Access and Benefit-Sharing and the *Nagoya Protocol*

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NATURAL HISTORY MUSEUM

The Convention on Biological Diversity

Role:

- International legal framework
- Political agreement
- To initiate and facilitate action

Entered into Force in 1993

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

- 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)

CBD and ABS

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

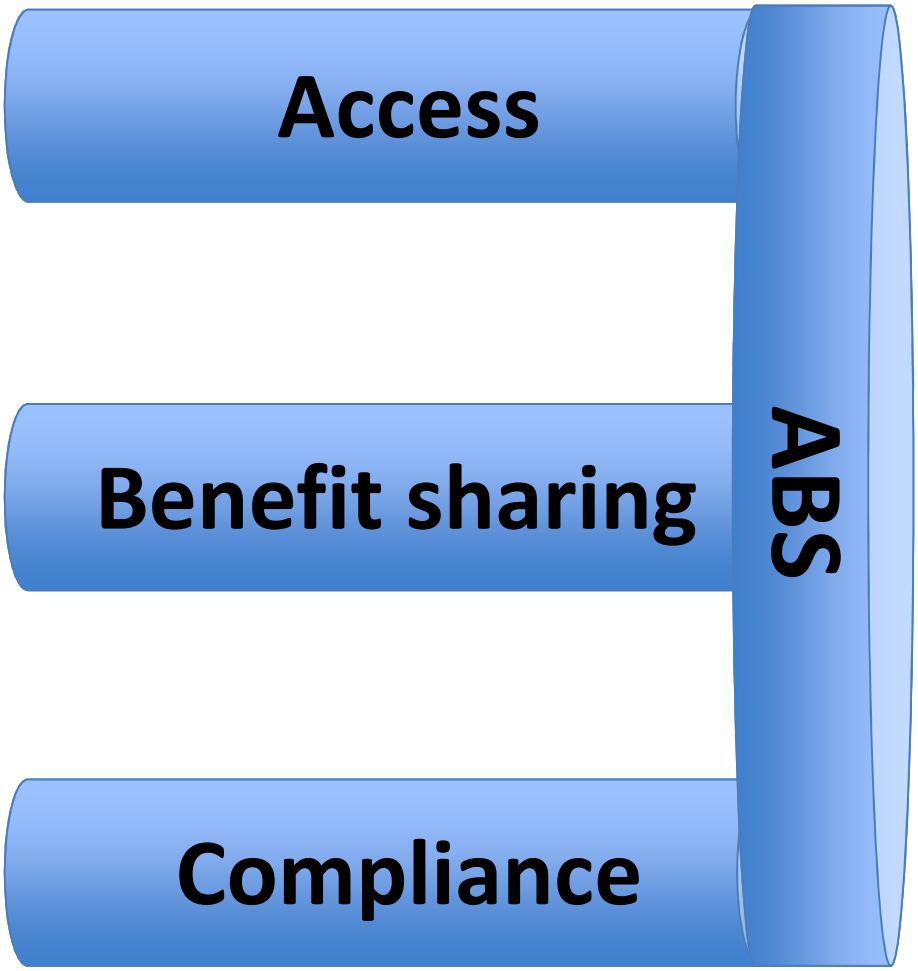
These are effectively bilateral contracts:

The researcher can collect material for agreed purposes

(‘*Prior Informed Consent*’)

Under agreed conditions

(‘*Mutually Agreed Terms*’)


Access
Benefit sharing
Compliance
ABS

The Nagoya Protocol

2010: CBD Parties agreed an International Regime on Access and Benefit-Sharing (‘**Nagoya Protocol**’)

Came into force on 12th October 2014

Nagoya Protocol: Ratifications

- 62 countries so far Ratified the Protocol
- EU Ratified in May 2014
  - EU Regulation applied from 12th October 2014 (whether Member State has ratified the Protocol or not)
  - EC Implementing Act in force from 12th October 2015
  - The EU Regulation focusses on compliance
- Member States
  - will Ratify separately
  - developing their own implementing legislation
  - Access provisions are up to the MS

Scope

The Nagoya Protocol applies to:

Genetic resources within the scope of Article 15 of the CBD

Traditional knowledge associated with those genetic resources

Scope

Does not apply to human genetic resources

But **does** cover human pathogens, parasites and other associated organisms carrying genetic material

What does it mean to us?

- Nagoya Protocol allows for ‘Simplified Access’
- Parties to the Protocol shall:
  - “*Create conditions to promote and encourage* ***research which contributes to the conservation and sustainable use of biological diversit****y, particularly in developing countries, including through simplified measures on access for non-commercial research purposes*….”

Nagoya Protocol Implementation and Non-commercial Research

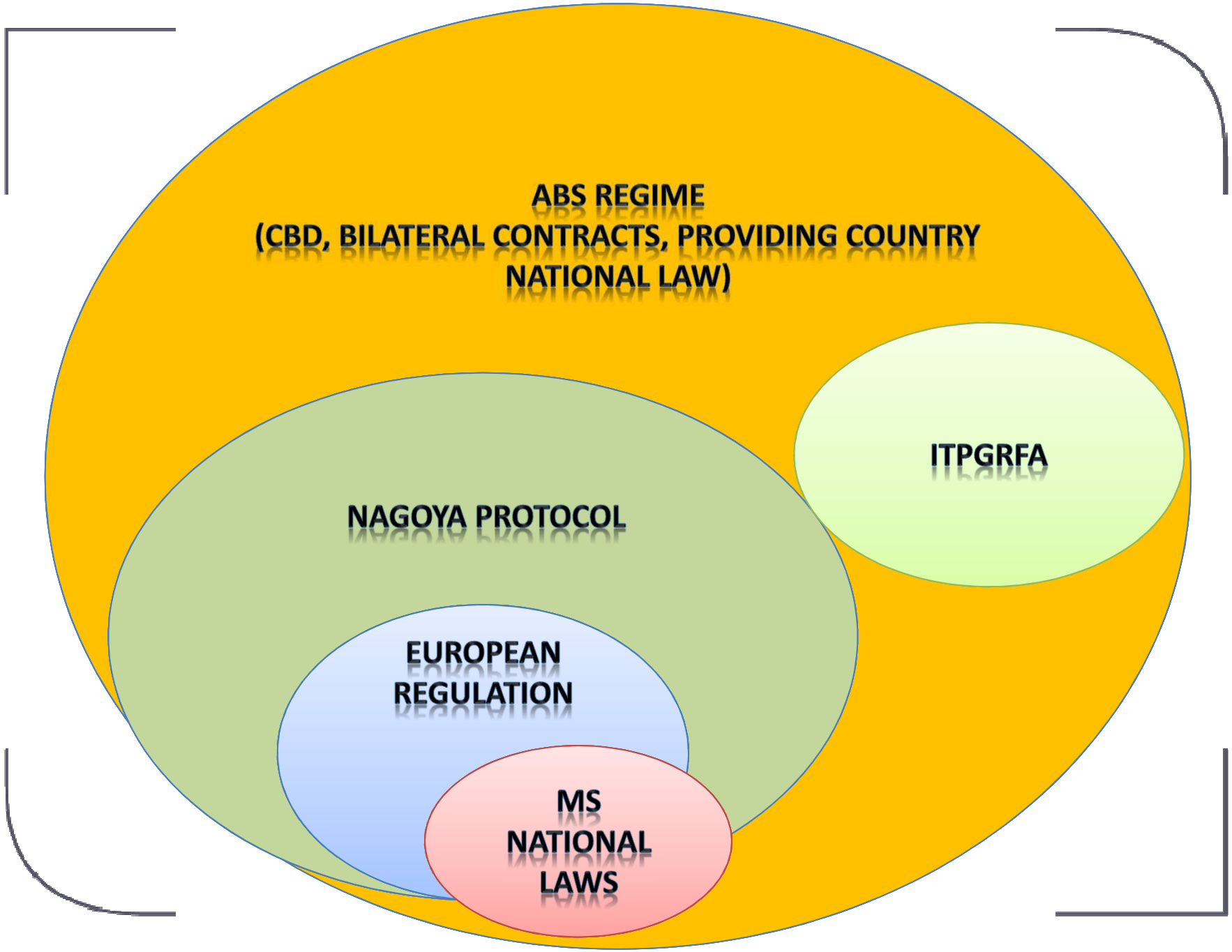
- Implementation a national matter & up to countries to develop
- Difficult to tell non-commercial research from commercial research (expressed intent? Actual end-product? Who is doing the work?)
- Many people see no difference in principle between taxonomy and bio-prospecting

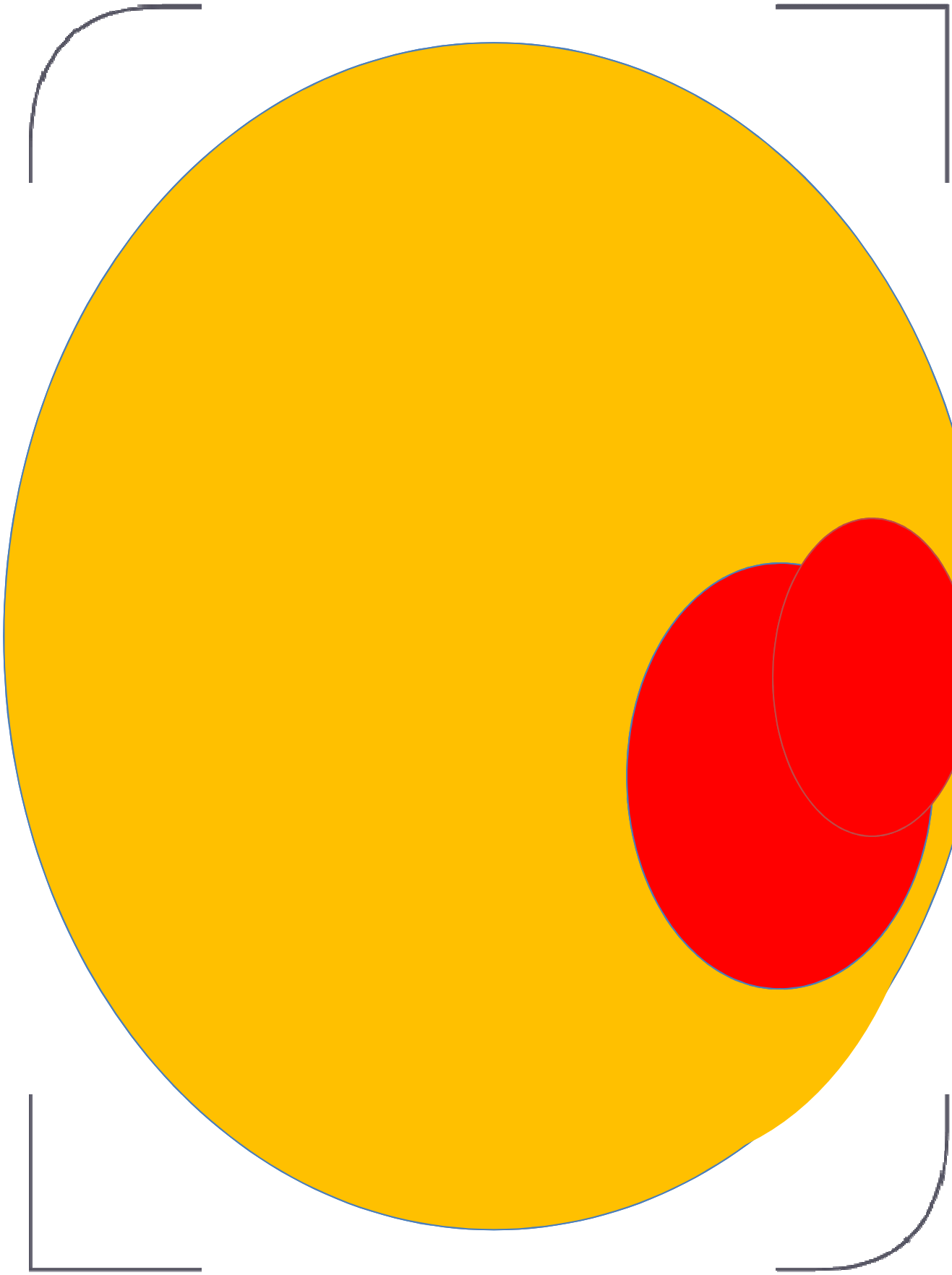
CONSORTIUM FOR THE BARCODE OF LIFE

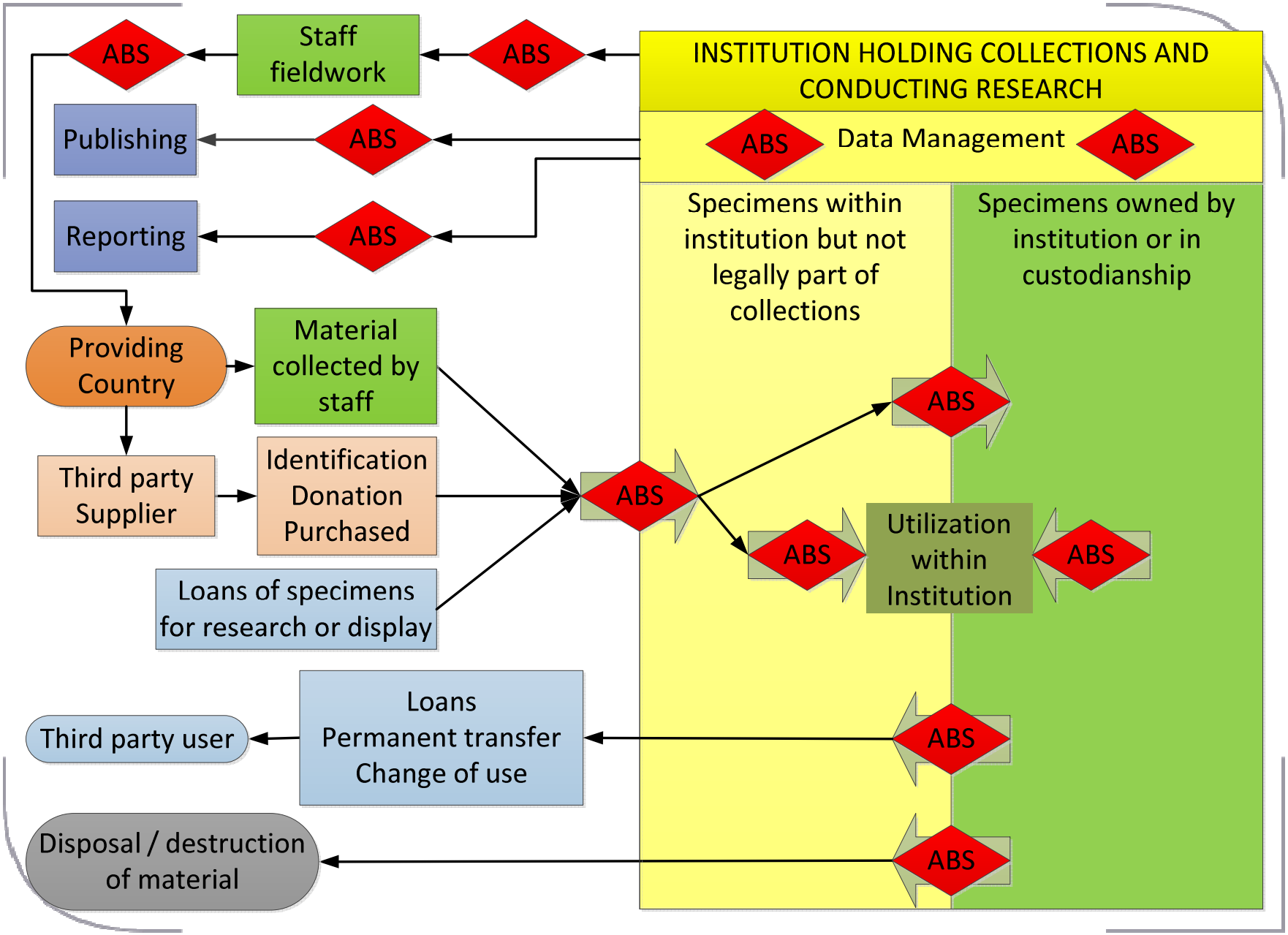
What does it mean to us?

We need to

- Comply with National Regulations and Legislation when we collect
- Be sure we can legally receive material
- Be sure we 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


ABS REGIME
(CBD, BILATERAL CONTRACTS, PROVIDING COUNTRY NATIONAL LAW)
ITPGRFA
NAGOYA PROTOCOL
EUROPEAN REGULATION
MS NATIONAL LAWS




INSTITUTION HOLDING COLLECTIONS AND CONDUCTING RESEARCH
Data Management
ABS
Staff fieldwork
Publishing
Reporting
Providing Country
Material collected by staff
Third party Supplier
Identification Donation Purchased
Loans of specimens for research or display
Specimens within institution but not legally part of collections
Specimens owned by institution or in custodianship
Utilization within Institution
Loans Permanent transfer Change of use
Third party user
Disposal / destruction of material

What does it mean to us?
Code of Conduct and Best Practice

- Called for in Nagoya Protocol Art 20 & EU Regulation Art 8
- Assists institutions develop 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

CETAF
CONSORTIUM OF EUROPEAN TAXONOMIC FACILITIES

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
- Build on existing Codes and Practices (e.g. Botanic Gardens Principles, Swiss Academy of Sciences guidelines)
- Drafts developed by **Consortium of European Taxo[illegible]**
  Facilities and **Global Genome Biodiversity Netwo[illegible]**

CETAF
CONSORTIUM OF EUROPEAN TAXONOMIC FACILITIES

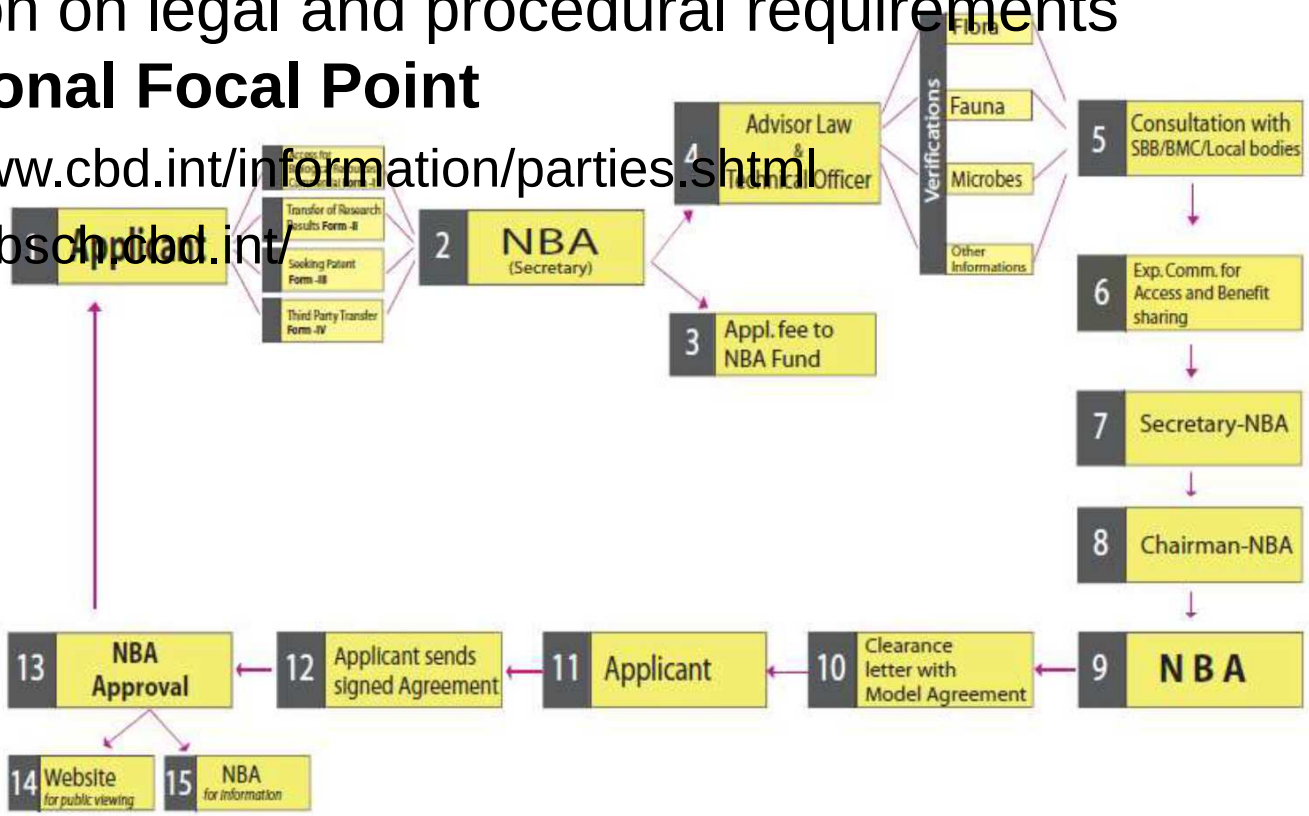
Product	Purpose
Standard Material Access Agreement (GGBN, TRUST)	Contract covering Biological Material being provided to institution, including necessary accompanying documentation
Standard Material Transfer Agreement (GGBN, TRUST)	Contract covering Biological Material being provided by institution, including necessary accompanying documentation
Use of Biological Materials Statement (CETAF, GGBN)	Statement outlining uses to which material being accessed might be put, for use in seeking Prior Informed Consent
Use of material checklist	To facilitate clarity of PIC
Standard clauses for Mutually Agreed Terms	To facilitate negotiation, data management and delivery
Standard MoUs	To help clarify agreements between researchers in different institutions and countries
Standard Data Use agreements	To help clarify agreements between researchers in different institutions and countries
Extensions to Darwin Core (GGBN)	To facilitate data sharing on ABS
Use restriction statement for publications databases etc. (CETAF)	To add to publications and so reduce risk of inappropriate use by 3rd parties

The Natural History Museum and ABS: responses

- Failure to respond effectively to the NP poses a risk to our activities
- Put together a team to review and develop new policies and processes
- Worked with CETAF, GGBN, CBD Secretariat, RBG Kew etc
- Sought to inform Defra, Europ Parliament
- Revised all NHM Policies
- Currently revising processes
- Planning training

Nagoya Protocol: Gaining Access

- Information on legal and procedural requirements from **National Focal Point**
  - http://www.cbd.int/information/parties.shtml
  - https://absch.cbd.int/



Nagoya Protocol: Gaining Access

- Part of obtaining permission to access genetic resources is agreeing conditions - ‘Benefits’
- Monetary
  - When research and developments leads to a commercial product
  - royalties, milestone payments, licensing fees, etc
- Non-monetary
  - Identifications, biological inventories, technology transfer, training, sharing research results, research partnerships, access to scientific information relevant to conservation and sustainable use of biological diversity, etc
  - May be helpful to agree benefits in the context of the NBSAP
- Need to be sure we can comply!
- Some countries check up!

Nagoya Protocol: Gaining Access

- Plan Ahead!
  - Obtain permits, which may include:
    - research
    - permission to collect
    - CITES
    - export & import permits
    - plant health
- Work with local partners where appropriate
- Keep written records
  - permits, letters, emails, notes
  - Good documentation can reduce risk

CBD and us

- It does influence our work
- Is a factor in most countries we visit
- Can help us to advance science
- Is a means of preserving biodiversity
- Does require our expertise

We should seek to link our work where possible to CBD implementation

Two other key terms

Access: Acquisition of a genetic resource (from in situ or ex situ sources)

Utilization: Research and development on the genetic and/or biochemical composition of genetic resources

EU Regulation on ABS

Came into force on 12 October 2014

Implementing Act for Articles 4, 7, 9 comes into force 12 October 2015

These apply to all Member States (MS)

MS legislation to implement the Regulation is being enacted independently

The EU Regulation focusses on compliance

Access provisions are up to the MS

Risks

Three areas of risk that may impact biobanks and associated research:

- Legal non-compliance
- Failure to manage contractual agreements (benefit-sharing)
- Reputational risks

Legal Risks: EU Regulation

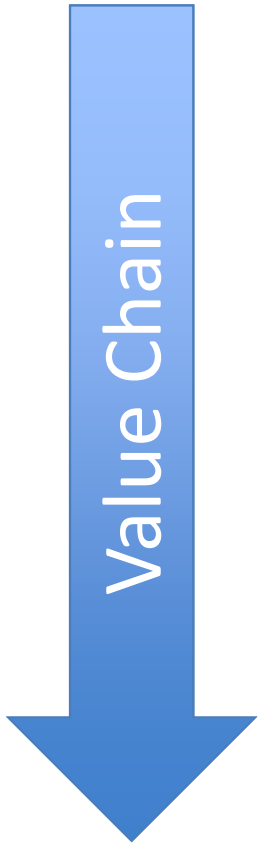
For GR accessed from Parties to the Nagoya Protocol:

Due Diligence when GR are acquired / accessed

Requirements when transferred to a 3rd Party

Reporting when they are utilized

Reporting when results of utilization are placed on the EU market



Legal Risks: EU Regulation

Aids for compliance:

- Registered Collections for supply

- Best Practice recognised by the Commission

Contractual Risks

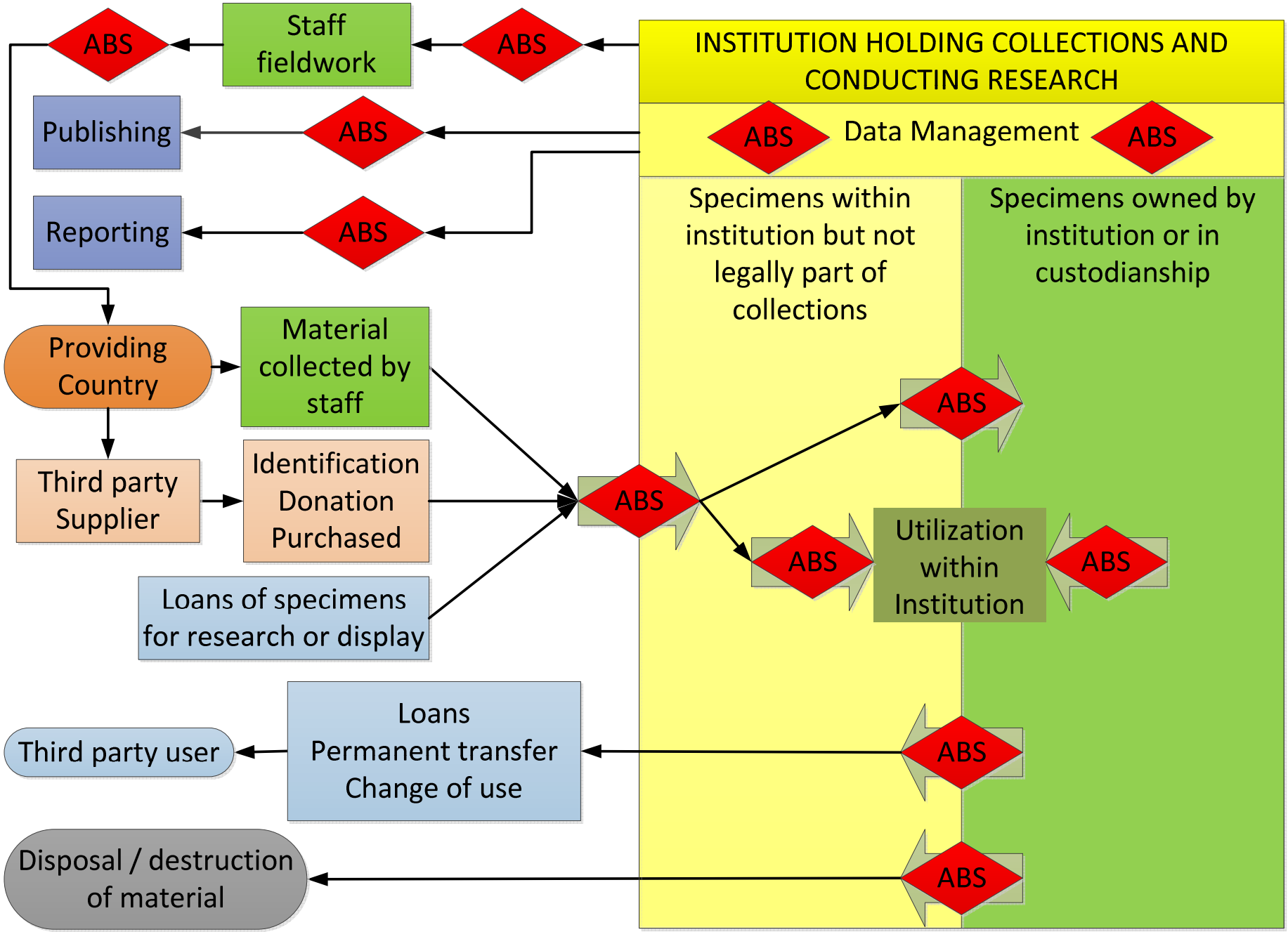
For all GR, wherever Accessed:

- Compliance with clauses in Permit / Mutually Agreed terms (MAT)
- Management of 3rd party transfer
- Requirements on change of use

Reputational Risks

Arise from:

- Failure to meet legal obligations in EU or providing country
- Failure to meet contractual obligations
- Failure to manage change of use (e.g. commercialisation)
- Failure to share benefits appropriately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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

Why a Code of Conduct and Best Practice?

- Assist signatories in developing their own compliance policies and processes
- Helps manage legal and contractual compliance
- Build trust in Providing Countries
- Nagoya Protocol asks for them
- EU Regulation calls for them
  - importance of Best Practice in supporting Due Diligence and thus compliance checks

Best Practices

Being developed by a number of relevant bodies, including:

- Consortium of European Taxonomic Facilities (CETAF)
- Global Genome Biodiversity network (GGBN)
- Microbial Resource Research Infrastructure (MIRRI)
- And of course ISBER

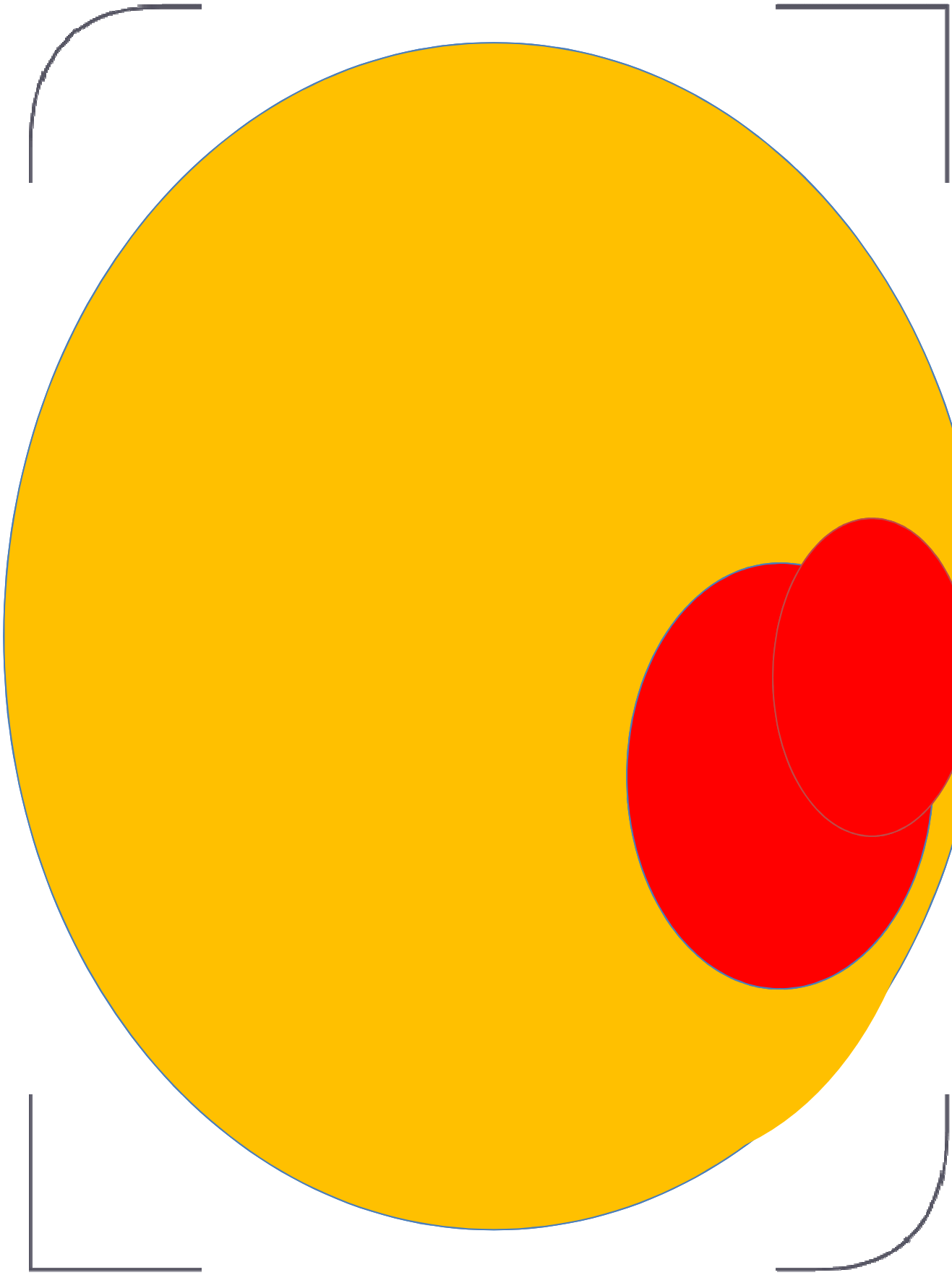
CETAF Best Practice

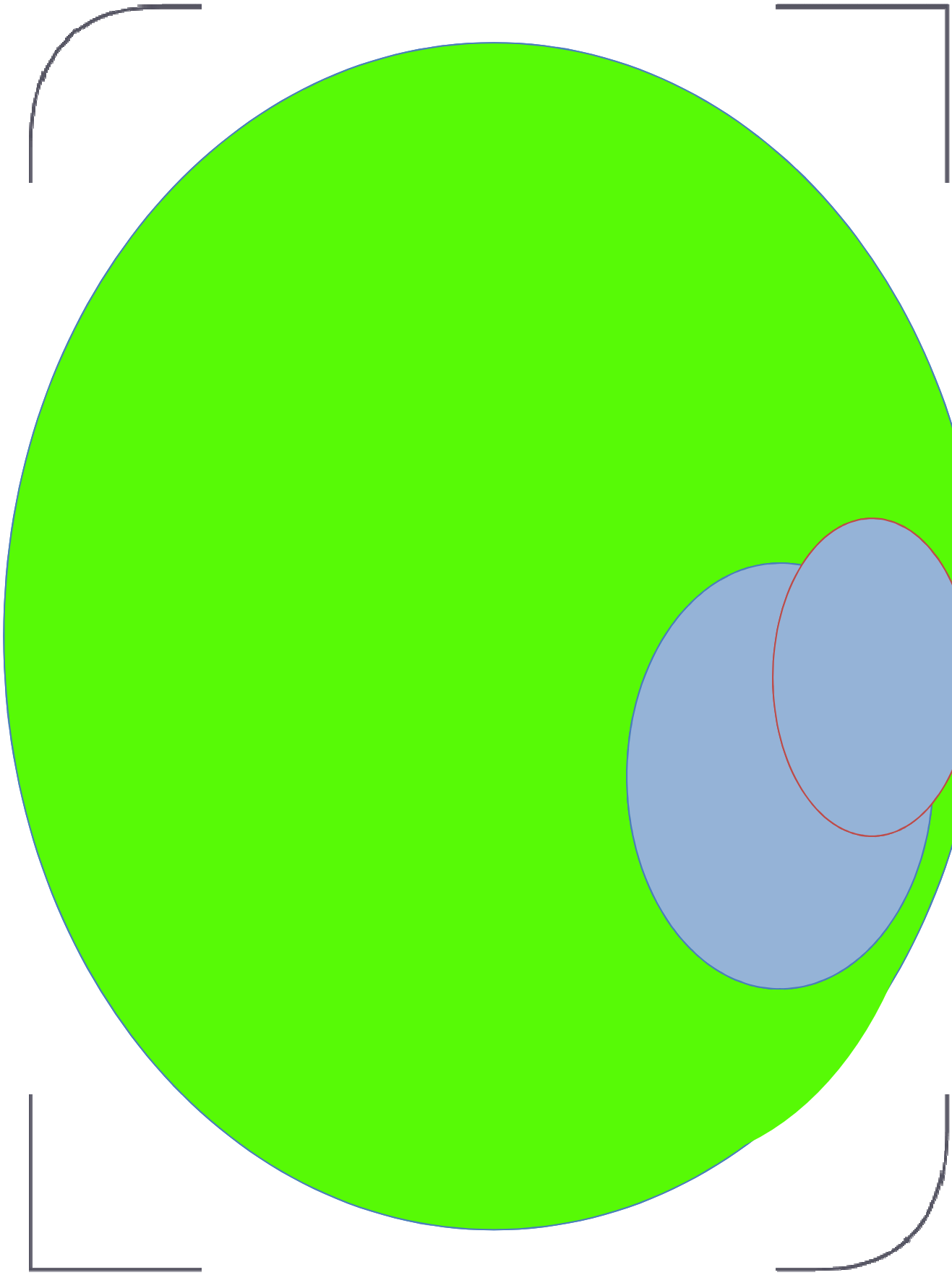
1. **Code of Conduct on Access & Benefit-Sharing**
   - The agreed principles by which we govern our activities
2. **Best Practice**
   - The way in which we implement those principles, including recommendations for policies and processes.
3. **Tools:**

- **Use of Biological Material**
  - What we do with Biological and Genetic Material
  - To support obtaining PIC
  - To provide a reference for text in the other documents.
- **Standard Material Transfer Agreements**
  - Sets out terms under which specimens are transferred from one party to another, in the context of the Code of Conduct and Best Practice.

Workflows and workload

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





Raising profile

Reliability – trusted to be legally compliant and diligent in meeting contractual obligations

Registered Collection – if effectively managed, may be seen as a way of effective pathway to monetary benefits

Targetting benefits at Policy relevant needs

Potential for setting up networks (cf IPEN, NIEMA)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