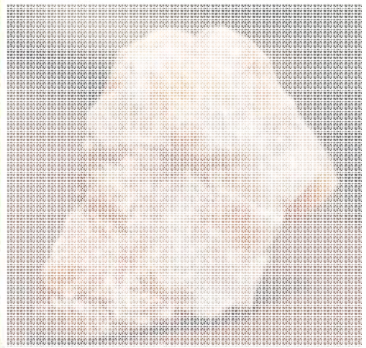
CETAF
CONSORTIUM OF EUROPEAN TAXONOMIC FACILITIES

CETAF Code of Conduct & Best Practice

CETAF Legislation and Regulations Liaison Group



CETAF WORKSHOP ON ABS - Berlin, 25 June 2016

CETAF Code of Conduct & Best Practice

Why a Code of Conduct and Best Practice?

Because Policy calls for them

Nagoya Protocol Article 20

… the development, update and use of voluntary codes of conduct, guidelines and best practices … in relation to ABS

EU Regulation Article 13

… development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic, university and non-commercial researchers

EU Regulation Article 8

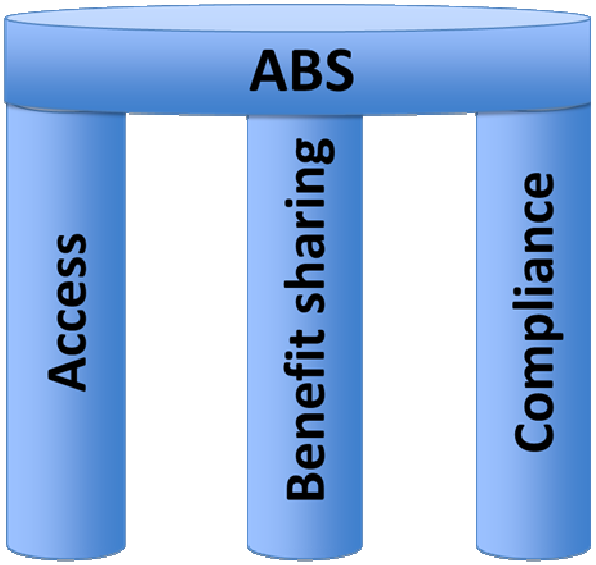
… importance of Best Practice in supporting Due Diligence and thus compliance checks

CETAF Code of Conduct & Best Practice

Why a Code of Conduct and Best Practice?

Because Provider countries find them helpful

- Addresses lack of trust of provider countries and fears of misuse of their genetic resources ('biopiracy')



CETAF Code of Conduct & Best Practice

Why a Code of Conduct and Best Practice?

Because they help management in the context of ABS

- It reduces risks:
  - associated with legal non compliance (with EU No. 511/2014)
  - associated with contract (permit conditions) management
  - reputational risk

CETAF Code of Conduct & Best Practice

Why a Code of Conduct and Best Practice?

Because they help management in the context of ABS

- It reduces risks:
  - associated with legal non compliance (with EU No. 511/2014)
  - associated with contract (permit conditions) management
  - reputational risk
- It helps:
  - in developing institutional-level compliance policies and processes
  - National Regulators assess us under their risk-based approach, and ease the administrative load

CETAF Code of Conduct & Best Practice

Why a Code of Conduct and Best Practice?

Sikkim alerts tour operators to bio-pirates – US and UK nationals collect seeds of plants without permission, says forest department

Posted By Kalimpongnews.net On January 12th, 2016 09:15 AM | News

http://kalimpongnews.net/2016/01/12/sikkim-alerts-tour-operators-bio-pirates-uk-nationals-collect-seeds-plants-permission-forest-department/

Seeds of a rare *Rhododendron* only used for commercial propagation

"Collection of any … flora or fauna, without government permission is a blatant violation of the existing laws of the state and the country and constitutes bio-piracy."

But there was no ABS relevant access or utilisation

CETAF Code of Conduct & Best Practice

Why a Code of Conduct and Best Practice?

Sikkim alerts tour operators to bio-pirates – US and UK researchers [your institution name appears here] collect seeds of plants without permission, says forest department

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http://kalimpongnews.net/2016/01/12/sikkim-alerts-tour-operators-bio-pirates-uk-nationals-collect-seeds-plants-permission-forest-department/

Imagine, this headline becomes viral on the internet …

This part now gets irrelevant:

But there was no ABS relevant access or utilisation

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Who else has a Code of Conduct?

- Botanic Garden principles
  https://www.bgci.org/policy/abs_principles/
- Global Genome Biodiversity Network
  http://wiki.ggbn.org/ggbn/Documents
- MOSAICC (now being superseded by TRUST)
  http://bccm.belspo.be/projects/trust
- MIRRI (in development)
  http://www.mirri.org/user-service/nagoya-protocol.html
- Mediterranean Science Commission
  http://www.ciesm.org/forums/index.php?post/2013/03/14/CIESM-Charter-on-ABS
- International Federation of Pharmaceutical Manufacturers and Associations
  http://www.ifpma.org/ethics/ifpma-code-of-practice/ifpma-code-of-practice.html
- And many others – see
  https://www.cbd.int/abs/instruments/

CETAF Code of Conduct & Best Practice

The CETAF process

2012-2013

Working Group set up

Working Group develops draft document package

Sep 2013

Circulated to membership for comment

May 2014

CoC approved by CETAF General Meeting

2015

Best Practice approved by CETAF General Meeting

Jan 2016

Package submitted to EU Commission for Recognition

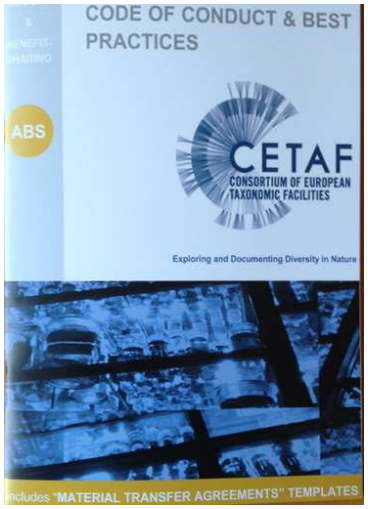
CETAF Code of Conduct & Best Practice

CETAF Tools to manage ABS

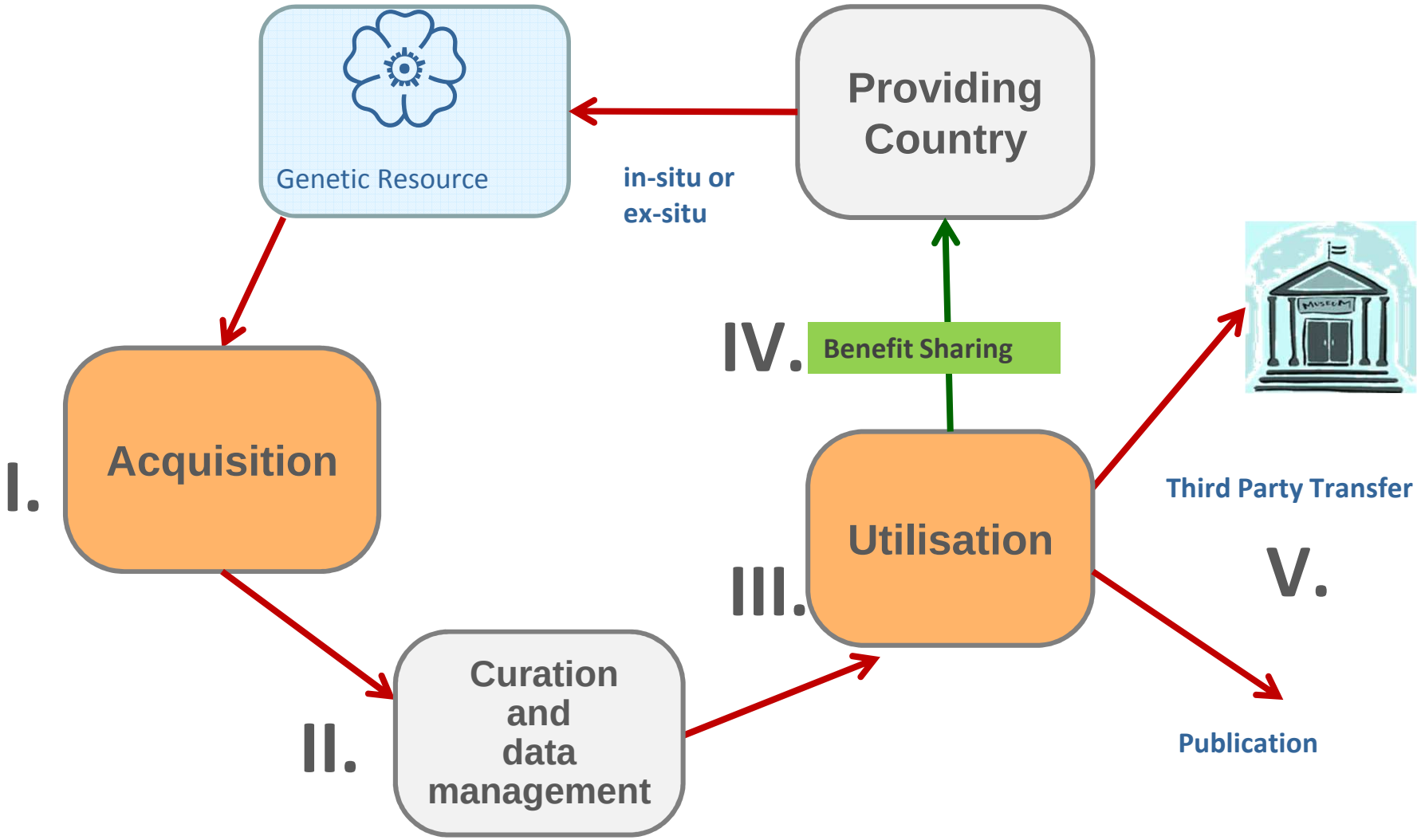
1. Code of Conduct on Access & Benefit-Sharing
   - The agreed principles by which we govern our activities

2. Best Practice
   - The way in which we implement those principles, including recommendations for policies and processes.

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



5 key elements of CETAF Best Practice



Sections: Code of Conduct	Reference in the annexed Best Practice
1. Convention on Biological Diversity and laws related to ABS	
2. Acquisition of biological material	1. Acquisition of biological material
3. Utilization of genetic resources	3. Utilization of genetic resources
4. Supply of biological material to Third Parties	4. Supply to Third Parties
5. Use of written agreements	
6. Traditional Knowledge associated with Genetic Resources	
7. Benefit-sharing	5. Benefit-sharing
8. Curation	2. Curation and Data-Management
9. Policies	6. Institutional Policies
	7. Staff training

CETAF Code of Conduct & Best Practice

Why 'Biological material' instead of 'genetic material'

- 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

Key elements of Compliance

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"

CETAF 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 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".

Relevant for demonstrating due diligence

And generate trust of providers

CETAF 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 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

CETAF Recommendation on 'ACQUISITION'

Identify responsibilities:

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

CETAF Recommendation on 'ACQUISITION'

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 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)

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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 & Best Practice

3. Utilisation

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

CETAF Recommendation on '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)

CETAF Recommendation on 'UTILISATION'

if the participating institution wishes to utilise GR outside existing contracts:

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

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Traditional Knowledge associated with Genetic Resources (TKaGR)

- 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”

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Traditional Knowledge associated with Genetic Resources (TKaGR)

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

'traditional knowledge associated with genetic resources' 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

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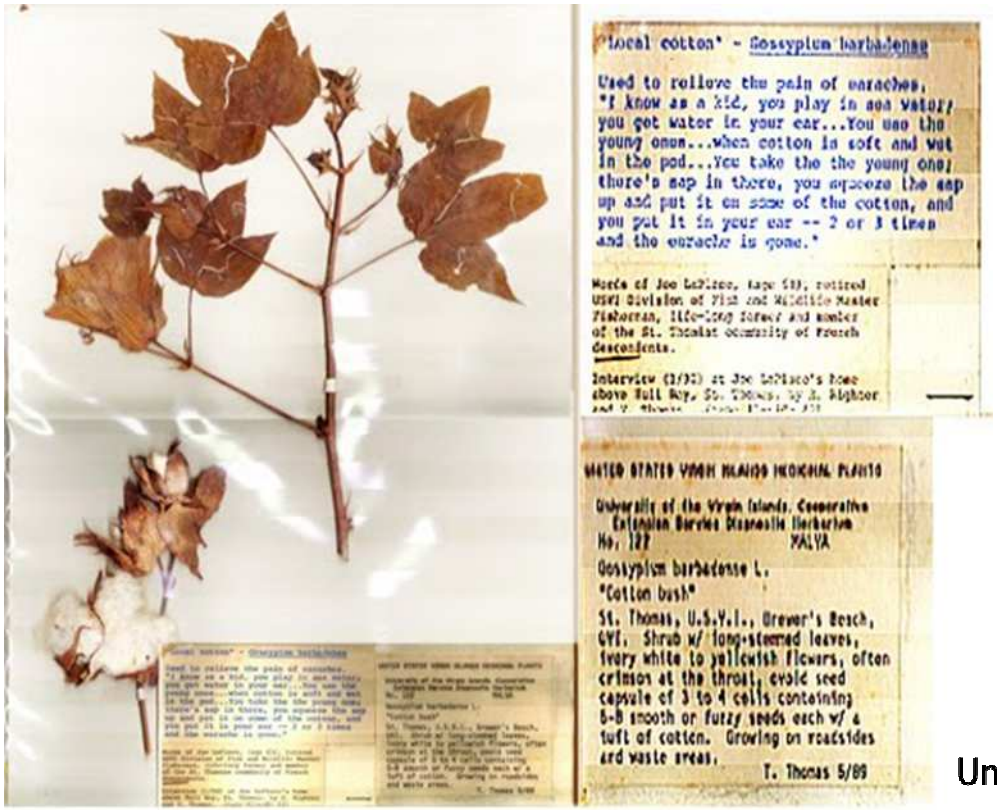
Traditional Knowledge associated with Genetic Resources (TKaGR)

Example were TK is associated with a herbarium specimen



University of the of the Virgin Islands diagnostic herbarium

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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)

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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'

xxx needs wordsmithing – check language – delete this text box afterwards

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

CETAF Code of Conduct & Best Practice

Curation and data management

"Participating institutions will develop appropriate internal mechanisms and procedures to:

- record the terms and conditions under which biological material is accessed or otherwise acquired;
- record relevant information on their utilisation of genetic resources, and benefits arising from that utilisation;
- record supply of biological material to Third Parties permanently or on loan, including the terms and conditions of supply; and
- record when and how biological material passes permanently out of custodianship, including complete consumption of samples or disposal."

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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 & Best Practice

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 Recommendation on 'Curation & Management'

Important to consider:

- application of unique identifiers which should travel with all specimens and subsamples
- Retention and location of original documentation
- Data management needs to consider ABS relevant decisions
  (do they require further steps, e.g. checking of original permits)
- horizontal transfer of data (objects → subsamples)
- Provides for a collection audit on ABS
  (e.g. under due diligence obligations of EU law)

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Staff Training

- ABS compliance and the new legislation can be new to many staff
- Training strategy and materials will be invaluable
- Institutions policies and processes should be clearly understood
- Rationale of Provider Countries' approach must be understood

ABS working group

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