



# Novel challenges and predicted trends for culture collections in the age of the Nagoya Protocol

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# Challenges – Predictions – Possible Solutions

- Risks and transaction costs for users of microbial resources
- EU-registered collections – first experiences of the DSMZ
- Future deposits in culture collections
- Harmonization of accession policy between culture collections
- Exploitation of microbial resources for bioeconomy

EU Regulation EU 511/2014

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=EN>



# Risks and transaction costs for users

## Compliance

- (1) legally acquire and document any microbial resource
- (2) declare and prove due diligence
- (3) enable inspections by the national authorities

## Reporting duties

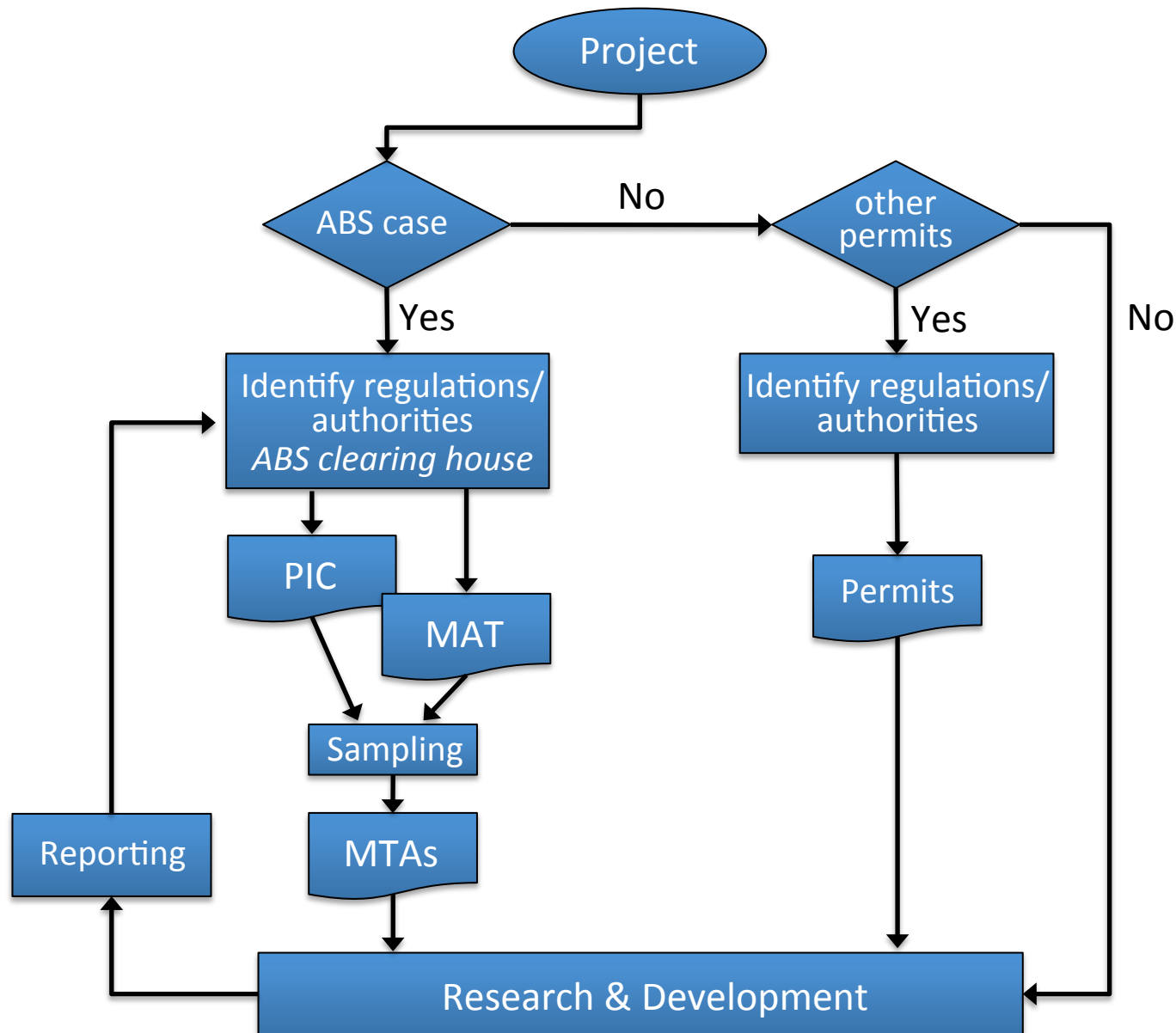
- declaration of due diligence when research funding is received (Art 7, §1) for project involving strains from abroad. Provide declaration acc. to Art 7(1) EU 511/2014 and Art 5, EU 2015/1866.
- for final development of product (Art. 7, §2).

## Exercise due diligence

Traceability (for 20 years), risk mitigation, risk assessment; transfer of information to subsequent user!



# Procedure to comply with CBD and NP





# Risks and transaction costs for users

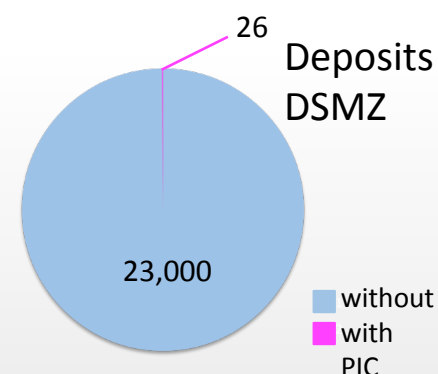
**PIC** = general information about intended research

**MAT** = contractual agreement on use and benefit sharing

**MTA** = information on origin, provider, recipient, use, distribution

Valid **PIC** and **MAT** (sometimes labeled "MTA") with

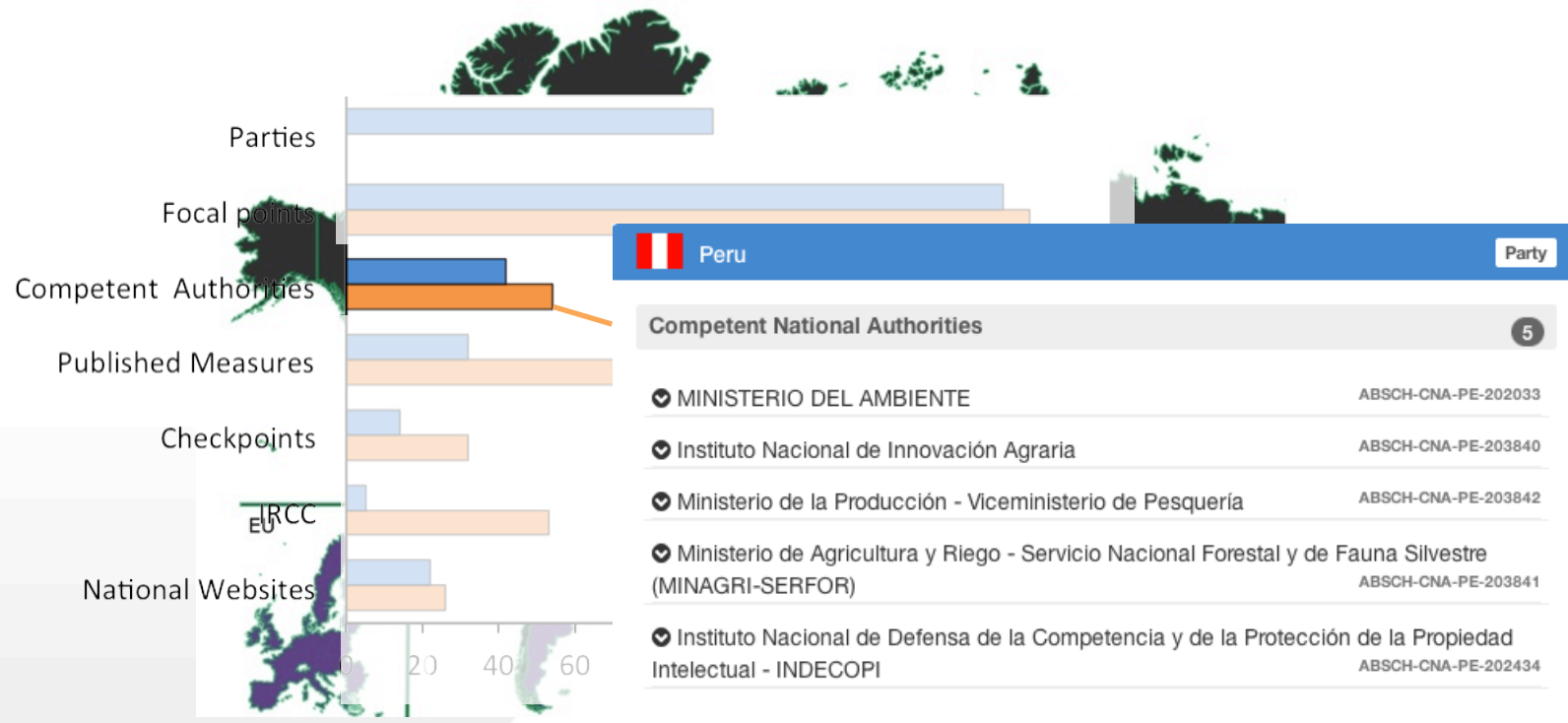
- names, addresses, authorized signatories of provider and recipient
- country of origin, place and date of sampling, sampling person
- description of genetic resource, sample/strain no. for traceability
- source and subsequent users
- terms of use (testing, research, commercial: MTA) and of ABS
- access/export permits
- records to be kept for 20 years



**For compliance: to be obtained for any strain where applicable**



# Current state of implementation



Essential for international implementation:

*ABS Clearing House (ABSCH)*- platform for exchanging information on ABS

<https://absch.cbd.int/search/national-records/MSR>



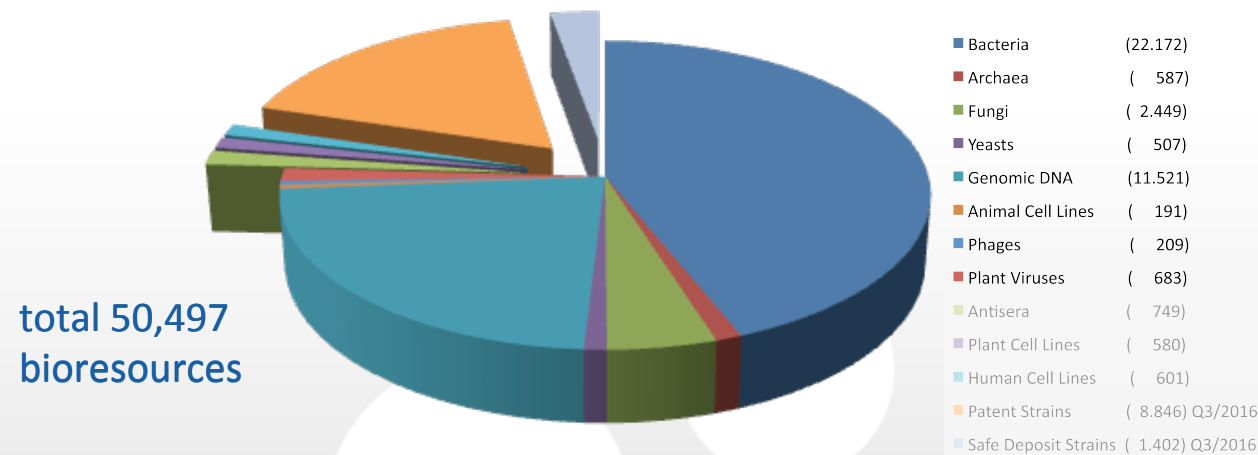
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# EU-registered collections

**Acquisition of genetic resources from EU-Registered Collection considered as exercised due diligence (Regulation 511/2014, Art 5 §3; Implementing Regulation 2015/1866)**



# Applies to majority of microbial resources kept in Microbial Resource Centers such as DSMZ



# EU-registered collections

## ⇒ Transaction costs shifted to culture collection Need to check compliance for deposited strains

- ① Substantial legal issues require an in-house lawyer at DSMZ
- ② Increasing bureaucratic burden (foreign official languages)
- ③ Establishing and maintaining a suitable IT infrastructure
  - Online accession form for all departments, with automated functions
  - Document management system
  - Digital storage information (institute-wide)
  - Website updates (for depositors, customers, draft PIC/MAT documents)
  - Consolidated web catalog


### **E.1 Für Bürgerinnen und Bürger bzw. die Wirtschaft:**

Durch die Verordnung (EU) Nr. 511/2014 entstehen betroffenen Bürgerinnen und Bürgern sowie der Wirtschaft Zeitaufwand und Mehrkosten aufgrund von Melde-, Aufbewahrungs-, Auskunfts- und Mitwirkungspflichten sowie insbesondere aufgrund der Sorgfaltspflichtregelung aus Artikel 4 der Verordnung (EU) Nr. 511/2014. Durch das


from: Draft of  
German legislation



# Ensuring the compliance with CBD and NP



**Leibniz-Institut DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH**  
*Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures*



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**Nagoya Protocol**

Member of



Deposit > Nagoya Protocol


## Deposit of biological material at the DSMZ: Compliance with the Nagoya Protocol

The Leibniz Institute DSMZ is subject to German national laws as well as European Union laws and regulations. In October 2014, the implementation of the Nagoya Protocol (NP) went into effect across the EU Member States. Germany has subsequently passed implementing legislation of EU Regulation 511/2014. These laws deal with the accession and distribution of all genetic resources (i.e., biological material) except human genetic resources. Genetic resources collected prior to December 29, 1993 were not subject to international laws on biodiversity. **Please review your legal situation before beginning the depositing process and be prepared to upload all associated legal documentation.** The [ABS Clearinghouse](#) can be a helpful place to start.

**ALL DSMZ depositors of non-human biological material MUST** provide the following information:

NOTE (as of May 2016): The online accession forms are currently being updated to match the format below. In the interim, please have the information available as requested.



- 1) The **country** where the genetic resource was collected. (Samples collected in "International Waters" or in "Antarctica" should be listed under these locations.)
- 2) The **exact location** where the genetic resource was collected (GPS coordinates where possible).
- 3) The **date** of collection.

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# Ensuring the compliance with CBD and NP

**Failure to provide the information above could result in rejection of a deposit at the DSMZ.**

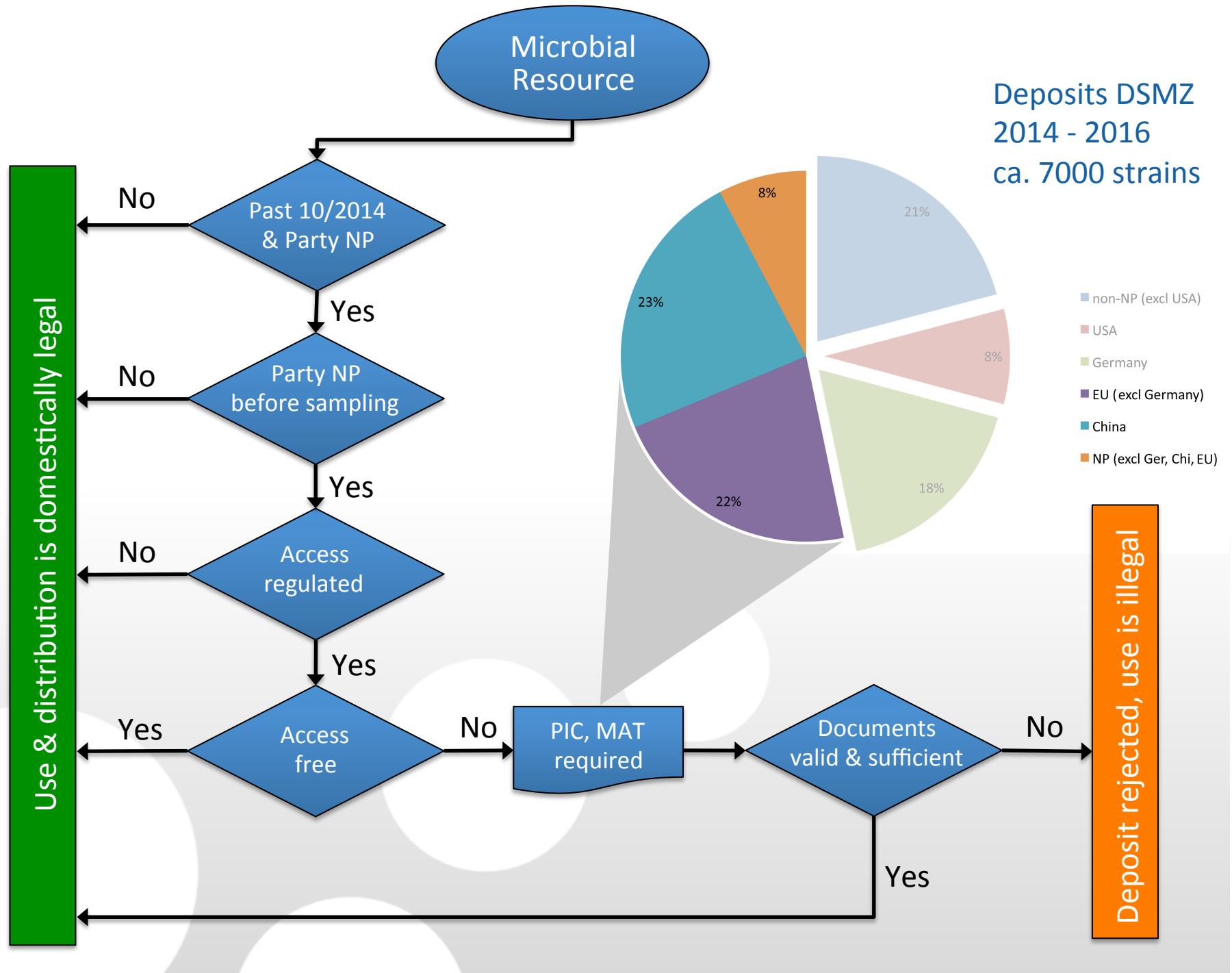
Based on the instructions shown above, the following scheme may give you an overview about the information you have to provide to the DSMZ, depending on your specific resource:

What applies to your resource? <small>Specific questions? See ABS Clearinghouse (<a href="https://absch.cbd.int">absch.cbd.int</a>)</small>	Please provide:	
<ul style="list-style-type: none"> <li>→ Collected prior to Dec. 29, 1993 or</li> <li>→ Collected in international waters or Antarctica or</li> <li>→ Country where collected is non-party or did not ratify CBD* (e.g., USA) or</li> <li>→ Country is a party to CBD and to NP*, but provides free access to their genetic resources or has no access legislation (e.g., Germany).</li> </ul>	Basic Information	
<ul style="list-style-type: none"> <li>→ Country is party to CBD, but not NP (e.g., China, Canada, New Zealand) or</li> <li>→ Country is party to CBD and signatory to NP, but has (had) not yet passed implementing legislation or</li> <li>→ Country is party to CBD and to NP and does not provide free access but sample was collected <u>before October 12, 2014</u></li> </ul>	Basic Information	Additional Information Documentation (recommended)
<ul style="list-style-type: none"> <li>→ Country is party to CBD and party to the NP and does not provide free access and sample was collected <u>after October 12, 2014</u></li> </ul>	Basic Information	Additional Information Documentation (required)
Basic Information	Additional Information	Documentation
<ul style="list-style-type: none"> <li>• Country and exact location where genetic resource was collected.</li> <li>• Date of collection.</li> </ul>	<ul style="list-style-type: none"> <li>• Name of the national competent authority that granted access.</li> <li>• Confirmation that DSMZ is allowed to deposit and distribute your biological resource.</li> </ul>	<ul style="list-style-type: none"> <li>• Prior Informed Consent (PIC) and/or Mutually Agreed Terms (MAT), and a Material Transfer Agreement (MTA) from the provider country.</li> </ul>

\* CBD: Convention on Biological Diversity  
NP: Nagoya Protocol









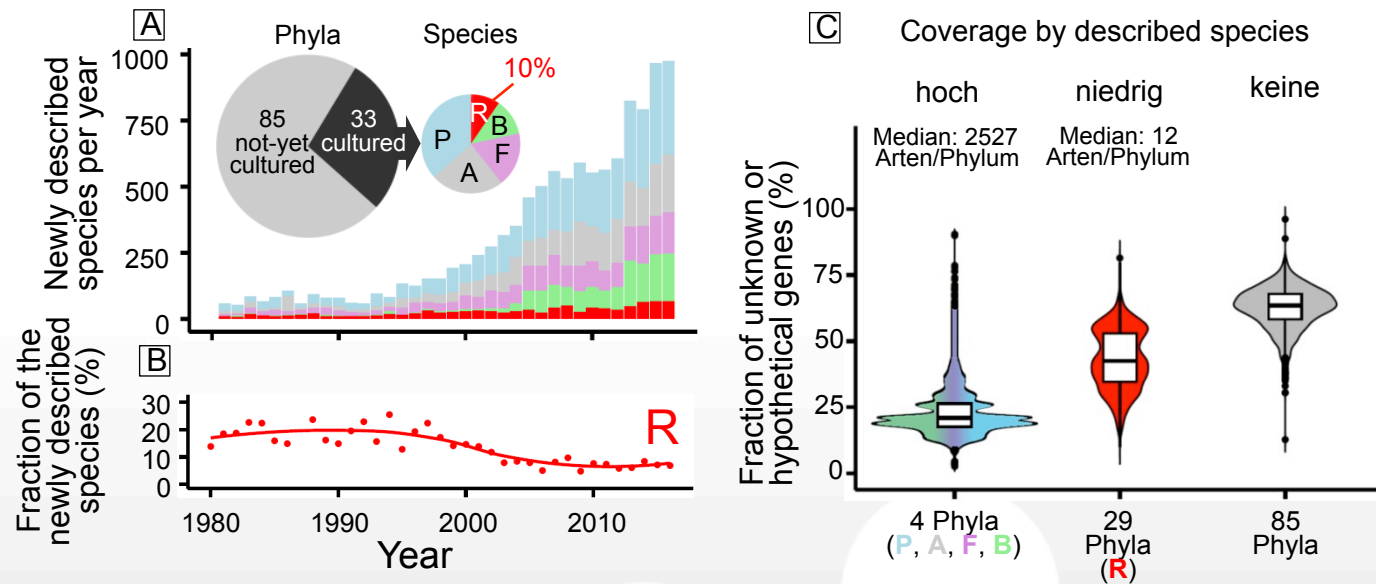
# Future deposits in culture collections

## Who will describe – and publish – new taxa?

- Currently: 2/3 of strains in the Global Catalogue of Microorganisms from Europe & industrialized Asian countries (BUT: current massive decline in deposits from PR China)
- Bilateral collaborations in basic research (Germany: SPPs/SFBs funded by DFG; BMBF program TFO, Biodiversity and Health Indonesia) particularly affected by NP
- Competitive success in description of novel taxa severely impeded by legal restrictive policies of provider country. Domestic researchers outcompeted, if not
  - given permission to deposit in international public repositories
  - given permission to exchange material with international collaborators
  - getting access to bioresources from foreign countries



# Future deposits in culture collections



Large opportunities to elucidate and access microbial diversity

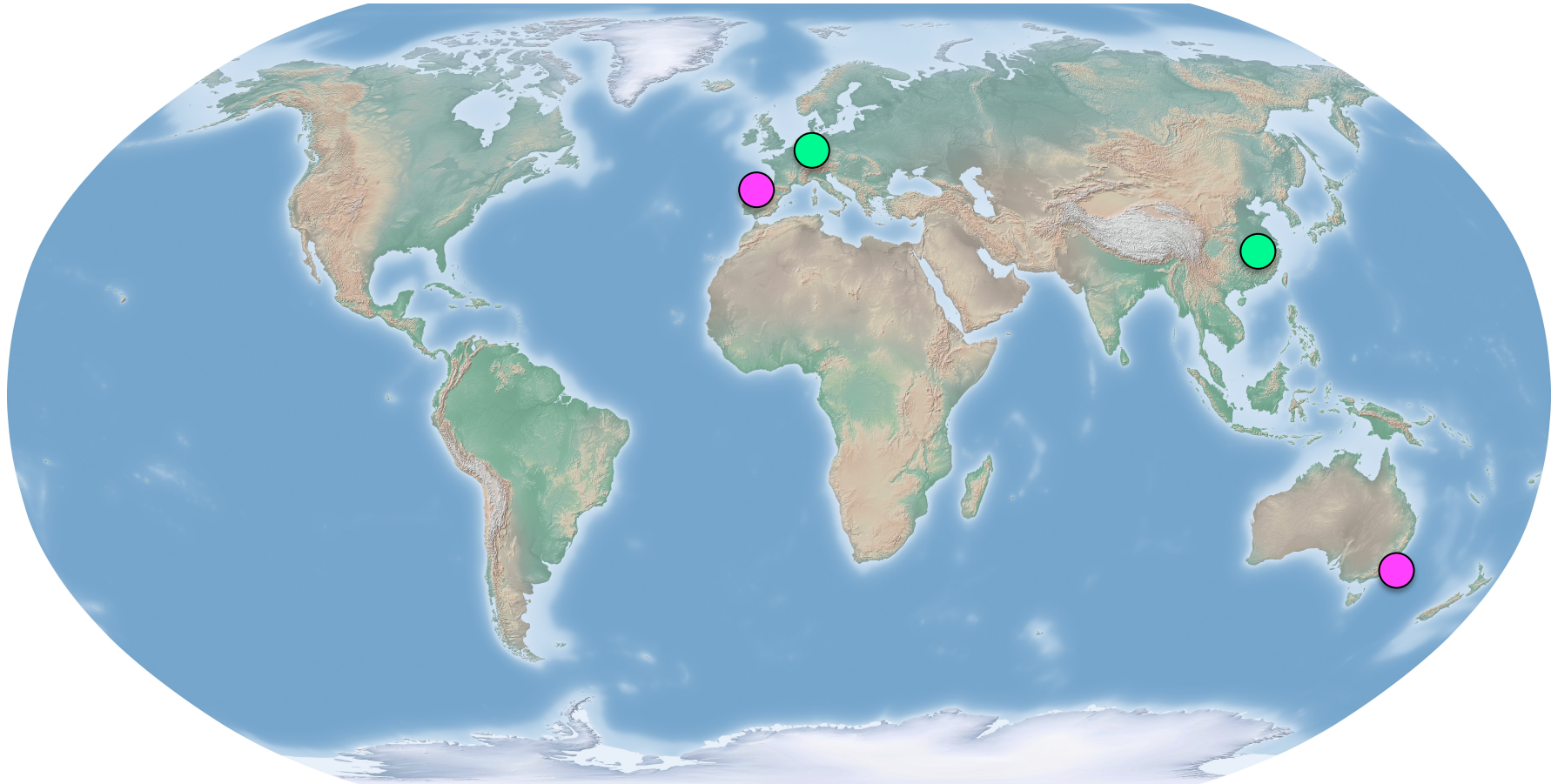
# Biogeography of microorganisms: no endemisms

*"Candidatus Kuenenia stuttgartiensis"* (Anammox Planctomycetes●)

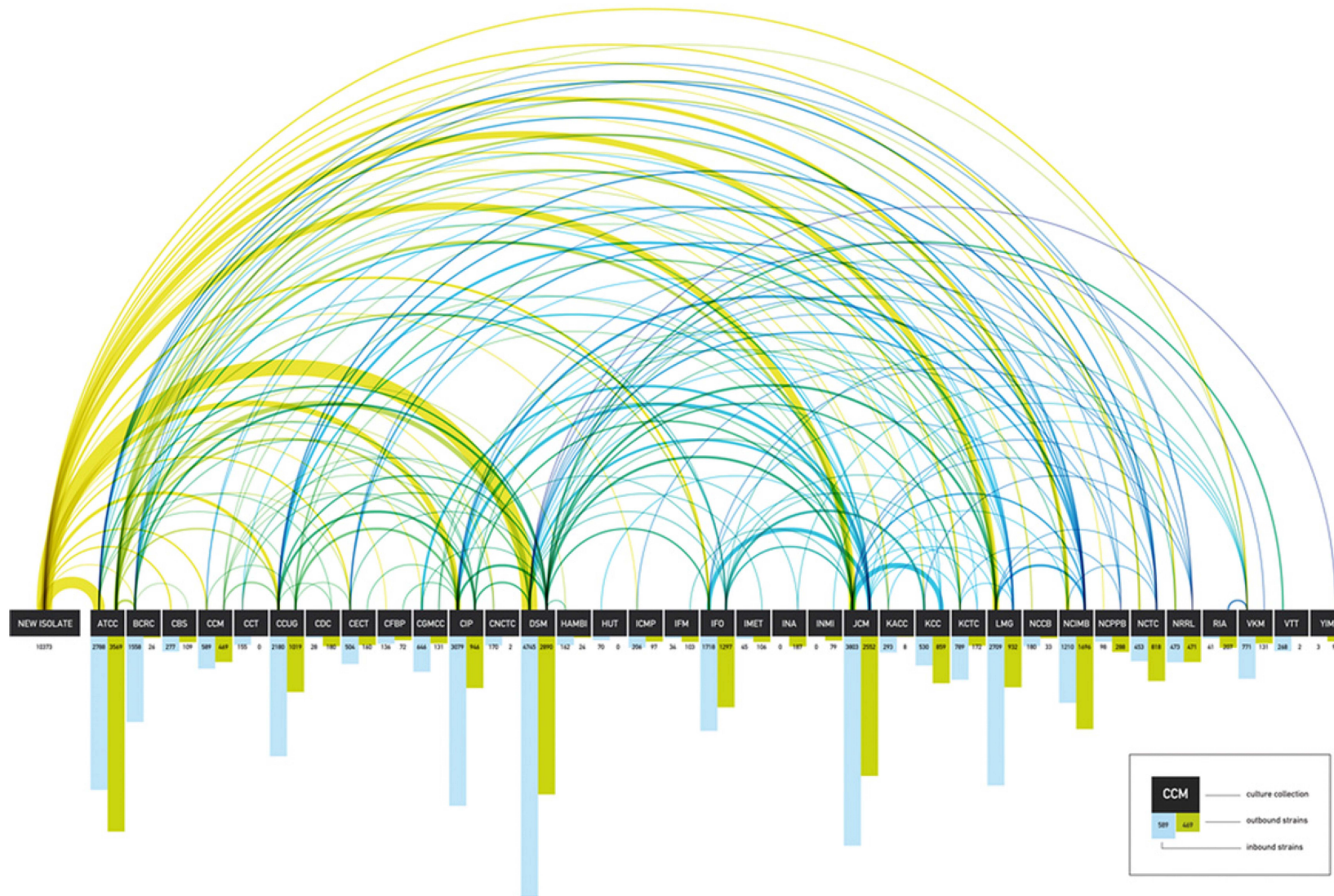
- 100% sequence identity 16S rRNA, >99% sequence identity genomes strains RU1 / CH1
- CH1 lacks 11 kb in 31 genomic regions, 220 kb unique, mostly mobile elements

*Phaeobacter gallaeciensis* (on surfaces, antibiotic TDA●)

- 100% sequence identity 16S rRNA, 97% sequence identity genomes strains DSM17395 / 2.10
- share 88-93% of genes, genomes and plasmids highly syntenous; diff. LGT and prophages



# Harmonization of accession policy between CCs





# Harmonization of accession policy between CCs

## Solution

- Need more transparent and harmonized access policy between CC
- Unambiguous policy of publication and validation of new species (in particular, IJSEM)

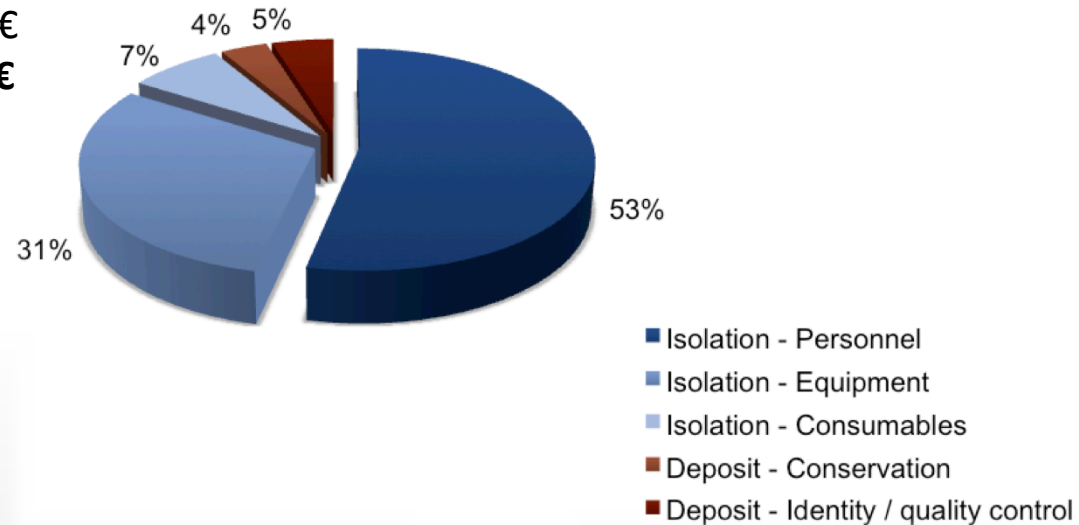


# Application of microbial resources in bioeconomy

- Most access to genetic resources done without commercial intent (Buck & Hamilton, 2011)
- Customers with commercial intent abstain from strains from public collections
- DSMZ: per year 40,000 microbial resources delivered for research, only 1 for commercial use
- Only <1.5% of applications at German Patent Office were from universities in 2012
- Successful commercial ABS very rare (BMBF project Pro-benefit 2003-2008 in Ecuador, framework for establishing commercial bioprospecting. No final agreement)
- Industrialized and developing countries similarly attractive for studying microbial diversity: opportunities in Germany, Denmark (w/o Greenland, Faroe), Sweden, Norway, Finland, The Netherlands, UK, Czech Republic, and countries with similar policy in EU will be increasingly exploited

# Monetary value of bacteria *in situ* and *ex situ*

Isolation	9,836 €
Deposit	918 €
<b>Total</b>	<b>10,754 €</b>



- individual bacteria no monetary value *in situ* (functional redundancy, no endemisms)
- isolation requires considerable investment (10,000 €/strain)
- untargeted approach not viable:  
e.g., per drug 100,000 strains x 10,000 €/strain = 1 b€

# Application of microbial resources in bioeconomy

## Requirements bioindustry ≠ expectations provider countries

- Bioindustry often **avoids initial costly steps** of bioprospection
- Bioindustry interested in ABS negotiations for **promising** microbial resources only (not for all microbial resources that may be isolated), will accept only **strains with PIC/MAT**, negotiated change of intent
- Promising strains are those with sufficiently **detailed information** (particularly from first line screening) – extended characterization
- **Exclusive** access to strains of interest, selected by key data
- **Scale** - collectives of overall 10,000 strains, single orders of 50 strains

⇒ **Bioindustry seeks reliable source of strains and honest broker**





# Conclusions

- ① Without professional support, most users will face increasing transaction costs ⇒ abandon work on non-domestic microbial cultures, or run into risk of non-compliance and fines
- ② Contrary to perceptions in national politics, implementation of NP will incur significant transaction costs for culture collections, if registering
- ③ Harmonization of accession policy is a key measure for a meaningful implementation of the NP in European culture collections
- ④ Industrialized and developing countries offer similarly attractive opportunities for bioprospection
- ⑤ Future, novel roles of microbial resources centers and MRC networks are foreseeable and are key for the development of bioeconomy

# Thank you



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