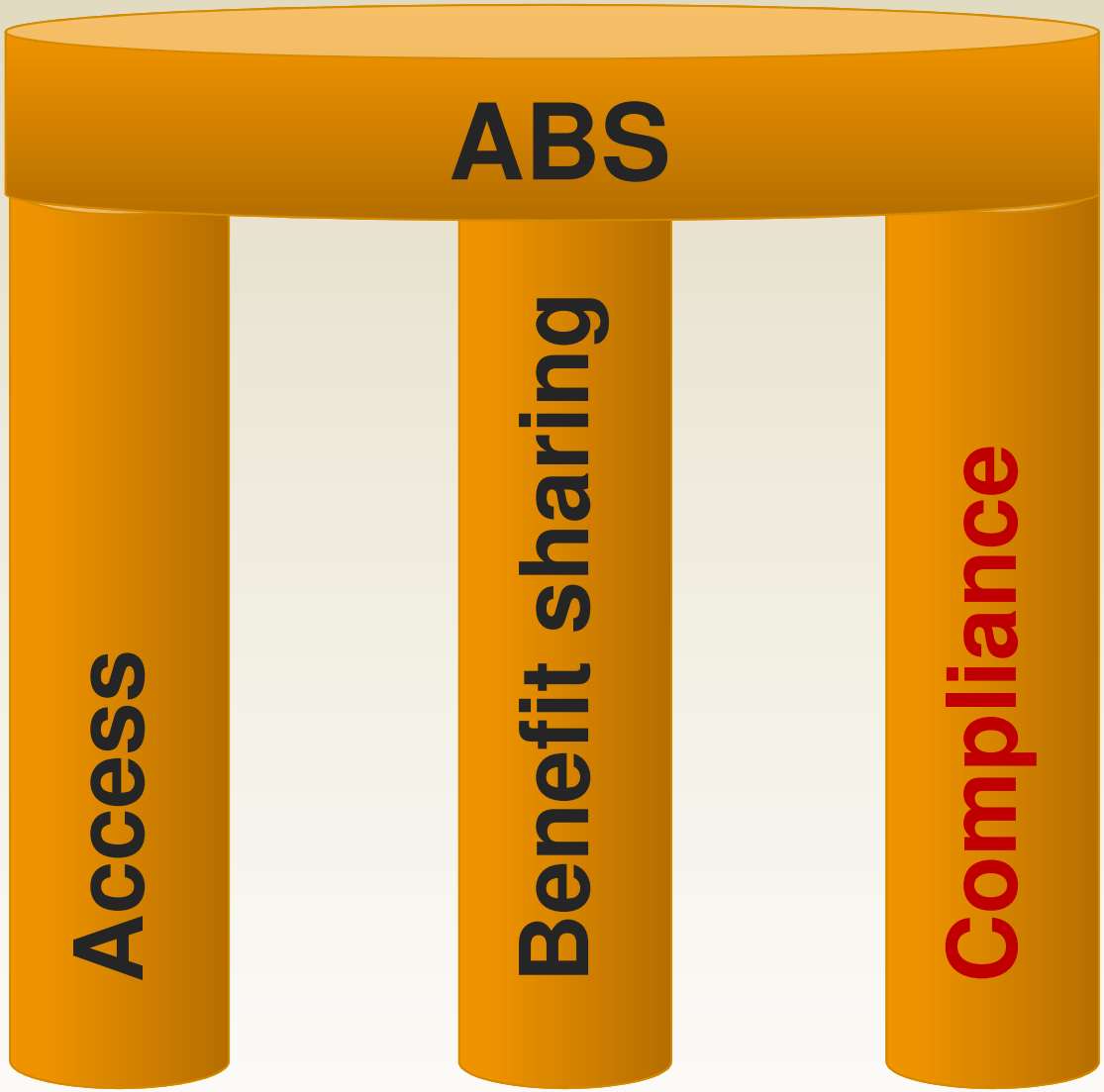
Transfer of specimens under the Nagoya Protocol & ABS

1. Legal Background
2. Due Diligence and Compliance
3. Challenges
4. Opportunities
5. Homework to do

1. Legal Background

The three Pillars of ABS



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1. Legal Background ABS in Theory

Access

States (also within EU) **may regulate access** to their genetic resources

→ *National Legislation*

Get permission (PIC, prior informed consent) from the competent national authority

Benefit-Sharing

Users must agree with providers about Benefit-Sharing

→ *Mutually agreed terms (MAT)*

Record and abide by the provisions of the MAT, and share benefits

Compliance

States must ensure that users comply with the Nagoya Protocol

→ *EU Regulation*

Fulfill due diligence obligations e.g under EU Regulation

NEW!

2. Due Diligence and Compliance

Has been good practice anyway

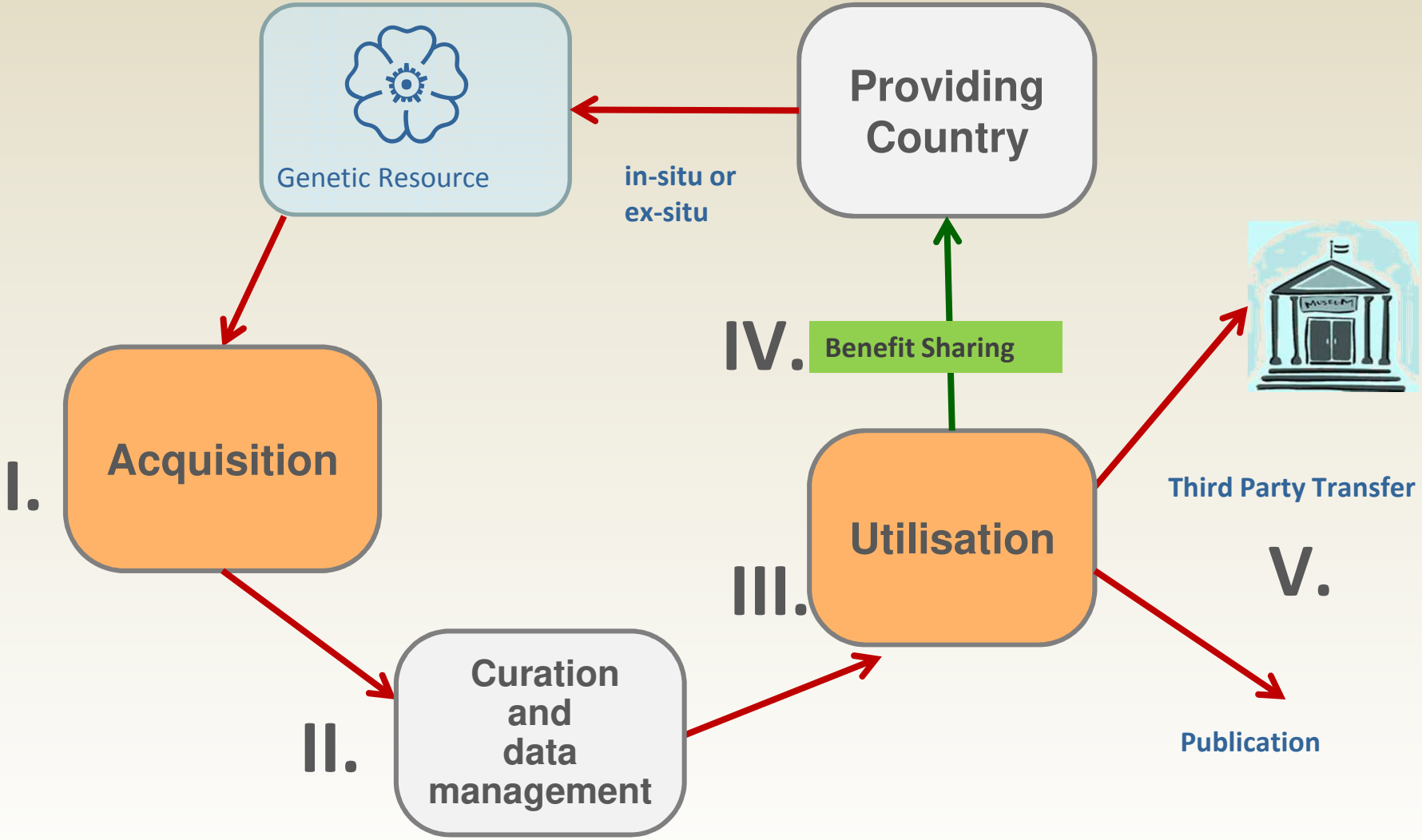
1. **Legal compliance**. You have comply with all legal requirements (as per current legislation).

2. **Contractual agreements**. You already negotiate access with providing countries. Now, you need to follow the documentation requirements.

3. **Reputational conditions**. The benefit sharing has been done for decades; it is already an implemented practice for researchers (on non-monetary basis).

2. Due Diligence and Compliance

Has been good practice anyway



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2. Due Diligence and Compliance

Has been good practice anyway

Why then a Code of Conduct and Best Practice?

1. To **support management** in the context of ABS

2. To **reduce risks** associated with ABS:
   - legal non compliance (with EU No. 511/2014)
   - contract (permit conditions) management
   - reputational risk

3. Challenges – legal obligations

- § Due Diligence is now a requirement
- § Permit management system is required
- § Use and Users need to be recorded

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  - ! A "**User**" can be internal staff, external guests/visitors/PhD students, etc.
  - ! **Utilisation** may happen **inside or outside the institution**

3. Challenges – practical management

1. Responsibilities of the Institution.

- ✓ relevant **ABS** data is **recorded independent of individual persons**
- ✓ relevant **ABS** data is **documented independent of individual computers**
- ✓ the **linkage of relevant ABS data and specimens and all parts or derivatives thereof** is kept persistently all points

2. Responsibilities of curators/registrars.

- ✓ **foresightful** project planning
- ✓ support **centralised record keeping** of ABS relevant documents and data
- ✓ respect **due diligence obligations** (no illegal utilisation)
- ✓ respect **reporting obligation** when projects terminate
- ✓ respect and support **benefit sharing obligations**

3. Challenges – practical management

3. Responsibilities of ABS representatives of the Institution.

- ✓ support functioning of internal institutional check-points
- ✓ support and enhance internal procedures and record keeping
- ✓ support curators and research during negotiations with Providers
- ✓ support curators and research to meet their due diligence obligations
- ✓ check compliance with relevant ABS obligations resulting from ABS contracts

4. Opportunities for Natural History Collections

Does this sound familiar to you ?

- ✓ Who is the responsible contact person
- ✓ Where do I find the samples
- ✓ Where do I find the respective data and documents:
  - File copies of relevant ABS-documents
  - Databases with sample data (sample ID, point of accession, date of accession, user, date of utilisation) and respective ABS access data (permits, notifications, emails, etc.)

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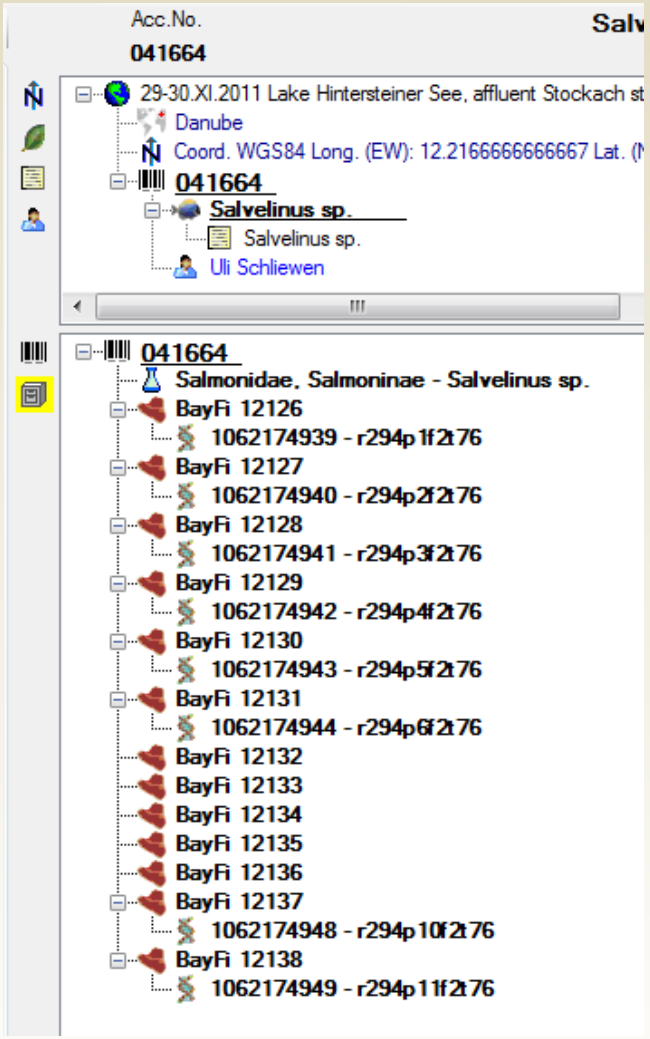
Due Diligence Obligations Art 4 (1) (EU) No 511/2014

All this – has nothing to do with ABS in the first place

but it requires to establish well curated biorepositories

AND

sophisticated permit management systems



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4. Opportunities for Natural History Collections

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

Nov 2016

Re-submission to EU Commission for Recognition

Apr – Nov 2017

finally acknowledged

4. Opportunities for Natural History Collections

CETAF Tools to manage ABS

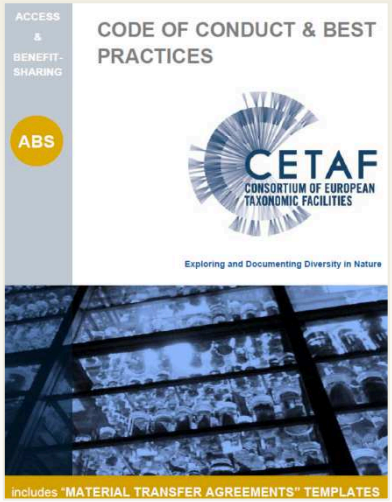
1. Code of Conduct on Access & Benefit-Sharing

   ✓ 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)



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4. Opportunities for Natural History Collections

Finally acknowledged CETAF CoC & BP

Officially recognised **principles how European Natural History Collections handle ABS obligations** ***by EU Com***

Access → *National Legislation (PIC)*

Benefit-Sharing → *Mutually agreed terms (MAT)*

Compliance → *EU Regulation*

1. *Documentation*
2. ~~*Reporting*~~

4. Opportunities for Natural History Collections

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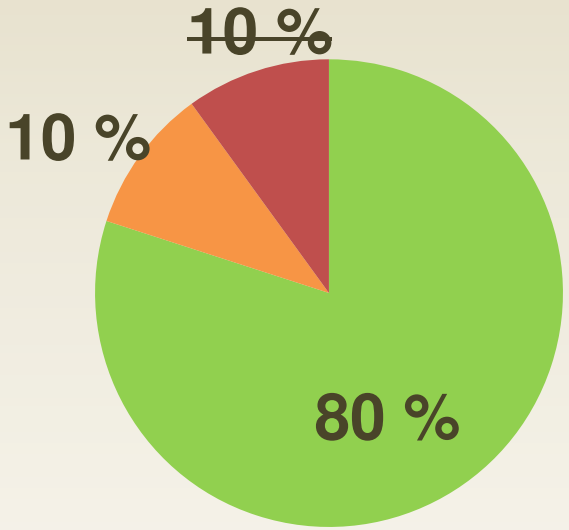

Documentation

- ✓ of provenance (80%)
- ≈ of permits (PIC & MAT) (10%)
- § *reporting towards Providers*
- ~~§ *reporting under EU law (10%)*~~

Compliance

→ ***EU Regulation***

1. ***Documentation***
2. ~~***Reporting under EU ABS law***~~

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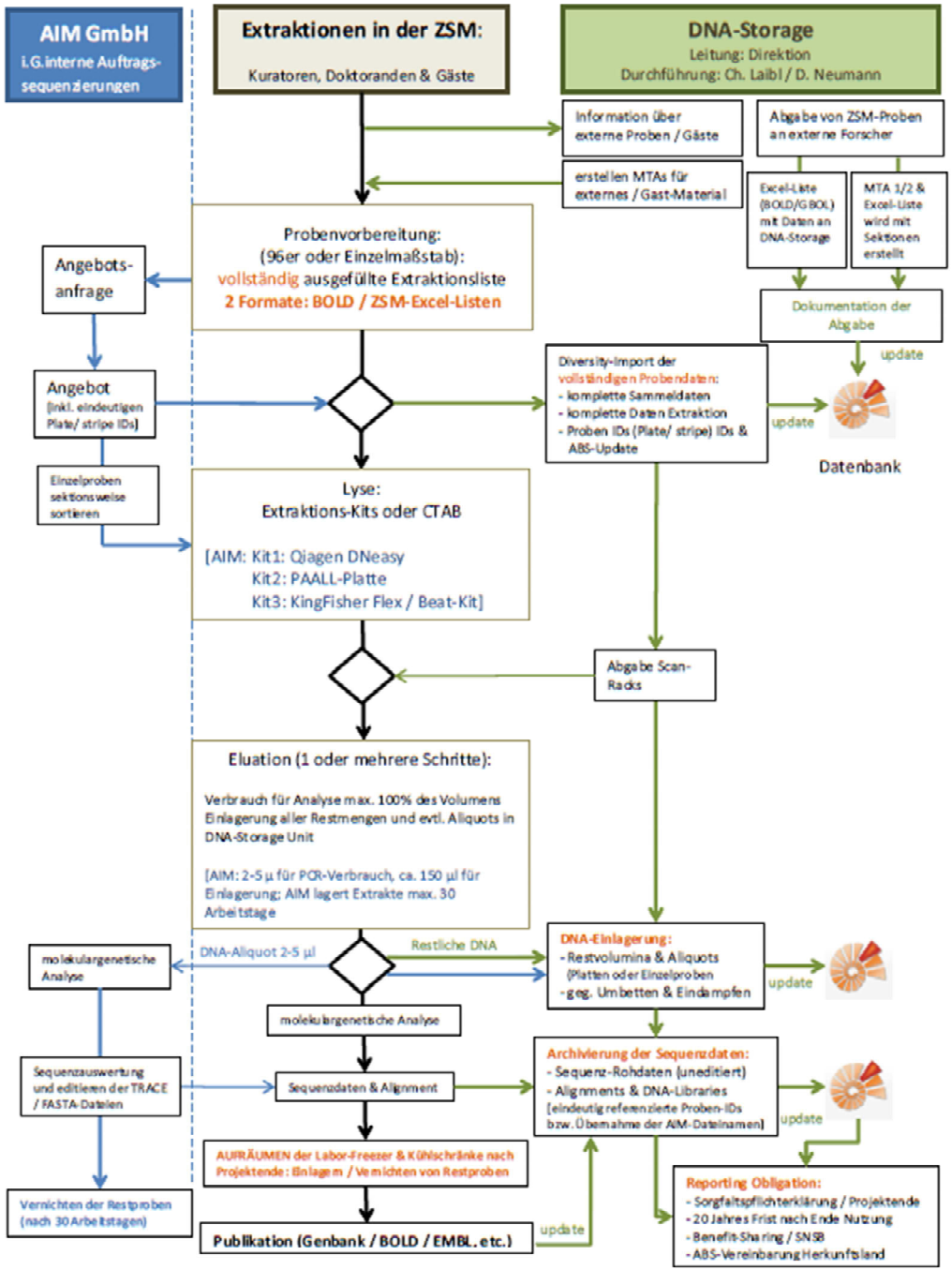
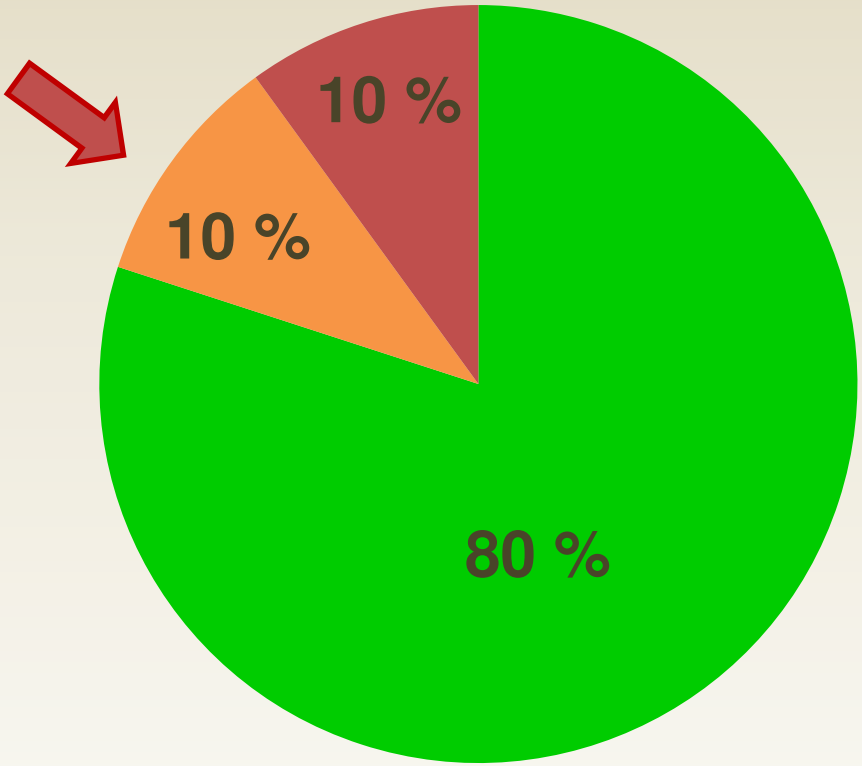
5. Homework to do

1. **Establish standardised procedures for**
   - ✓ project proposals (check point)
   - ✓ travel applications (check point)
   - ✓ acquisition of biological material (check point)
   - ✓ utilisation of GR inside the institution (check point)
   - ✓ transfer of biological material (MTA)
   - ✓ DNA-storage facilities (ecord utilisation and storage of utilised samples)
   - ✓ guest researchers bringing materials into the institution
   - ✓ the documentation of shared benefits (check point)

Arbeitsablauf DNA-Extraktion & Einlagerung in der ZSM /





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Acc.No.
041664

Salvelinus sp.

29-30.XI.2011 Lake Hintersteiner See, affluent Stockach stream contributes to Ir
Danube
Coord. WGS84 Long. (EW): 12.2166666666667 Lat. (NS): 7.541666666666
041664
Salvelinus sp.
Salvelinus sp.
Uli Schliewen

041664
Salmonidae, Salmoninae - Salvelinus sp.
BayFi 12126
1062174939 - r294p1f2t76
BayFi 12127
1062174940 - r294p2f2t76
BayFi 12128
1062174941 - r294p3f2t76
BayFi 12129
1062174942 - r294p4f2t76
BayFi 12130
1062174943 - r294p5f2t76
BayFi 12131
1062174944 - r294p6f2t76
BayFi 12132
BayFi 12133
BayFi 12134
BayFi 12135
BayFi 12136
BayFi 12137
1062174948 - r294p10f2t76
BayFi 12138
1062174949 - r294p11f2t76

IDES

ordnen nach: Specimen Acc.No

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5. Homework to do

Curation & Management

→ How many people know this order ?
→ How many people can access these specimens ?
→ How many sections are involved here ?

Scenario (maybe a drastic one):

https://upload.wikimedia.org/wikipedia/commons/4/4a/Verkehrsunfall_Moers_A40_1.JPG

5. Homework to do

1. Establish clear structures and responsibilities:

- ✓ nominate ABS representatives
- ✓ designate persons which supervise ABS responsibilities of the institution
- ✓ establish close linkage between staff (temporary & permanent) & projects AND collections
- ✓ develop procedures for and supervision of the DNA-lab
- ✓ establish common workflows in the DNA-lab
  - ➢ for projects, internal/external students, PhDs, etc.
- ✓ establish coherent data structures
  - ➢ for projects, internal/external students, PhDs, etc.
  - ➢ design & syntax of Excel lists, databases etc.
- ✓ establish coherent workflows for DNA collections

ABS working group

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