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## CETAF Workshop on Access and Benefit Sharing

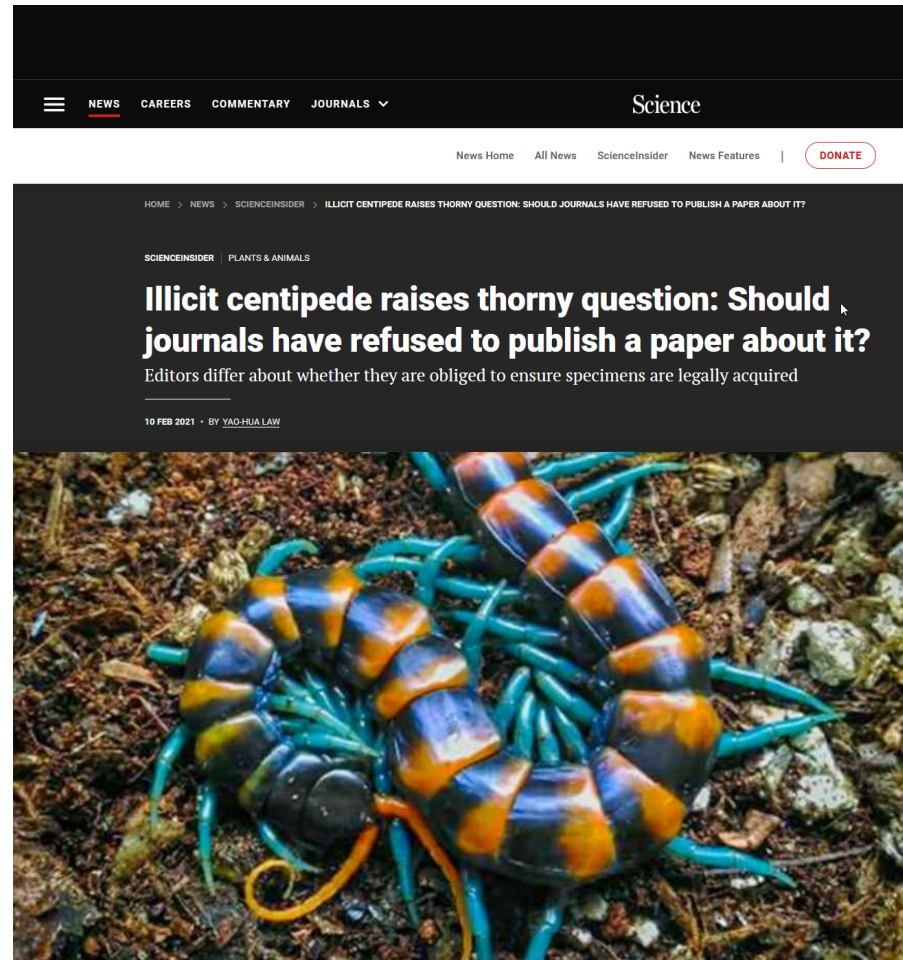
Practical Experiences:

Model Clauses, Pitfalls and Risk Management



# Institutional Risk Management:

## ... BEING ON THE SAFE SIDE



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### Illicit centipede raises thorny question: Should journals have refused to publish a paper about it?

Editors differ about whether they are obliged to ensure specimens are legally acquired

10 FEB 2021 • BY YAO-HUA LAW

doi: 10.1126/science.abh0269

<https://www.science.org/content/article/illegal-centipede-raises-thorny-question-should-journals-have-refused-publish-paper>

# Institutional Risk Management:

... BEING ON THE SAFE SIDE

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SHARE



This amazing blue tarantula is a new spider species— but did researchers break the law when they studied it?

By Yao-Hua Law | Feb. 27, 2019 , 12:00 PM

Keywords: Malaysia – bio-piracy – Entomological Collection – illegally collected tarantulas  
Oxford University Museum of Natural History - breach of UK laws

# Institutional Risk Management:

## ... BEING ON THE SAFE SIDE

including those that have huge economic potential. “In the past, Indonesia only issued around 200 research permits per year. Since 2010, we issued around 500 permits. The interest is growing, especially in biodiversity, such as zoology, botany and marine biology,” Sri said.

The regulation thus also aims to fight a subtler and more controversial form of biopiracy: unfair research cooperation agreements between local and foreign scientists.

Rosichon Ubaidillah, the head of zoology at the Indonesian Institute of Sciences (LIPI) biology research department, claimed to have evidence showing that many agreements signed by Indonesian universities and their foreign counterparts tend to benefit the latter. “Foreign researchers may have collected research materials legally, but what they have been doing is not always ethical,” Rosichon said.

LIPI, he said, had to cancel scientific cooperation with a German institution last year because the latter refused to change a material transfer agreement (MTA) LIPI deemed as disadvantaging Indonesia.

<https://www.thejakartapost.com/news/2017/03/20/ri-steps-up-fight-against-biopiracy.html>

<https://www.businesstimes.com.sg/opinion-features/columns/indonesia-strengthens-laws-against-biopirates>

# Legal and reputational risks for institutions

## Three major areas of risk

### 1. *LEGAL NON-COMPLIANCE*

- ▶ Access: with access laws or contractual obligations of Provider Countries
- ▶ Compliance: with compliance laws in User Countries and/or breach of contractual obligations with Provider Countries

### 2. *FAILURE TO MANAGE AGREED BENEFIT-SHARING*

- ▶ Agreed Benefit Sharing are not or only partially met
- ▶ Shared Benefits are not recorded and acknowledged at end of project

### 3. *REPUTATIONAL RISKS*

- ▶ For the institution
- ▶ For the individual scientist

# Compliance Checks of EU Member States

- Due Diligence Declarations (DDD)
  - ▶ 363 active users of the electronic submission tool DECLARE
  - ▶ 231 DDD research stage, 46 DDD at final stage product development, in 13 EU MS
- Compliance Checks
  - ▶ On spot checks in more than half of EU MS
  - ▶ Several cases of non-compliance were reported
  - ▶ Violations and penalties in rare cases, including fines (5,000-10,000 EUR) and withdrawal of published papers
  - ▶ Example Germany: 5 control cycles since 2028, >400 questionnaires, 35-40 on spot checks annually, 13 violations, 2 fined violations, several issued warnings

## AND:

- ▶ Also Provider Countries screen available data for Nagoya Compliance

Information shared by EU COM at 10th ABS Consultation Forum, 10 April 2025



# Legal and reputational risks for institutions

## Three major areas of risk

### 1. *LEGAL NON-COMPLIANCE*

- ▶ **Institutions should know their contractual obligations** they entered into
- ▶ **Scientists** (permanent, associate and guest researchers) should **understand their institutional responsibilities**

### 2. *FAILURE TO MANAGE AGREED BENEFIT-SHARING*

- ▶ **May provoke penalties**
- ▶ **Can discredit the reputation of the entire institution**

### 3. *REPUTATIONAL RISKS*

- ▶ **May affect** the ability of the institution to successfully negotiate **new contracts**
- ▶ **May affect** the **image of the institution** and its scientists

# ... better being on the safe side

- **Legal compliance** – You have to comply with all legal requirements (as per current legislation)
- **Contractual agreements** – You already negotiate access with providing countries. Now, you need to follow the documentation requirements
- **Reputational conditions** – The benefit sharing has been done for decades, it is already an implemented practice for researchers (on non-monetary basis)

Keep in mind:

**Publications** are read outside our peer group and used **for automatised compliance checks** of Provider and/or User Countries



# Implementation: Six basic steps (CETAF CoC, Annex5)

## 1. Designate ABS-representatives

- ✓ 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

## 2. Define Institutional ABS-responsibilities

- ✓ Define institutional check-points
- ✓ Develop institutional policies, for acquisition, use and sharing and deaccession of GR and permit and data management

## 3. Evaluate current policies and workflows for suited synergies

## 4. Provide resources and training

- ✓ Good scientific practice agrees with the rational of the NP and EU ABS Reg
- ✓ Centralised resources minimise errors and support risk management

# Implementation: Six basic steps (CETAF CoC, Annex5)

## 5. Contract management and record keeping

- ✓ Documenting requirements for accessed biological material (EU ABS Reg)
- ✓ Documenting requirements for transfer of biological materials to third (e.g. CETAF Standard Material Transfer Agreements)
- ✓ Data management (metadata including utilisation and publication and associated permits, contracts and other relevant documents)
- ✓ Centralised contract management system with clear responsibilities

## 6. Define internal check-points for ABS compliance to cover

- ✓ Field Work (e.g., travel application form or process)
- ✓ Object entry partly (e.g., CETAF MTAs or contracts)
- ✓ DNA extraction (e.g., adjusted standardised barcoding lists)
- ✓ Transfer and sharing of samples (CETAF MTAs 1-3)
- ✓ Visiting guest scientists (CETAF MTAs 4)
- ✓ Delivery of agreed benefits to Provider Country
- ✓ Disposal, consumption and sharing of accessioned biological material

# Implementation: useful to consider

## 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**

# Negotiating with providing countries

## 1. Practical advice: CETAF Annex 5

- ✓ Planning a project and grant proposal
- ✓ Planning of field work
- ✓ Before starting negotiations
- ✓ During negotiations with National Competent Authority Point of Provider Country
- ✓ Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT)
- ✓ Before you start field work
- ✓ During field work

# Negotiating with providing countries

## 2. Key considerations when negotiating

- ✓ **Respect the interests of the providing country**
- ✓ **Respect the interest of the collaboration partners**
- ✓ Negotiating in good faith is key, taking concerns serious builds up trust
- ✓ Demonstrate that your institution takes the compliance obligations of the EU ABS Regulation serious
- ✓ Document contact and responses with the NCA, including eventual non-responsiveness of Provider Country NCA
- ✓ Actively engage local collaborator (some countries require this)
- ✓ Be aware that the some Provider Countries are very selective which whom they want to collaborate with
- ✓ Use standardised template texts when emailing NCAs, explaining your intended research and collaboration (be aware that your contacts may not have a biological background)

# Record keeping and data management: accessioning

- ▶ Material is accessioned as usual in different sections
- ▶ Any permit (travel, export, etc.) receives a document number by the responsible ABS representative and is filed
- ▶ MAT & PIC receive document numbers in central administration and are filed there
- ▶ Curators reference document number to incoming material

# Record keeping and data management: accessioning

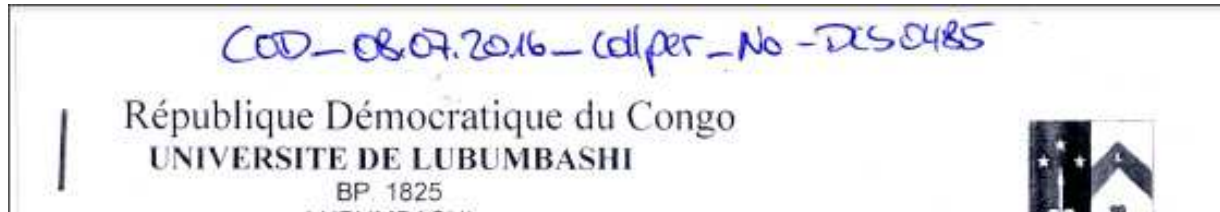


Remark	tissue subsamp	Permit
ZSM 45056 ex ZSM 44677 (2 now 1); det. Schedel: 30.12.2015; male		ZMB_05.10.2015_ExpPer
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net; ZSM DNA tissue collection (fin samples), I		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net; ZSM DNA tissue collection (fin samples)		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net; ZSM DNA tissue collection (fin sample), s		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net; ZSM DNA tissue collection (fin samples)		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net; ZSM DNA tissue collection (fin samples)		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net; ZSM DNA tissue collection (fin samples)		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016
Loc. DRC 2016-10; alt.: 1075; method: gill net, rotenone, frame net, hand net; ZSM DNA tissue collection (fin samples)		COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016

# Record keeping and data management: DNA extraction

- ▶ Standardised Excel sheets,, e.g. lab management software or barcoding submission files
- ▶ Additional fields for permits and extraction details (who, when, how much, etc.)
- ▶ Recording of failed extractions (also utilisation)
- ▶ Easy mapping of tissue, DNA and corresponding permit ID

# Record keeping and data management: DNA extraction



Orientation for name on tube	Tissue No.	Collecting Permit No.	Permit issued by	trade restrictions	ABS_MAT	ABS_PIC
Ab_B7	AB54002492	COD_08.08.2016_CollPer_N-REF-FAC-AGRO-100			not applicable, ratified but laws not ready [DN 02.Dez.2016]	n/a
Ab_B8	AB54002597	COD_08.08.2016_CollPer_N-REF-FAC-AGRO-100			not applicable, ratified but laws not ready [DN 02.Dez.2016]	n/a
Ab_B9	AB54002608	COD_08.08.2016_CollPer_N-REF-FAC-AGRO-100			not applicable, ratified but laws not ready [DN 02.Dez.2016]	n/a
Ab_B10	AB54002848	COD_08.08.2016_CollPer_N-REF-FAC-AGRO-100			not applicable, ratified but laws not ready [DN 02.Dez.2016]	n/a
Ab_B11	AB54002854	COD_08.08.2016_CollPer_N-REF-FAC-AGRO-100			not applicable, ratified but laws not ready [DN 02.Dez.2016]	n/a
Ab_B12	AB54002864	COD_08.08.2016_CollPer_N-REF-FAC-AGRO-100			not applicable, ratified but laws not ready [DN 02.Dez.2016]	n/a
AB_C1	AB54002870	COD_08.08.2016_CollPer_N-REF-FAC-AGRO-100			not applicable, ratified but laws not ready [DN 02.Dez.2016]	n/a
AB_C2	DRC-2008/0267				pre-NP, ABS not applicable	
AB_C3	DRC-2008/0332				pre-NP, ABS not applicable	
AB_C4	DRC-2008/0406				pre-NP, ABS not applicable	
AB_C5	DRC-2008/0624				pre-NP, ABS not applicable	
AB_C6	DRC-2009/0794				pre-NP, ABS not applicable	
AB_C7	DRC-2009/0857				pre-NP, ABS not applicable	
AB_C8	DRC-2009/0907				pre-NP, ABS not applicable	
AB_C9	DRC-2012/1213				pre-NP, ABS not applicable	
AB_C10	DRC-2012/1220				pre-NP, ABS not applicable	
AB_C11	DRC-2012/1224				pre-NP, ABS not applicable	
AB_C12	DRC-2012/1287				pre-NP, ABS not applicable	
Ab_D1	DRC-2012/1317				pre-NP, ABS not applicable	
Ab_D2	DRC-2012/1430				pre-NP, ABS not applicable	
Ab_D3	DRC-2013/1814				pre-NP, ABS not applicable	
Ab_D4	DRC-2016/4106	COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016 UK FS				
Ab_D5	DRC-2016/4154	COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016 UK FS				
Ab_D6	DRC-2016/4162	COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016 UK FS				
Ab_D7	DRC-2016/4399	COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016 UK FS				
Ab_D8	DRC-2016/4414	COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016 UK FS				
Ab_D9	DRC-2016/4415	COD_08.07.2016_CollPer_No-DCS485_DRC Katanga 2016 UK FS				

# Record keeping and data management: DNA extraction

Tissue No.	Collecting Permit No.	Permit issued by	trade restrictions	ABS_MAT	ABS_PIC	Authorised by	Blocked for wrapper	Blocked until	BOLD sample ID	DNA Bank No.	date extraction	kit used	storage medium of extracted DNA	extraction staff	DNA Konz. [extinction]
AB48930051	COD_16.08.2016_CollPer_H.Kat_REF			not applica	n/a	MRAC Tervuren				r419p1f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	73.4
AB49131286	COD_16.08.2016_CollPer_H.Kat_REF			not applica	n/a	MRAC Tervuren				r419p2f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	88.7
AB48930037	COD_16.08.2016_CollPer_H.Kat_REF			not applica	n/a	MRAC Tervuren				r419p3f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	77.8
AB48949127	COD_16.08.2016_CollPer_H.Kat_REF			not applica	n/a	MRAC Tervuren				r419p4f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	910
AB48949128	COD_16.08.2016_CollPer_H.Kat_REF			not applica	n/a	MRAC Tervuren				r419p5f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	794.8
AB48949830	COD_16.08.2016_CollPer_H.Kat_REF			not applica	n/a	MRAC Tervuren				r419p6f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	971
AB48949831	COD_16.08.2016_CollPer_H.Kat_REF			not applica	n/a	MRAC Tervuren				r419p7f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	447.4
AB49128214	COD_08.08.2016_CollPer_N-REF-FA			not applica	n/a	MRAC Tervuren				r419p8f1t94	07.12.2016	CTAB	AE Buffer	Emmanuel abwe	88.4
AB49128225	COD_08.08.2016_CollPer_N-REF-FA			not applica	n/a	MRAC Tervuren				r419p9f1t94	08.12.2016	CTAB	AE Buffer	Emmanuel abwe	67.7
AB53923685	COD_07.06.2013_CollPer_No038-ICG			not applica	n/a	MRAC Tervuren				r419p10f1t94	08.12.2016	CTAB	AE Buffer	Emmanuel abwe	452.8
AB54001008	COD_08.08.2016_CollPer_N-REF-FA			not applica	n/a	MRAC Tervuren				r419p11f1t94	08.12.2016	CTAB	AE Buffer	Emmanuel abwe	222.7
AB54001026	COD_08.08.2016_CollPer_N-REF-FA			not applica	n/a	MRAC Tervuren				r419p12f1t94	08.12.2016	CTAB	AE Buffer	Emmanuel abwe	100.0
AB54001181															
AB54001183															
AB54002312															
AB54002318															
AB54002485	AB48930051	Ab_A1	20 µl					1	94	419	A01		1		
AB54002491	AB49131286	Ab_A2	20 µl					1	94	419	A02		2		
AB54002492	AB48930037	Ab_A3	20 µl					1	94	419	A03		3		
AB54002597	AB48949127	Ab_A4	20 µl					1	94	419	A04		4		
AB54002608	AB48949128	Ab_A5	20 µl					1	94	419	A05		5		
AB54002848	AB48949830	Ab_A6	20 µl					1	94	419	A06		6		
	AB48949831	Ab_A7	20 µl					1	94	419	A07		7		
	AB49128214	Ab_A8	20 µl					1	94	419	A08		8		
	AB49128225	Ab_A9	20 µl					1	94	419	A09		9		
	AB53923685	Ab_A10	20 µl					1	94	419	A10		10		
	AB54001008	Ab_A11	20 µl					1	94	419	A11		11		
	AB54001026	Ab_A12	20 µl					1	94	419	A12		12		
	AB54001181	Ab_B1	20 µl					1	94	419	B01		13		
	AB54001183	Ab_B2	20 µl					1	94	419	B02		14		
	AB54002312	Ab_B3	20 µl					1	94	419	B03		15		
	AB54002318	Ab_B4	20 µl					1	94	419	B04		16		

# ABS Contracts: Model Clauses

- **Main components** of ABS contracts should include
  - ▷ **Opening**, preambular or recital clauses – describe the intention of the contract
  - ▷ **Objectives** – define the general aims and clarify terms and relation of the contract, also regarding subsequent or additional or sub-contracts
  - ▷ **Scope** – indicative list that define in detail planned (joined) activities and contractual duties for both partners that arise (may be in separate article ‘Responsibilities of the Parties’)
  - ▷ **Access / Sharing / Deposition / Ownership of biological material** – clarify details on accessed or jointly collected biological material including deposition and sharing with third
  - ▷ **Financial Obligations** – clarifies any direct or indirect financial obligations or activities which require financial contributions, such as field collection or coverage of publication costs
  - ▷ **Intellectual Property Rights and publication** – cover, e.g. existing copyrights of analytical software that will be shared, specifies joint ownership of any IPR that arises from joint research activities, and clarifies, that research results must be published jointly, e.g. guided by FAIR principles

# ABS Contracts: Model Clauses

- **General components** of ABS contracts
  - ▷ **Validity and modifications** – define the duration and modalities for the possible renewal of the contract
  - ▷ **Settlement of dispute** – clarifies which notifications in writing are necessary and with time periods must be observed
  - ▷ **Final Provisions** – clarify the how the contract shall be governed
- **Optional components**
  - ▷ Utilisation of GR
  - ▷ Sharing or GR with Third
  - ▷ Record keeping and reporting
  - ▷ Benefit Sharing
  - ▷ Commercial use and sharing

# ABS Contracts: Model Clauses

- German Research Foundation (Deutsche Forschungsgemeinschaft, DFG)
  - ▶ Commented version explaining content and meaning; <https://www.dfg.de/resource>
  - ▶ Content
    1. Opening or recital clauses
    2. Objectives
    3. Definitions
    4. Goals, e.g. joint research, scientific collaboration, capacity building
    5. Access
    6. Export and Deposition
    7. Utilisation of GR
    8. Sharing or GR with Third
    9. Record keeping and reporting
    10. Benefit Sharing
    11. Publication of joint results
    12. Commercial use and sharing
    13. Other laws
    14. Liability and Endemnation
    15. Duration and Termination
    16. Dispute and Resolution

# ABS Contracts: remarks and pitfalls

- **Definitions**

- ▶ **Indigenous biological resource** instead of Genetic Resource – relates to Traditional Knowledge that might be associated with biological material and Indigenous People and Local Communities (IPLCs); not a defined term in CBD or NP, role and status often not clearly defined in national access laws
- ▶ **Genetic Heritage** instead of Genetic Resource – relates to cultural heritage protection laws, includes ‘information’ associated with biological material, including metabolites; not a defined term in CBD or NP, may require to explicitly state in contracts that biological material can exclusively be used for non-commercial basic research to provide legal certainty for what the material can be used – or not.
- ▶ **Genetic Resources and Traditional Knowledge (GRTK)** instead of Genetic Resource – combines GR and TKaGR and can entail “any other biotic component of ecosystems **with actual or potential use or value for humanity**”; “Traditional Knowledge is content or substance of knowledge that is the result of intellectual activity and inside a traditional complex, including the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems”; not a defined term in CBD or NP, aims to link Intellectual Property Rights and Copyright to accessed biological material; creates huge legal uncertainty and compliance risks

# ABS Contracts: remarks and pitfalls

- **Scope**

- ▶ Should **list all planned** in the partnership/joint research, **define who will do what**, and **reaffirm the aims** of the collaboration, e.g.
  - ▶ Reference to specific Research Programs or Monitoring Schemes, specifically the Country's National Biodiversity Strategy and Action Plans
  - ▶ Details regarding the biodiversity of the partner country
  - ▶ Specific aims or details of the intended scientific collaboration, e.g. promotion of
    - Biodiversity research
    - Conservation efforts
    - Capacity Building
    - Technology Transfer and Education
    - Scientific infrastructures at the partner institution
  - ▶ Specific skills, such as field recording techniques, analytical capacities
  - ▶ Mention of national or international laws and regulations that need to be observed by both partners, e.g. the EU ABS Regulation if visits of guest scientists are planned
  - ▶ Obligatory principles or general requirements for the envisioned collaboration or projects to be established

# ABS Contracts: remarks and pitfalls

- **Access / Sharing / Deposition / Ownership of biological material**
  - ▷ Be aware that some countries do not transfer ownership, i.e. the **accessed biological material** can be used and taken into possession, but **not be owned**. This may conflict with the institutions mission statement or policies.
  - ▷ Jointly collected material will be shared between the Parties
    - ▷ **fairly**: depends how ‘fairly’ is defined; can be 1:99 specimens if parties agree this is fair
    - ▷ **equally**: material will be shared 50:50
    - ▷ **equitably**: can but does not need to be equally, but shall be fair so that both partners profit and gain from the splitting
  - ▷ Ownership: for example, “any shared material will become ownership of the respective receiving party”
  - ▷ **Jointly** collected: both parties contributed to the obtaining (not only the ‘user’)
  - ▷ Use of the material:
    - ▷ Any biological material collected under or deposited will be made available to both Parties
    - ▷ and to third partners [optional: as agreed by the Parties]
    - ▷ exclusively for the purpose of conducting non-commercial research [restriction to minimise legal risks]

# ABS Contracts: remarks and pitfalls

- **Intellectual Property Rights**

- ▶ Clearly state that any licenses, analytical processes and workflow descriptions or shared methodological guidelines to perform analytical processes owned or possessed and provided by one of the parties for the completion of joint research will remain property of the respective party.
- ▶ Each party shall **indemnify** the other from and **against all claims by third parties** arising out from the ownership or the infringement of Intellectual Property Rights.
- ▶ **Ownership arising from joint research:** IPR or related rights and/or information generated through joint research projects should be owned by both parties as co-owners [affirms that both parties own the results from joint research]
- ▶ **Association of IPR to GR:**
  - be aware that some model clauses advice Providing Countries to associate Intellectual Property Rights to ensure that IPR entitlement is affirmed in accessed GR to prevent uncontrolled commercialization (including through publication of molecular and genomic data).
  - Linking [potential] innovation and intellectual activity with GR or a ‘traditional complex’ poses considerable liability and reputational risks for users

# ABS Contracts: remarks and pitfalls

- **Publication**

- ▶ Clearly state that any publication of jointly generated research results **shall be made publicly available as soon as possible** after the generation of the results
- ▶ Clearly state that **joint publications** or jointly developed documents cover **any kind medium** of publication (online, print media, submission in INSDC databases, etc.)
- ▶ Clearly **exclude any embargo** for the publication of generated data results.
- ▶ Each party shall **indemnify** the other from and **against all claims by third parties** arising out from the ownership or the infringement of Intellectual Property Rights.
- ▶ **Clauses to hold back or publish scientific results:**
  - be aware that contracts of some Providing Countries include clauses that request ‘affirmation’ or registration or want to ‘approve’ or ‘review’ for research results and/or publications.
  - This usually collides with publication requirements of funding bodies and the principle of freedom of research

# ABS Contracts: remarks and pitfalls

- **Duration and termination**

- ▶ Be aware that **contracts are terminated** and may be renewed to avoid that they expire
- ▶ Even if a contract expires, the **contractual conditions** [e.g. for the biological material] **should persist**, which may cover
  - Subsequent usage of accessed biological material for new projects
  - Transfer of biological material to third
  - Conditions to share unpublished data
- ▶ In case of breach of contract, contract clauses should prevent the immediate termination of running projects (and prevent potential liability risks towards funding bodies)

# CETAF Material Transfer Agreements

- **Part of the approved EU Best Practice**

- ▶ Meet the documenting requirements of the EU ABS Regulation
- ▶ Cover all relevant legal areas that need to be considered
  - Supplier, Recipient and User of GR
  - Terms on how the biological material can be used
  - Available documentation and permit that are relevant and must be considered
- ▶ Easily transformed into an PDF form
- ▶ CETAF [MTA 1](#); [MTA 2-4](#)

## CETAF MTA 1

### Material Transfer Agreement for PROVISION OF MATERIAL, with no change in ownership

#### Parties to the AGREEMENT

SUPPLIER (responsible researcher or staff):

RECIPIENT (receiving Institution):

USER of transferred GENETIC RESOURCES:

RESPONSIBLE PROJECT LEADER <sup>4</sup>:

#### Preamble

- This AGREEMENT covers the temporary transfer of MATERIAL containing GENETIC RESOURCES for non-commercial UTILISATION<sup>1</sup> with no change in ownership / permanent custodianship.
- The activities of our institution are guided by the Convention on Biological Diversity (CBD)<sup>2</sup> and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their UTILISATION (ABS)<sup>3</sup>. MATERIAL is transferred between both parties to this AGREEMENT on the condition that users agree to use MATERIALS and DATA in compliance with international laws and conventions. This AGREEMENT is designed to promote and facilitate non-commercial scientific research and transfer of GENETIC RESOURCES by research institutions and researchers that are associated to such institutions.

<sup>1</sup> This MTA is an advanced version of the Material Transfer Agreement that was developed jointly with the Global Genome Biodiversity Network (GGBN).

<sup>2</sup> <http://www.cbd.int/convention/text/>

<sup>3</sup> <http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

# CETAF Material Transfer Agreements

- **Why different MTAs?**

- ▶ MTA1 – transfer with no change in ownership
  - Ownership transfer might be prohibited by original permit
  - Institution may not want to share ownership (i.e. remains liable)
- ▶ MTA 2 – transfer with change in ownership
  - Ownership transfer might be required
  - Ownership transfer might be useful to support compliance and risk management (to exclude liability for third)

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CETAF MTA 1

Material Transfer Agreement for PROVISION OF MATERIAL, with no change in ownership

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CETAF MTA 2

Material Transfer Agreement for PROVISION OF MATERIAL, with change in ownership

Parties to AGREEMENT

SUPPLIER:

RECIPIENT (receiving institution):

USER of transferred GENETIC RESOURCES and/or RESPONSIBLE PROJECT LEADER:

Preamble

# CETAF Material Transfer Agreements

- Why different MTAs?

- ▶ MTA3 – receipt with change in ownership

- Ownership transfer might be prohibited by original permit
- Institution may not want to share ownership (i.e. remains liable)

## CETAF MTA 3

### Material Transfer Agreement for RECEIPT OF MATERIAL, with change in ownership

#### Parties to AGREEMENT

SUPPLIER:

RECIPIENT (receiving Institution):

USER of transferred GENETIC RESOURCES:

RESPONSIBLE PROJECT LEADER<sup>4</sup>:

#### Preamble

- This AGREEMENT covers the permanent transfer of MATERIAL containing GENETIC RESOURCES for non-commercial UTILISATION<sup>1</sup> with change in ownership / permanent custodianship.
- CETAF's activities are guided by the Convention on Biological Diversity (CBD)<sup>2</sup> and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS)<sup>3</sup>. MATERIAL is transferred between both parties to this AGREEMENT on the condition that users agree to use MATERIAL and DATA in compliance with international laws and conventions. This AGREEMENT is designed to promote and facilitate non-commercial scientific research and transfer of GENETIC RESOURCES, whilst recognising the terms on which the SUPPLIER acquired the MATERIAL.
- The conditions and clauses set out in MUTUALLY AGREED TERMS with the PROVIDING COUNTRY for the access of the GENETIC RESOURCES transferred under this AGREEMENT remain valid for the RECIPIENT and the subsequent UTILISATION of this MATERIAL. The SUPPLIER reserves the right not to supply any MATERIAL if such supply would be contrary to any terms attached to the MATERIAL and/or is not consistent with provisions of the CBD.

<sup>1</sup> This MTA is an advanced version of the Material Transfer Agreement that was developed jointly with the Global Genome Biodiversity Network (GGBN)

<sup>2</sup> <http://www.cbd.int/convention/text/>


<sup>3</sup> <http://www.cbd.int/abs/doc/nagoya-protocol-en.pdf>

# CETAF Material Transfer Agreements

- Why different MTAs?

- ▶ MTA3 – receipt with change in ownership
  - Ownership transfer might be prohibited by original permit
  - Institution may not want to share ownership (i.e. remains liable)
- ▶ MTA 4 – guest scientists with own GR
  - Ownership transfer might be required
  - Ownership transfer might be useful to support compliance and risk management (to exclude liability for third)

LIB Leibniz-Institut zur Analyse des Biodiversitätswandels



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CETAF MTA 4  
Agreement for guest researchers BRINGING BIOLOGICAL MATERIAL to facilitate their own research at hosting institutions

Parties to AGREEMENT

<u>GUEST RESEARCHER</u> _____ (name and institution)	<u>HOSTING INSTITUTION</u> (name and Department):
<input type="text"/>	<input type="text"/>
<u>USER OF THE GENETIC RESSOURCES:</u> (name and institution)	<u>RESPONSIBLE PROJECT LEADER<sup>1</sup></u>
<input type="text"/>	<input type="text"/>

<sup>1</sup> person that may have or is appointed with ABS-reporting obligations

CETAF MTA 4 developed jointly by The Smithsonian Institute (USA) and the CETAF Legislations and Regulations core team  
ANNEX 6.4 to the CETAF CoC for ABS, UPDATED 26 October 2018

# CETAF Material Transfer Agreements

- **Why different MTAs?**

- ▶ Transfer of ownership determines which MTA should be filled in
- ▶ Check boxes guide you through relevant decisions / points
- ▶ Original signatures are required before the material is transferred (no email-scans, JPGs, etc.)
- ▶ Update traditional loan forms to prohibit destructive sampling (DNA extraction is consumptive, thus nothing can be loaned and returned)



## ABS working group drafting CETAF CoC

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