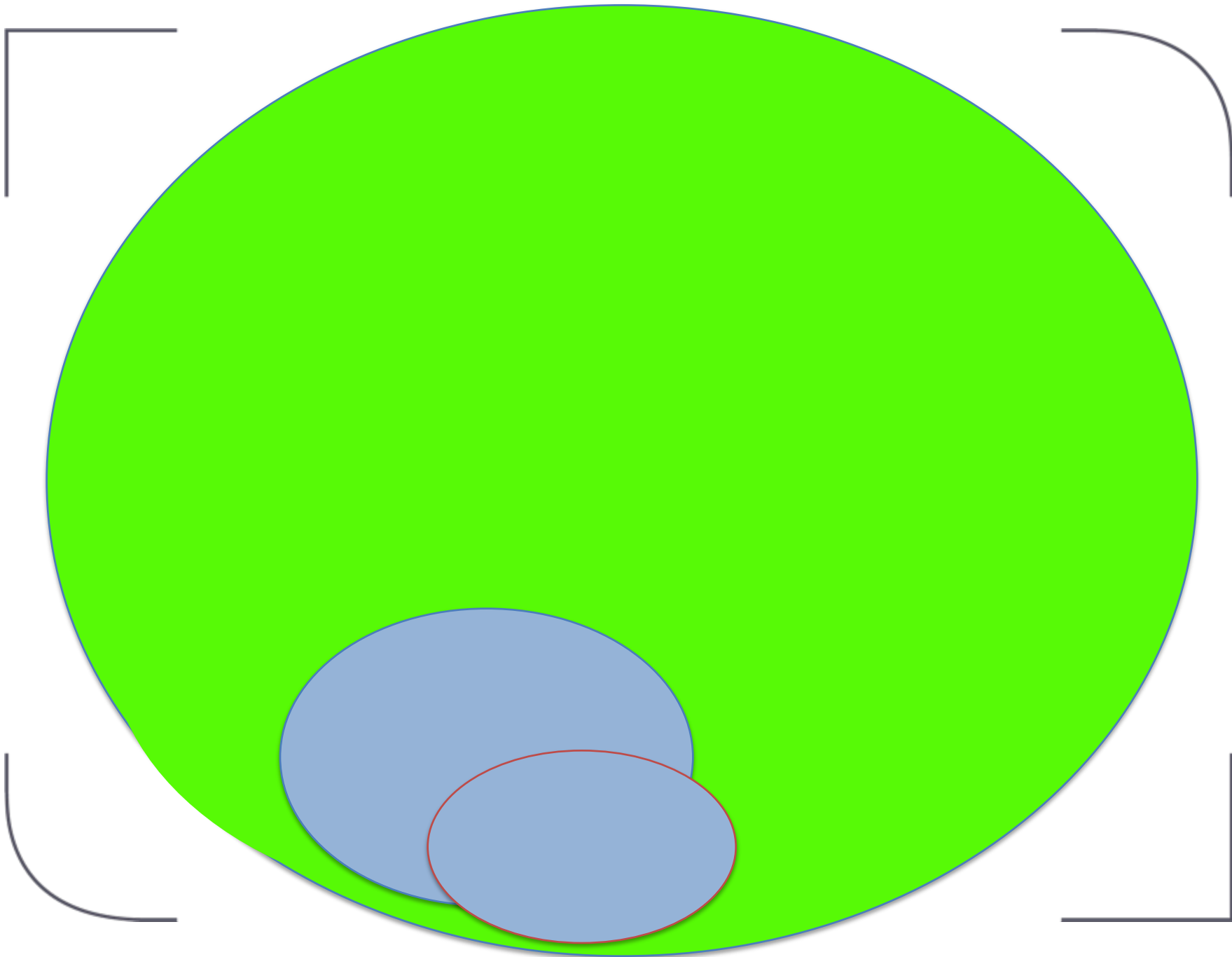


CETAF and GGBN Best Practices

17 policy areas identified, which should ensure:

- institution understands its rights and responsibilities;
- staff abide by national and international laws and regulations;
- biological resources are obtained with appropriate legal certainty;
- biological resources deposited in the institution can legally be retained;
- terms and conditions governing samples are complied with by the repository and third parties using the repository;
- renegotiation with country of origin if proposed change in use;
- terms and conditions recorded and can be accessed effectively;
- institution can address benefit-sharing before and after CBD / NP.





Benefit sharing

- 'Benefits' may include names, specimens, capacity building etc
- The organisation must know:
 - What benefits were agreed?
 - When were they to be delivered?
 - Who is responsible?
 - How do they know they are responsible?
 - How is this managed?

Benefit sharing

- ABS is intended to deliver against Conservation and Sustainable Use
- Ideally non-monetary benefits should be directed effectively at this
- May involve engagement with National Biodiversity Strategy and Action Plan of country
- Opportunity to make a difference!



Benefit-Sharing: future development

- To share non-monetary benefits that result from collection and research develop pipelines:
 - GBIF for specimen data
 - BHL for publications
 - BOLD / Genbank etc for molecular information
 - EoL for descriptions
 - Etc
- And ensure they feed into environmental management systems

