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## CETAF Workshop on Access and Benefit Sharing The CETAF Code of Conduct

First and currently only  
**officially recognised Best Practice**  
for Nagoya compliance





Johan Bodegård 1960 - 31 August 2017  
Deputy Director of the Natural History Museum of Stockholm (SE)

The CETAF Code of Conduct and Best Practice, this Training material, and the work of the CETAF Legislation and Regulation Working Group hugely benefited from the permanent support and judicious advice of our respected colleague.

He made a lot possible and encouraged us to see and take the opportunities.

# Why do we need to meet and manage our obligations?



# Key requirements to manage scientific collections

- ✓ Date and place where material was collected
- ✓ Description and identification of the used material
- ✓ Source where material was directly obtained
- ✓ Relevant Permits (e.g. collecting, access, export, import permits)
- ✓ Who is the responsible scientist for the samples
- ✓ Where I can find samples and documents in 20 years

Does this sound familiar?

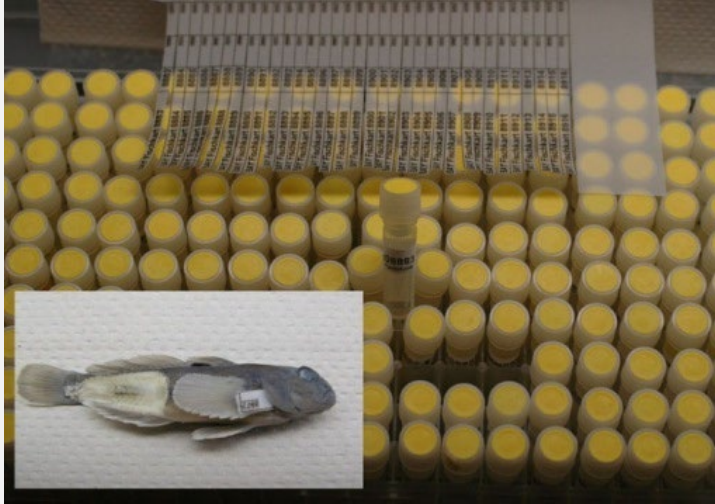


# Due Diligence Requirements, Art.4 EU ABS Regulation

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# Collection management maintains the scientific value ABS obligations manage our legal responsibilities and risks



# Key challenges to manage scientific collections



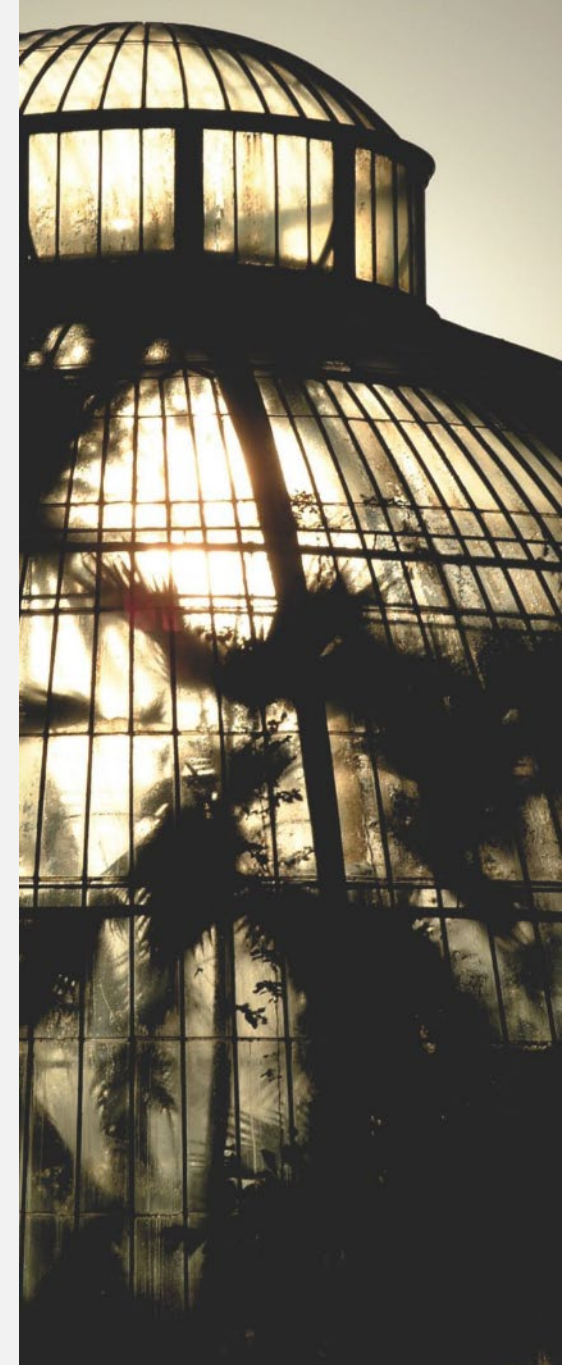
# Complexity of collections

presented by CETAF ABS Core group to European CNAs, Isle of Vilm, 23 April 2018

## Example: Kew Gardens\*

- ▶ Herbarium (7.5 M) & Fungarium (1.25 M)
- ▶ Living collections (>30,000 species)
- ▶ Millennium Seed Bank (>30,000 species; ~ 2 billion seeds)
- ▶ DNA and tissue bank (>42,000 accessions)
- ▶ DNA C-value (>7,000 species)
- ▶ Slide collections (>100,000 slides)
- ▶ Library (> 750,000 volumes), archives (250,000), artwork (> 175,000) , paintings, prints and drawings
- ▶ Hundreds of scientists bringing material each year
- ▶ Exchange over 60,000 herbarium specimens, 10,000 live plants and seeds each year

\* KEW Gardens figures from China Williams, CETAF Side Event Pyeongchang, Republic of Korea, 2014



# Complexity of collections

presented by CETAF ABS Core group to European CNAs, Isle of Vilm, 23 April 2018

## Example: SNSB Collections, Munich

Hosts approximately 35 mio objects

- ▶ Botanical Garden (living collections, plants & seeds)
- ▶ Zoological collections, including tissue and DNA collections
- ▶ Archaeozoological collections
- ▶ Anthropological collections
- ▶ Palaeontological Collections
- ▶ Geological Collections
- ▶ Mineralogical Collections



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**ABS relevant ?**



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## Example: SNSB Collections, Munich

Hosts approximately 35 mio objects



Impact Assessment EU COM, Brussels, 4.10.2012 SWD(2012) 292 final:

**Page 9, Box 1:** “A French researcher seeks to collect a little-known **marine sponge** from the **Great Barrier** reef in north-eastern Australia for basic research on its genetic ... properties. [...] He must put a reference sample of each collected species in the collection of **Queensland University** and also commits to sending them a copy of publications resulting from research on the collected sponges.”

~ 10,000 sponge samples of the **Palaeontological Collection of SNSB**, at that time visible via **DNA-Bank network online portal**.

# Complexity of collections

presented by CETAF ABS Core group to European CNAs, Isle of Vilm, 23 April 2018

## Example: SNSB Collections, Munich

**Hosts approximately 35 mio objects**



Collection objects may be of scientific interest to sample associated organisms like symbionts, ecto-/endoparasites, viruses etc.

# Complexity of collections

presented by CETAF ABS Core group to European CNAs, Isle of Vilm, 23 April 2018

**Example: SNSB Collections, Munich**

**Hosts approximately 35 mio objects**



Archaeological material of SNSB was analysed for plague strains

A screenshot of a PLOS ONE research article page. At the top left is the PLOS ONE logo. To the right are navigation links for 'Publish', 'About', and 'Browse'. Below the navigation bar, there are icons for 'OPEN ACCESS' and 'PEER-REVIEWED', followed by the text 'RESEARCH ARTICLE'. The main title of the article is 'Genotyping *Yersinia pestis* in Historical Plague: Evidence for Long-Term Persistence of *Y. pestis* in Europe from the 14<sup>th</sup> to the 17<sup>th</sup> Century'. Below the title, the authors are listed: Lisa Seifert, Ingrid Wiechmann, Michaela Harbeck, Astrid Thomas, Gisela Grupe, Michaela Projahn, Holger C. Scholz, and Julia M. Riehm. At the bottom of the article preview, it says 'Published: January 13, 2016 • <https://doi.org/10.1371/journal.pone.0145194>'. Below the text is a photograph of several human skeletal remains, including long bones, a skull, and other fragments, laid out on a wooden surface in a laboratory or museum setting.

# Complexity of collections

presented by CETAF ABS Core group to European CNAs, Isle of Vilm, 23 April 2018

- ▶ Botanical Garden (living collections, plants & seeds)
- ▶ Zoological collections, including tissue and DNA collections
- ▶ Archaeozoological collections
- ▶ Anthropological collections
- ▶ Palaeontological Collections
- ▶ Geological Collections
- ▶ Mineralogical Collections
- ▶ Scientific archives, artwork, paintings, prints & drawings **may include TK**

**yes, eventually!**



# Complexity of collections

presented by CETAF ABS Core group to European CNAs, Isle of Vilm, 23 April 2018

Huge diversity and procedures to administrate, store and manage these collections

- ▶ Botanical Garden (living collections, plants & seeds)
- ▶ Zoological collections, including tissue and DNA collections
  - **taxonomic arrangement, storage-related, position related, unsorted bulk samples**, etc.
- ▶ Archaeozoological collections
- ▶ Anthropological collections
  - mostly **arranged according to excavation units or stratigraphy**
- ▶ Scientific artwork, paintings, prints and drawings
  - ▶ mostly arranged by **author, context**, etc.

# CETAF Code of Conduct and Best Practice

## The CETAF process

2012

Evaluation of applied management procedures of selected CETAF members by ABS Working Group:

- ▷ How are objects maintained, managed and accessed ?
- ▷ Can we identify common management features?

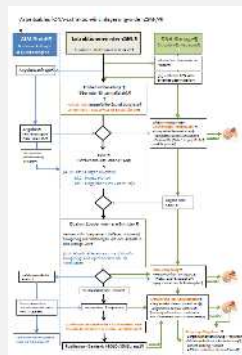


# CETAF Code of Conduct and Best Practice

## The CETAF process

2012 Evaluation of applied management procedures of selected CETAF members by ABS Working Group:

- ▷ How are objects maintained, managed and accessed ?
- ▷ Can we identify common management features?
- ▶ Can we map useful collection management tools across collections to manage our compliance and legal risks?



# CETAF Code of Conduct and Best Practice

## The CETAF process

- ▶ **General management schemes** are needed
- ▶ **Strict focus** on **genetic resources** is **unhelpful**
- ▶ We need to be sure under which **conditions biological material enters collections**
- ▶ We need to be sure **under which conditions biological material is accessioned** in our collections
- ▶ A **clear legal framework** that **supports the management of our collections** and meets the requirements of the CBD and the NP



# CETAF Code of Conduct and Best Practice

## Why 'biological material' instead of 'genetic resources'

- A **more inclusive term**, broadly covering our activities
- Biological material contains GR, and **this is what we collect or acquire**
- Working and using '**biological material**' *may or may not fall under the NP or EU Regulation*
- If utilisation does take place, **applying the CoC to 'biological material' provides legal certainty**

# CETAF Code of Conduct and Best Practice

Comments of EU COM and Member States, 19th July 2016

1. CETAF should oversee (= govern) the implementation of Best Practices at collections of CETAF members

- ▶ CETAF has no legal mandate for this
- ▶ would be beyond the requirements of Art 8 of the EU ABS regulation:

oversight of the Best Practices (para 1) is distinct from “effective implementation by a user” (para 2)



# CETAF Code of Conduct and Best Practice

## Comments of EU COM and Member States, 19th July 2016

2. CETAF CoC should be more strictly towards as response to (EU) No. 511/2014
  - ▶ CETAF represents European members, and not all of them are situated in EU MS (United Kingdom, Switzerland, Norway)
  - ▶ Submission of CETAF Best Practice is a bottom-up **response to meet ABS requirements globally**, “*in accordance with the requirements of [the EU ABS] Regulation*”

No legal requirement in Art 8, para 1 that recognition of an Best Practice needs to have an exclusive fit to the EU ABS Regulation



# CETAF Code of Conduct and Best Practice

Comments of EU COM and Member States, 19th July 2016

## 3. Lack of legal coherence and common workflows

- ▶ Complexity of CETAF collections make a **one-fits-all solution impossible**
- ▶ CETAF favours an **output-oriented approach that builds on established workflows** compared to procedural systems that do not reflect and cannot meet reality
- ▶ **Best Practice** is intended to be a strong and reliable **support for members to analyse their policies and procedures** and building appropriate systems to deliver compliance
- ▶ **Workflows without local ownership** at CETAF member institutions would run a **high risk of failure**



# CETAF Code of Conduct and Best Practice

Comments of EU COM and Member States, 19th July 2016

4. Scope of the document and use of “biological material” (instead of genetic resources)
  - ▶ **Management of genetic resources** in the legal context of the EU Regulation is a **small subset** of the management need of CETAF members
  - ▶ **Workflows** need to be in place for all **biological material being processed**, utilised and/or otherwise analysed
  - ▶ Even though large proportion of biological material acquired by taxonomic collections will never be utilised, the **legal status** of this material **when entering the institution needs to be documented to allow utilisation at a later point**



# CETAF Code of Conduct and Best Practice

## Three key points

- 1. Code of Conduct:** is a **response to legislators** and addresses legal matters
- 2. Best Practice:** is the **practical core**
  - 1. bottom-up approach;**
  - 2. builds strongly on common and established workflow elements** of scientific research collections
- 3. Official recognition** as ‘Best Practice’ by EU-COM and all EU Member States **increases our legal security** for what we are doing already anyway

# CETAF Code of Conduct and Best Practice



# CETAF Recommendation

## Institutional Policies should address

- **Acquiring new specimens**
  - **Collecting**
  - **Other acquisitions**
- **Managing the collection**
  - **Managing** compliance with **MAT**
  - **Incoming loans**, including DNA and tissues
  - **Special or** newly-developing collections, including **living collections**
  - Destructive and **invasive sampling**
  - **Traditional Knowledge** associated with Genetic Resources
  - Incoming and outgoing **exhibition loans/acquisition**
  - **Outgoing loans**
  - **Outgoing DNA** and tissues
  - Research and ABS
  - **Data management** and documentation
  - **Internal Collections Check Points**
- **Removal of specimens from the collection**
  - **Dispatch** and object exit
  - Loss or complete **consumption**
  - **Deaccessioning** and disposals (including exchanges and transfers)



# CETAF Code of Conduct and Best Practice

## Voluntary self-commitment

Participating institutions will

- ▶ “Honour the letter and spirit of the Convention on Biological Diversity (CBD), The Nagoya Protocol, and other relevant international agreements”
- ▶ “Abide by international and national laws and regulations relating to Access and Benefit-sharing”
- ▶ “Comply with Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and other agreements entered into with the Providing Country and Providers within that country”
- ▶ Non-CETAF institutions are free to commit themselves to meet the requirements of the CETAF CoC

# CETAF Code of Conduct and Best Practice

## 1. Acquisition

- **Biological material** (containing GR) and Traditional Knowledge Associated with Genetic Resources is usually acquired in from:
  - *In situ* sources (collecting)
  - *Ex situ* sources (other collections, commercial sources, donations, bequests etc)
  - ▷ special situations such as associated organisms like symbionts, ecto-/endoparasites, viruses etc.

# CETAF Code of Conduct and Best Practice

## 1. Acquisition - *In situ* access

Where possible:

- “obtain information on the Country’s access laws and the procedures for obtaining permits and PIC, and for agreeing MAT”
- “obtain PIC and relevant permits from the Government and other relevant stakeholders as required under national law”;
- “agree terms, according to applicable law and best practice”.

This is relevant

- ▷ for demonstrating due diligence
- ▷ to generate trust with providers

# CETAF Code of Conduct and Best Practice

## 1. Acquisition - *Ex situ* access

- “agree terms of use with the body governing the collection under which the material can be used”
  - Establishing rights and responsibilities
  - May require seeking PIC from providing country
- “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”
  - Due diligence obligation under EU Regulation

# CETAF Code of Conduct and Best Practice

## 1. Acquisition

## Check-Point 1

When acquiring material we need to document:

- legal compliance with relevant laws and rules of the
  - Provider country (national access laws – if in place)
  - User Country (e.g. EU law for utilisation inside the EU)
  - Institution's home country
- legal certainty of what can be done with the material
  - E.g. sequencing, transferring to 3rd parties, adding to collections
- existing benefit-sharing obligations if material is utilised
  - File relevant documents and data

## Identify responsibilities:

- on institutional level (centralised / decentralised management)
- on individual level
- staff competences  
(e.g. who is allowed to sign which agreements or contracts)



## Establish clear procedures & policies for:

- object entry of post-NP specimens  
(collected in-situ or acquired ex-situ after 12 Oct 2014)
- object entry of pre-NP specimens  
(collected in-situ or acquired ex-situ prior to 12 Oct 2014)
- object entry of pre-CBD specimens  
(collected in-situ or acquired ex-situ prior to 29 Dec 1993)



# CETAF Code of Conduct and Best Practice

## 2. Curation and data management

- Institutions should know:
  - ▷ What is held;
  - ▷ What responsibilities the institution has;
  - ▷ Whether these have been met;
  - ▷ What material has been provided to others;
  - ▷ Whether material is no longer is held.

# CETAF Code of Conduct and Best Practice

## 2. Curation and data management

### ▶ **EU Regulation requires**

- Records to be kept for 20 years after end of utilisation (infinite period if samples are kept);
- Certain information to be transferred to other users;
- Provided in reports to the national regulator, if appropriate

# CETAF Code of Conduct and Best Practice

## 3. Utilisation

## Check-Point 2

### of GR typically includes use of:

- ▶ External tissues  
(e.g. that guest researchers bring to your institution)
- ▶ Shared sequence data inside institution  
(e.g. horizontal transfer of genomic libraries, in joint DNA-labs operated under different procedures)
- ▶ Shared samples outside institution  
(Tissues, DNAs, sequence data or any analysis results or raw data exchanged with third researchers)
- ▶ Contracted sequencing  
(in the absence of clear contracts)
- ▶ Sequence data in the public domain  
(depending on the terms of the uploaded data)

# CETAF Code of Conduct and Best Practice

## 3. Utilisation

- ▶ **Check allowed uses** under existing permits (e.g. MAT may prohibit genomic sequencing or proteomics)
- ▶ **Keep data** on permission / restrictions associated with specimens and any subsamples
- ▶ **Enable staff** to discover rapidly any restrictions / requirements
- ▶ **Establish procedures** for inappropriate utilisation

## Institutions should be aware:

- ▷ that any utilisation of GR may fall under reporting obligations
- ▷ of the terms of utilised GR  
(mechanisms needed to inform staff in different departments about potential restrictions)
- ▷ that **records need to be kept** to meet reporting obligations  
(e.g. EU (No.) 511/2014 & )
- ▷ that “publication” includes paper and electronic publications  
(including online databases such as GenBank or EMBL)



If the participating institution wishes to utilise GR outside existing contracts (including for new projects):

- ▶ “Renegotiate PIC and MAT to cover terms which are not covered under the original agreements”



## Traditional Knowledge associated with Genetic Resources

- ▷ Be clear if TK is associated with your samples
- ▷ When acquiring TKaGR, always use written agreements (PIC & MAT) for legal certainty
- ▷ Record and document any agreement on TKaGR carefully
- ▷ “Use and supply TKaGR only in accordance with the terms and conditions under which it was acquired”



## Traditional Knowledge associated with Genetic Resources

- There are no clear definitions on TK in the CBD & NP

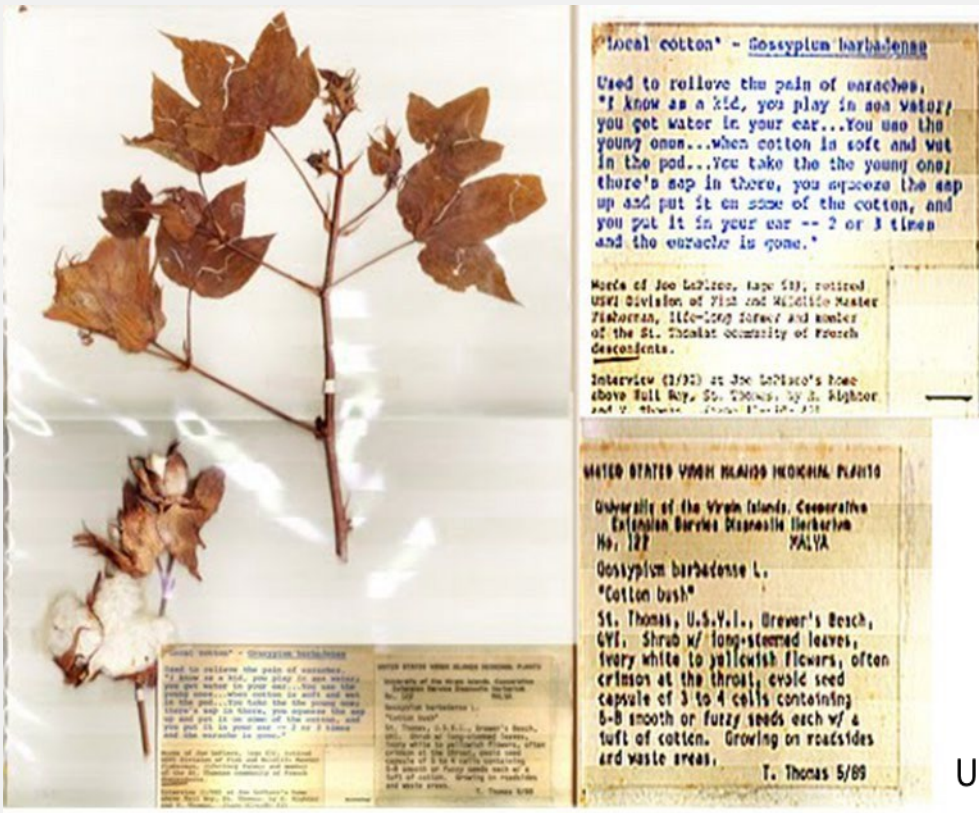
*'TKaGR' means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources;*  
*Art.3.7 (EU) No 511/2014*

- The intention is to protect the ancient wisdom on biological material against unjust utilisation and exploitation

Example for TK: flora and fauna used for arrow poisons

- Legislations and participation of indigenous communities is organised differently in individual Providing Countries

## Traditional Knowledge associated with Genetic Resources



University of the of the Virgin Islands diagnostic herbarium

# CETAF Code of Conduct and Best Practice

## 4. Benefit Sharing

- Examples of Benefits are listed in the Annex to the Nagoya Protocol (see annex of the NP on monetary or non-monetary benefits <https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-37>)
- May be monetary or non-monetary
- CETAF members most likely to share non-monetary benefits, e.g.  
capacity building, scientific training, education, transfer of technologies, collaboration on scientific work programmes, sharing of research results, sharing publications
- Generally what we are used to doing (although often we do not document it)

# CETAF Code of Conduct and Best Practice

## 4. Benefit Sharing

- In many circumstances not linked to utilisation, but likely to be on permit as a condition of access
  - ▶ Legal responsibility as an **agreed contractual clause**
- Details of benefit sharing not controlled by the European Regulation

# CETAF Recommendation on 'BENEFIT SHARING'

Benefit sharing in the CoC refers to the CBD and thus is open to cover pre-NP material if required

- it states that responsibility for retroactive claims should be accepted
- it shows good faith
- it helps to reduce reputational risk
- it may be a contractual requirement in MAT
  - (e.g. in pre-existing permits)
- it is not a legal requirement under (EU) No 511/2014

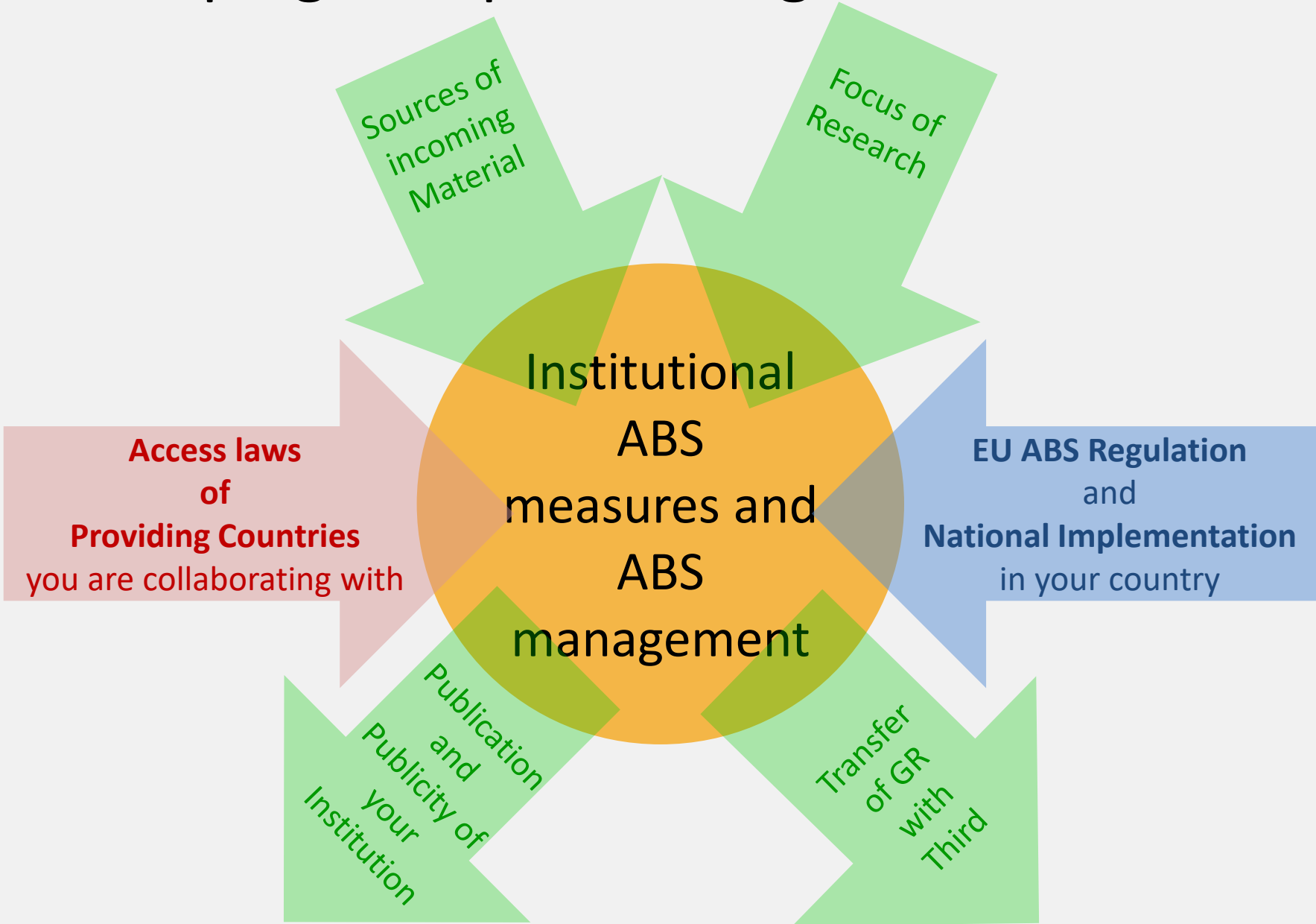


# Getting started ...

## Introducing the CETAF Code of Conduct



# Developing & implementing ABS measures



# Developing & implementing ABS measures

## Legal responsibilities

- Field Collectors / Curators ('Acquirer')
- Researchers / PIs ('Users')
- Institution ('ex-situ source for GR')
- Signatories of ABS-related contracts
- change in ownership

## Administration of contracts

- Legal requirements to deposit / share legal contracts in databases?
- Role and liability of staff filing / handling contract information?
- Accessibility and security of file stores?

# Developing & implementing ABS measures

## Which internal Check-points are useful?

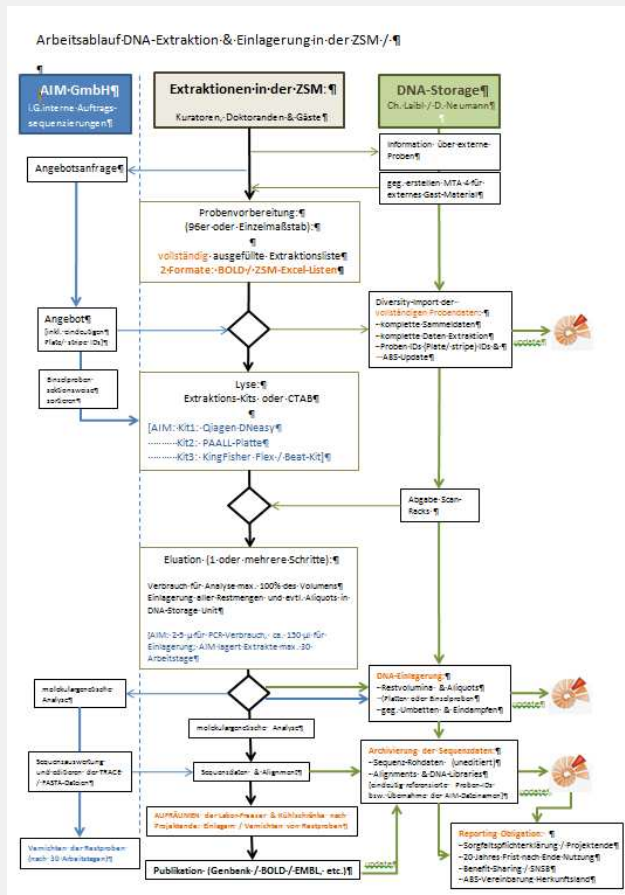
- travel application
- acquisition of material
- DNA-extraction
- transfer and sharing of samples
- visiting guest researchers

## Which synergies can be achieved?

- How can standardised workflows support colleagues and collection management?
- How can an ideal ABS management support researchers and project management?
- Which opportunities can be realised for Natural History Collections in an increasingly competitive research environment and increased pressure on project groups through an competent ABS management?

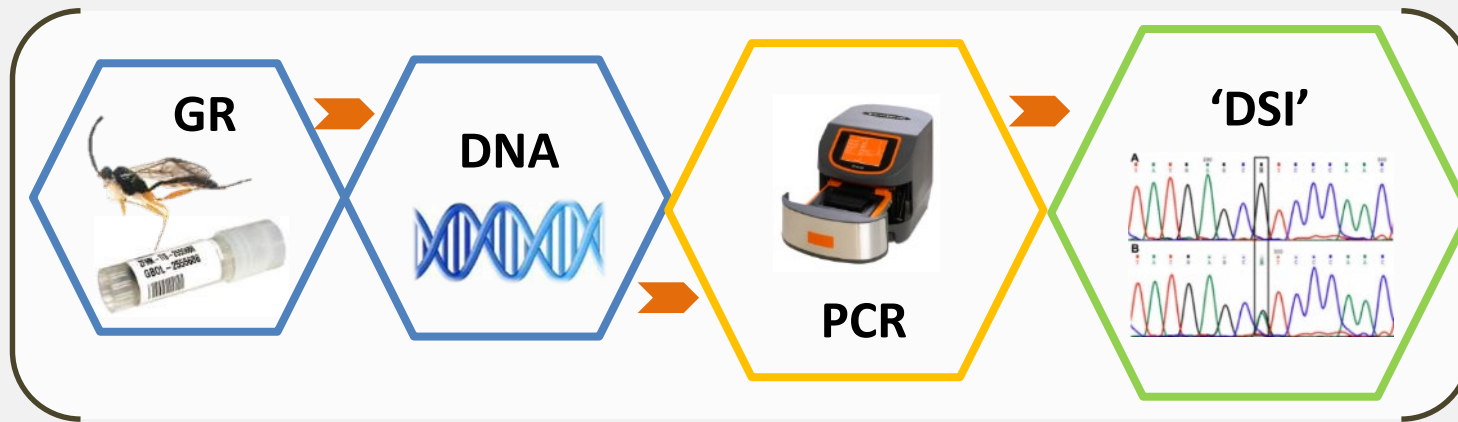
# Developing & implementing ABS measures

## Identification of internal workflows and needs



# Developing & implementing ABS measures

## ▶ Example: barcoding workflow



### GBOL: established User-Procedure

#### Standardised Processes for:

- handling, processing and sample submission
- data acquisition and accessioning of specimens
- sample management
- decentralised sequencing

# Developing & implementing ABS measures

## ▶ Example: barcoding workflow



**External experts (= user)**  
> 260 amateurs  
> 25 research institutions

**processed samples (= GR)**  
> 200.000 individuals  
> 25.000 species

**DNA-Barcodes (= DSI)**  
> 115.000 individuals  
> 20.000 species

# Developing & implementing ABS measures

## ▷ Example: barcoding workflow



### For GBOL uses

- ✓ Most useful sample management and submission tool
- ✓ locality data entered when processing samples
- ✓ full datasets required for sequencing job
- ✓ external sample management readily accepted

# Developing & implementing ABS measures

## ▷ Example: barcoding workflow



- **Standardised Excel-sheets** based on **widely accepted and used** GBOL-submission files
- Conversion of barcoding submission file into **single plane spreadsheet** (original distribution over several spreadsheets provoked copy & paste errors)
- **Additional permit fields** and extraction details (who, when, how much, etc.)
- Record keeping of failed extractions (also utilisation)

# Developing & implementing ABS measures

## ▶ Example: barcoding workflow

### For ABS management

- ⚡ too complicated
- ⚡ locality data not ready when extracting DNA
- ⚡ time constraints to accession material for projects
- ⚡ no need to share responsibility for my samples with others



# Developing & implementing ABS measures

## ▶ Main management challenges

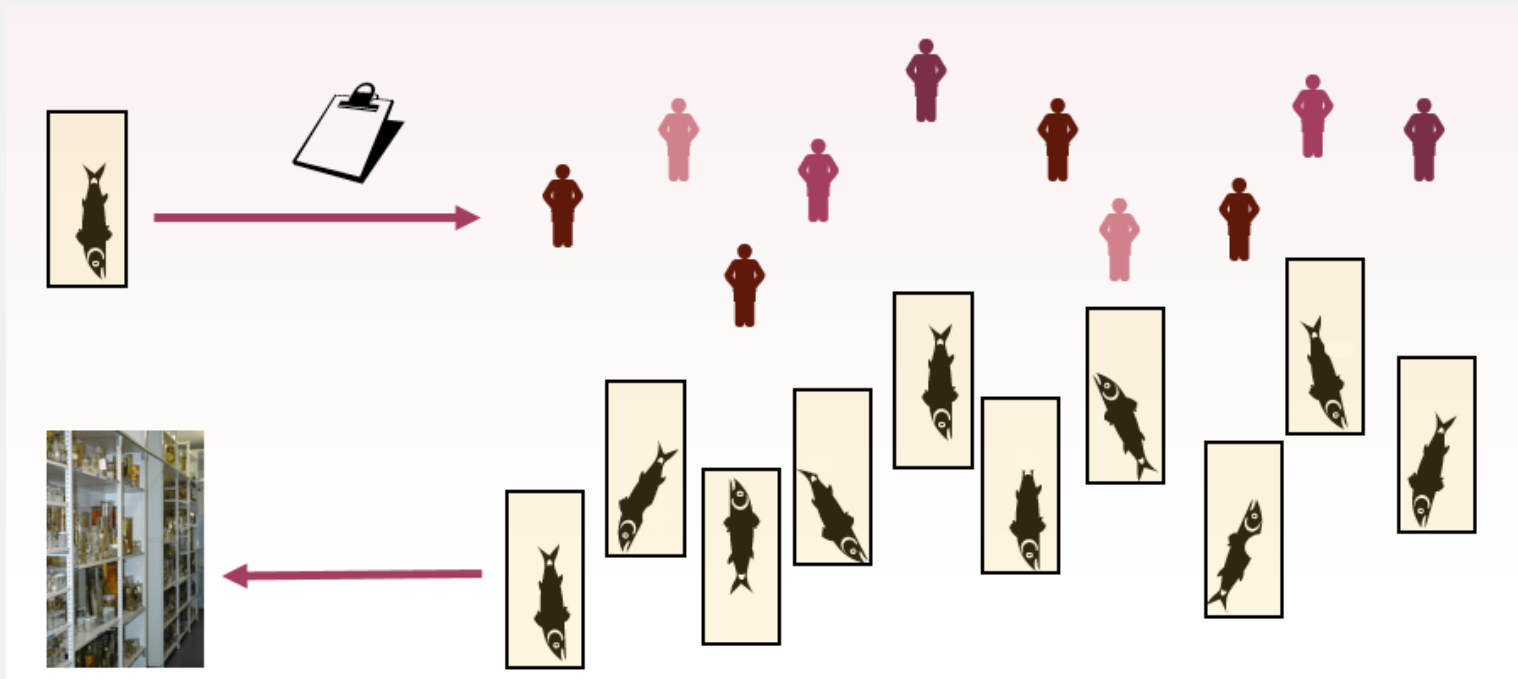
### 1. Entropy



# Developing & implementing ABS measures

## ► Main management challenges

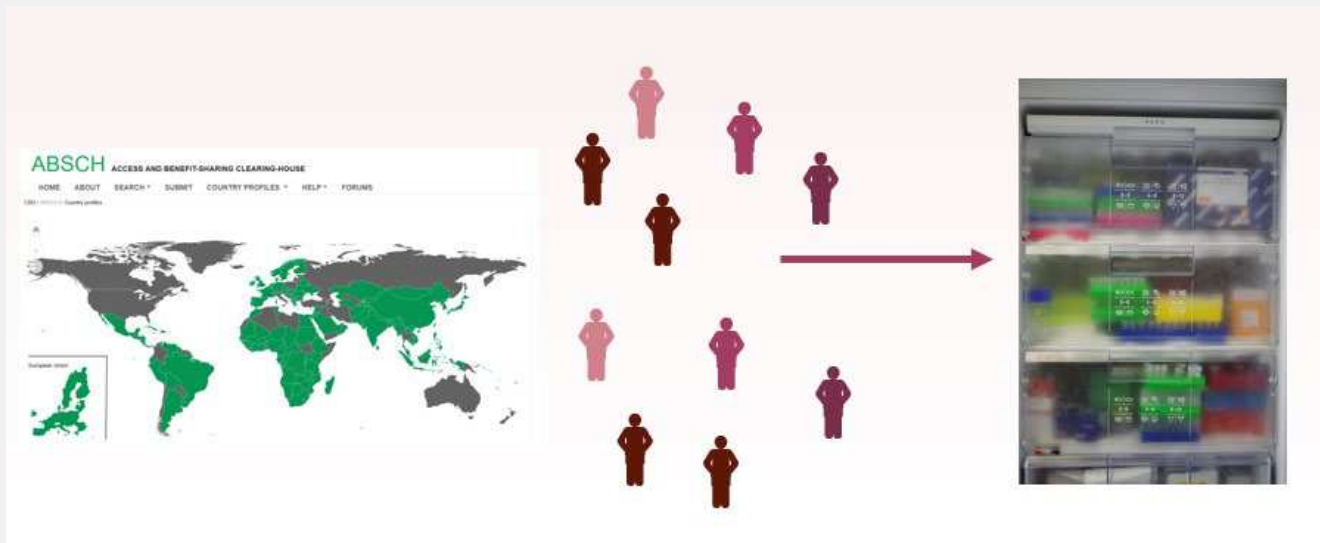
1. Entropy
2. Interpretation of standard protocols



# Developing & implementing ABS measures

## ▶ Main management challenges

1. Entropy
2. Interpretation of standard protocols
3. Unhelpful individualism



- Individual legal interpretation
- Individual Best Practice
- Individual best tubes and quality
- Individual ‚perfect‘ Excel sheets

# Key requirements to manage scientific collections

- ✓ Date and place where material was collected
- ✓ Description and identification of the used material
- ✓ Rapid accessioning of incoming material to secure all relevant metadata on the sourcing of the specimens
- ✓ Centralised permit and record keeping (e.g. collecting, access, export, import permits)
- ✓ Scientist need to take on their institutional responsibility
- ✓ Centralised accessioning and record keeping to ensure accessibility of specimens, samples and corresponding documents in 20 years and beyond

... agrees with good scientific practice!

