

#### The EU's first Registered Collection

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Amber Hartman Scholz, Ph.D. | Deputy to the Director

# Leibniz Institute DSMZ a Biological Resource Center



- 10,000 customers
- 86 countries
- 65% international customers
- 60% academic customers



## What in the heck is a Registered Collection?

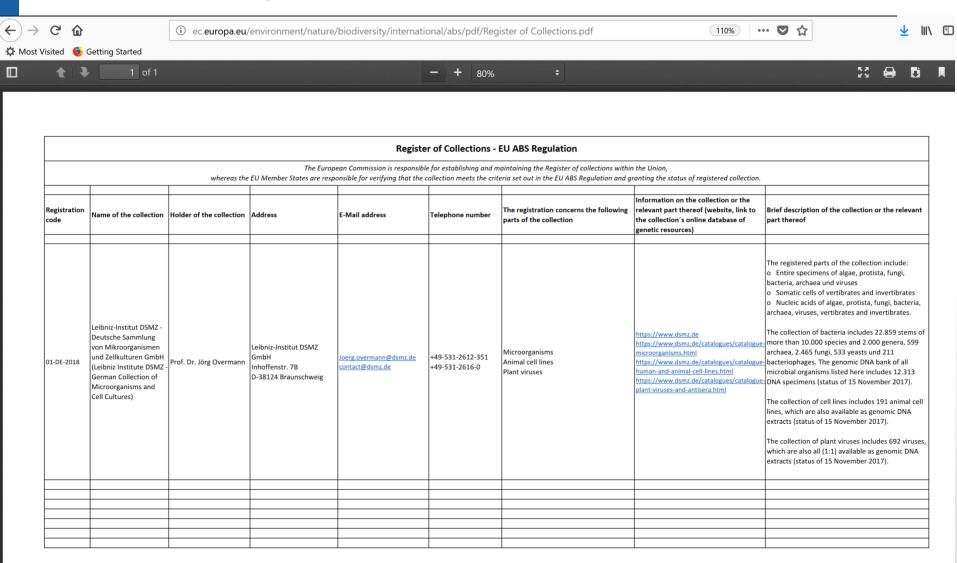


#### Article 5

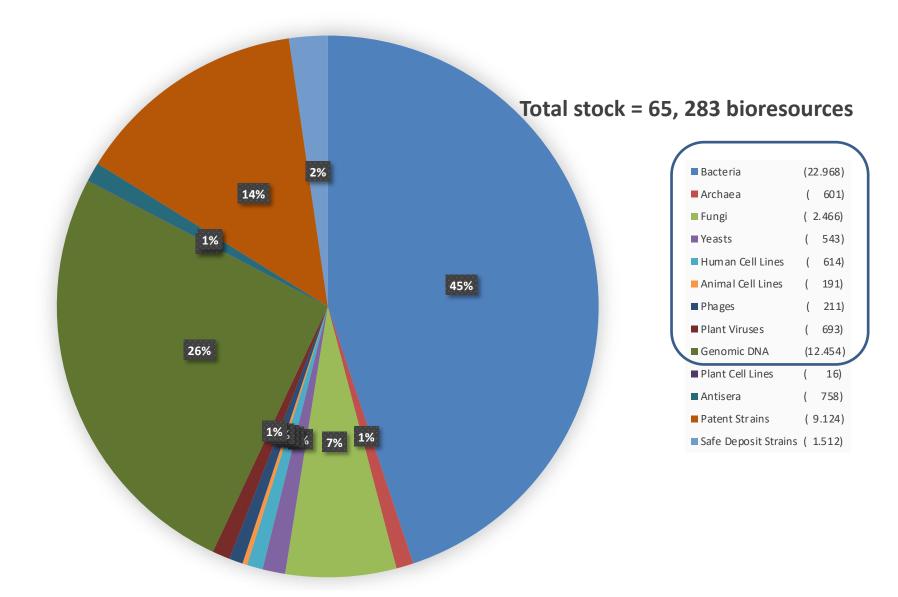
#### Register of collections

- 1. The Commission shall establish and maintain a register of collections within the Union ('the register'). The Commission shall ensure that the register is internet-based and is easily accessible to users. The register shall include the references of the collections of genetic resources, or of parts of those collections, identified as meeting the criteria set out in paragraph 3.
- 2. A Member State shall, upon request by a collection holder under its jurisdiction, consider the inclusion of that collection, or a part of it, in the register. After verifying that the collection, or a part of it, meets the criteria set out in paragraph 3, the Member State shall notify the Commission without undue delay of the name and contact details of the collection and of its holder, and of the type of collection concerned. The Commission shall without delay include the information received in the register.
- 3. In order for a collection or a part of a collection to be included in the register, a collection shall demonstrate its capacity to:
- (a) apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their utilisation in line with the Convention and the Nagoya Protocol;
- (b) supply genetic resources and related information to third persons for their utilisation only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with mutually agreed terms;
- (c) keep records of all samples of genetic resources and related information supplied to third persons for their utilisation;
- (d) establish or use unique identifiers, where possible, for samples of genetic resources supplied to third persons; and
- (e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

# It took 1.5 years to land here!



#### What did we register? 83% of the collection





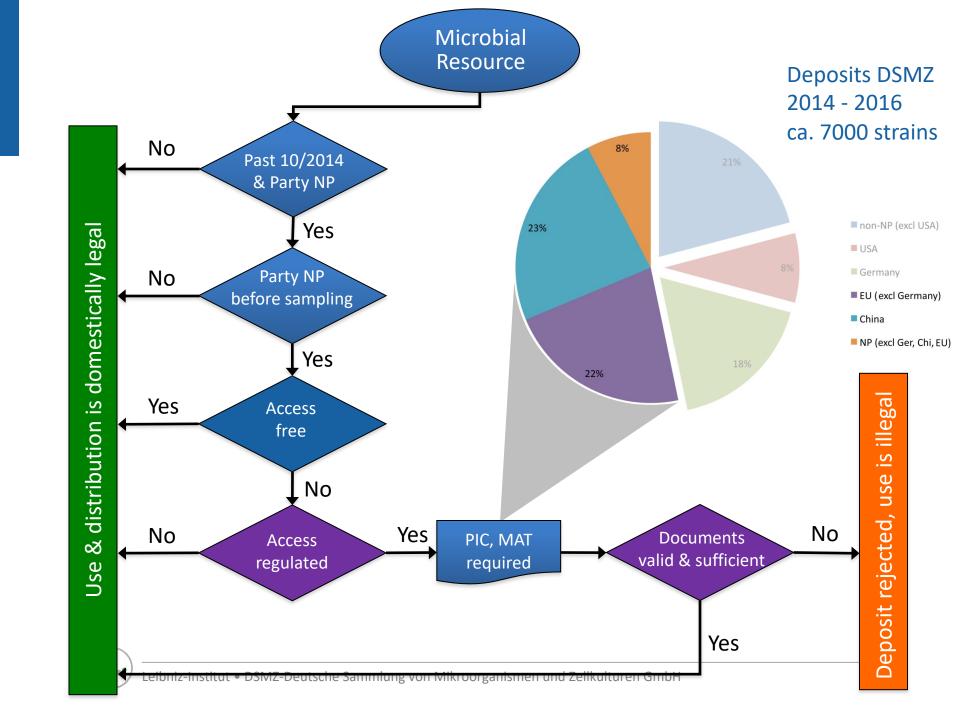
#### **Up-front information for depositors**

https://www.dsmz.de/deposit/nagoya-protocol.html

What applies to your resource?  Specific questions? See ABS Clearinghouse (absch.)	Please provide:	
<ul> <li>→ Collected prior to Dec. 29, 1993 or</li> <li>→ Collected in international waters** or Anta</li> <li>→ Country where collected is non-party of CB</li> <li>→ Country is a party to CBD and to NP*, but page 2</li> </ul>	Basic Information	
<ul> <li>→ Country is party to CBD, but not NP (e.g., Canada, New Zealand) or</li> <li>→ Country is party to CBD and party to NP, but has (had) not yet passed access regulations or legislation or</li> <li>→ Country is party to CBD and to NP and does not provide free access but sample was collected before October 12, 2014 or before the NP went into force in that country</li> </ul>		Basic Information Additional Information Documentation (recommended)
→ Country is party to CBD and party to the NP and does not provide free access and sample was collected after the NP went into force in that country		Basic Information Additional Information Documentation (required)
Basic Information	Additional Information	Documentation
<ul> <li>Country and exact location where genetic resource was collected.</li> <li>Date of collection.</li> </ul>	Name of the national competent authority that granted access.	Prior Informed Consent (PIC) and/or Mutually Agreed Terms (MAT), and a Material Transfer Agreement (MTA) if required by the provider country.

<sup>\*</sup> CBD: Convention on Biological Diversity NP: Nagoya Protocol

<sup>\*\*</sup> International waters are marine locations outside of territorial waters or Exclusive Economic Zones where no country exercises sovereign rights.



# Online accession form: dynamic connection to ABSCH API

https://absch.cbd.int/about/api

What information can you use From the API??

- Country
- NP/CBD status
- Effective date

#### NOT:

- Legislation yes/no
- Free access
- No information



#### Accession Form - Microorganisms

Make sure that you fill in the mandatory fields marked \*.

- ▶ Full Postal Address
- ▶ General
- ▶ Origin of Strain
- ▶ CBD and NP Compliance
- ▶ Strain History
- ▶ Additional Data
- Risk Assessment
- ▶ Plasmid Data
- ▶ Cultivation
- References

#### ▼ Finish

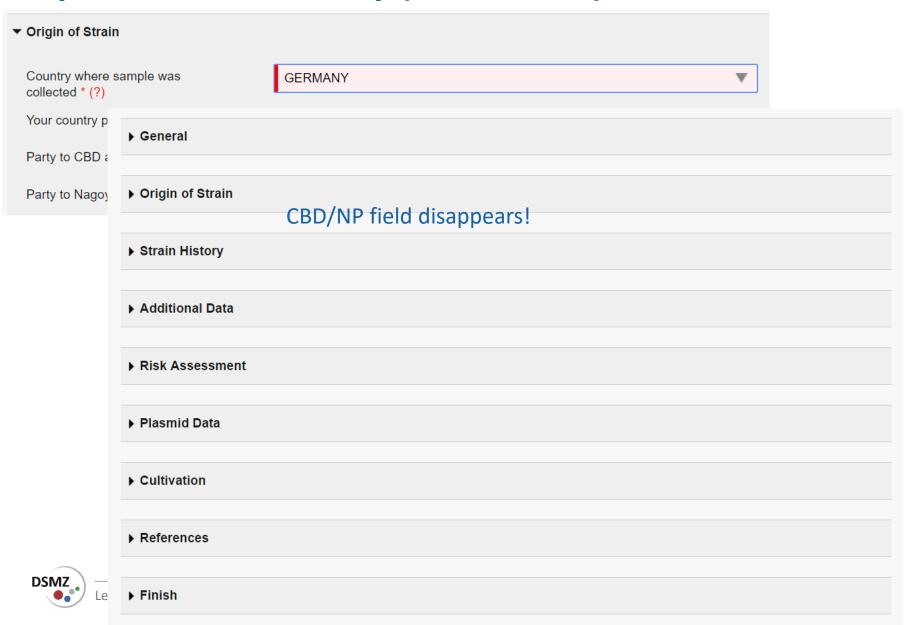
I hereby confirm that the above statements are true and, to the best of my knowledge, that the isolate was legally accessed in the country of origin. I understand that this accession form and the uploaded documents are evidence for the legally compliant acquisition, transfer, and utilization of the isolate in the public collection of DSMZ and to subsequent users.

I have read and accept the DSMZ GmbH Terms & Conditions (MTA) > (or AGB > in German). I understand that subcultures of the deposited strain will be listed online and distributed by the DSMZ for a reasonable fee to cover actual expenses.

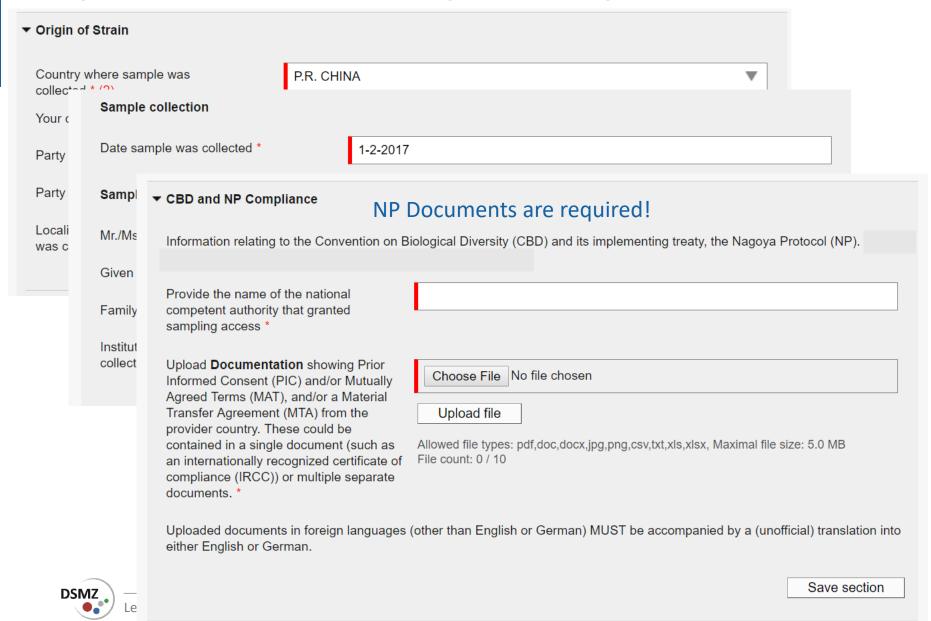
All deposits in the open collection will be handled confidentially until the DSM number, taxonomic name, or strain designation is published in a journal or the depositor indicates that the strain may be released. Otherwise, DSMZ reserves the right to release the strain four years after deposit.

Type strains are to be deposited in conformity with the International Code of Nomenclature of Prokaryotes a. This means that NO restrictions are placed on type strains for further distribution or access to them for the purpose of systematic research.

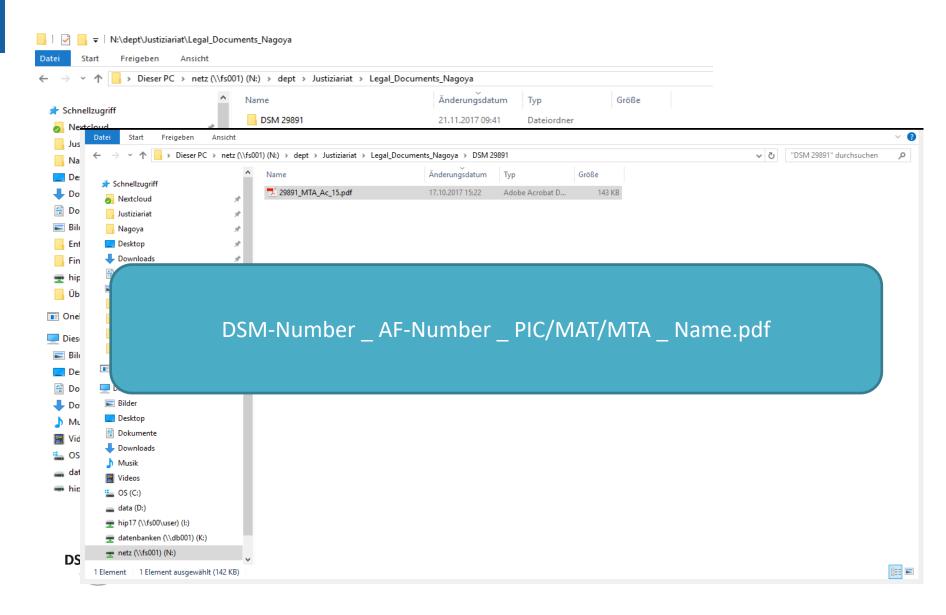
# **Deposit from Germany (free access)**



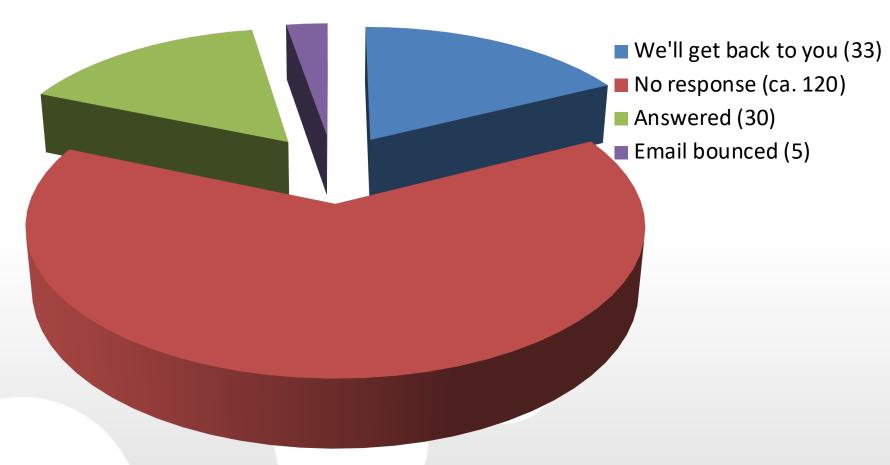
## **Deposit from China (Party since Sept. 2016)**



# Legal checks done manually by in-house counsel



# It is challenging to get information on CBD/NP compliance via ABS-Clearinghouse

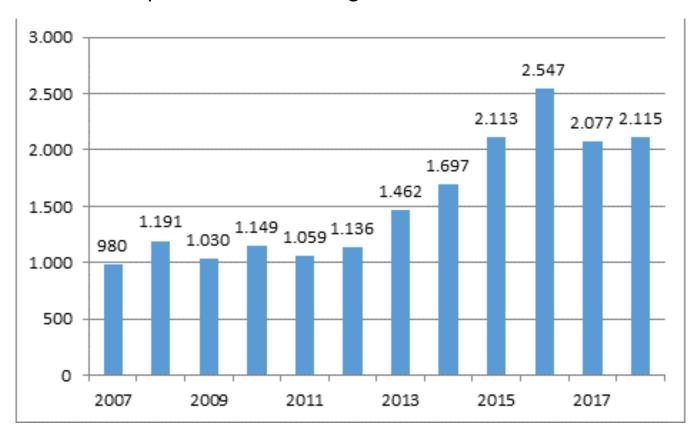


- Response rate of all 198 CBD countries after request for information
- Sept. 2017-June 2018



#### Unfortunate side effects: ~25% decrease in deposits

#### Deposits in the microorganisms collection





# India: sectorspecific problem

**CSMCRI** 

Prof. Bhavan **Chief Scientis** 

Resource can be deposited but not distributed without permission

This is

Dear S

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subject Bacter

**Bacterial Nomenclature** Rules: "must be freely available without restrictions"

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Thanks

Yours

Bhavar

Form - C

Deposition of micro-organism by Indian scientist/ researchers in non-Indian repository for claim of novel species

1.	Name of the depositor	Prof. Bhavanath Jha, Chief Scientist
2.	Complete Address with contact details	CSIR - Central Salt and Marine Chemicals Research Institute, G.B. Marg, Bhavnagar - 364002 Email: bjha@csmcli.pls.in
3.	Name(s) of the micro-organism(s) to be deposited in the foreign repository	<ol> <li>Streptomyces sp. JJ36</li> <li>Streptomyces sp. JJ38</li> <li>Streptomyces sp. JJ53</li> <li>Streptomyces sp. JJ66</li> <li>Styreptomyces sp. JJ73</li> <li>eg genus)</li> </ol>
4.	Geographical location microorganism was iso	Ip 20"N 70°57'400"E), Diu
5.	Name and contact detail repository where the resource(s) are to be deposited	SMZ-German Collection of and Cell Cultures, Germany
6.	Purpose of deposition	m of novel strains
7.	Name and contact details of repository where the biologicare deposited	Gerobial Culture Collection (IMCC) Type Culture Collection (MTCC,
8	Accession number allott repository to microorganisms	36 - IMCC1891 - IMCC1892 IMCC1893 Strepto - IMCC1894 Strepto - JJ73 - IMCC1895 Strain JJ - IMCC1896

#### Declaration

I Prof. Bhavanath Jha, an Indian chief scientist/ researcher, have read and understood the terms and conditions for depositing the microorganisms in recognized repositories outside India for claim of novel species.

I further declare and solemnly affirm that the information provided above is true and correct.

Place: Bhavnagar

Date: 28.11.2017

Signature of the Depositor

**DSMZ** Leibniz-Institut • D



# What does our catalog look like?

BACTERIA	${f \hat{I}}$ How to read the following data (Example) $\omega$	
Name:	Stenotrophobacter roseus Pascual et al. 2016	
DSM No.:	29891, Type strain	
Strain designation:	Ac_15_C4	
Other collection no. or WDCM no.:	LMG 28889	
Isolated from:	semi-arid old flood plain fallow soil	
Country and date of sampling:	Namibia, Kavango region, Mashare (17° 53' 37.9" S, 20° 14' 50.7" E)	
History:	<- A. Geppert, Leibniz-Institut DSMZ GmbH, Braunschweig, Germany; Ac_15_C4 <- A. Geppert and P. Kaul	
Genbank accession numbers:	16S rRNA gene: KP638489 ₽	
Cultivation conditions:	Medium 1426 pH 7.0 $\ensuremath{\omega}$ , use HEPES (2.38 g/l) instead of MES, adjust to pH 7.0, 28°C	
	Incubation time: 3-7 days	
	Complete DSMZ Media List $\omega$	
Summary and additional information:	<- A. Geppert, Leibniz-Institut DSMZ GmbH, Braunschweig, Germany; Ac_15_C4 <- A. Geppert and P. Kaul. Semi-arid old flood plain fallow soil; Namibia, Kavango region, Mashare (17° 53' 37.9" S, 20° 14' 50.7" E). Type strain. Taxonomy/description (25443, 25463). Sequence accession no. 16S rRNA gene: KP638489. (Medium 1426 pH 7.0, 28°C, use HEPES (2.38 g/l) instead of MES, adjust to pH 7.0).	
Literature:	25443 ₪, 25463 ₪	

Risk group:	1 (provisional classification by DSMZ)		
Restrictions:	Material transfer agreement, Category D 🗈		
Supplied as:	Delivery form         Prices           Freeze Dried         80,- €           Active culture on request         185,- €           DNA         120,- €           Price Category for this culture: 1		
Other cultures:	Freight and handling charges will be added. See price list.   All DSMZ cultures of the species »		
Nagoya Protocol Restrictions:	Documentation related to the Convention on Biological Diversity and the Nagoya Protocol. Users must download, read, and adhere to the terms listed in the document(s) listed here. Users are legally required to maintain records of these document(s) for 20 years after the last use of the resource.  File download   Protocol.		
Date of Collection (in situ sampling):	26.03.2011		



#### 1. Namibia



#### NATIONAL BOTANICAL RESEARCH INSTITUTE

# AGREEMENT FOR THE SUPPLY OF BIOLOGICAL MATERIAL FROM THE REPUBLIC OF NAMIBIA FOR SCIENTIFIC RESEARCH PURPOSES

Ac_28_D10  Acidobacteriaceae bacterium sg4	Live culture, isolated from Okavango riverside soil (JO- 2011-MRT5), collection permit 1569/2011, MTA of April 04, 2011	Deposit at DSMZ and LMG - mandatory for valid species description
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- 8. Permission is granted to deposit the named strains of microorganisms in two public collections (1. Leibniz-Institut DSMZ Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH; 2. BCCM/LMG Belgian Co-ordinated Collections of Micro-organisms / Laboratorium voor Microbiologie, Universiteit Gent) and these strains may be made available for strictly scientific purposes only under the user agreement of the respective culture collections. The user agreements should be no less restrictive than the conditions originally signed with NBRI.
- 9. The research of the strains made available by the respective culture collections to further users under this agreement (clause 8) shall be limited to scientific purposes. Any use for commercial research including genome sequencing or any use for commercial applications is excluded and requires prior written permission from the NBRI.
- 10. The above public culture collection making available the strain(s) for scientific purposes shall inform the NBRI in writing of such





## 2. Ethiopia

##C EBT 71/1091 [2017] Ref. No. 0 3 JAN 2017]

Addis Ababa University Institute of Biotechnology Addis Ababa, Ethiopia

Subject: Material Export Permit

#### 4. Utilization of Material

- The Researcher shall utilize the material for said research program.
- The Researcher cannot use the material for commercial purpose nor can he obtain any intellectual property right on the material.
- 3. The Researcher retains the material for the period of the research in Germany where upon completion he shall return any remaining unused material to the Provider. But, if any, new virus isolates and diagnostic antibodies are to be deposited as reference in and offered from the public collections of DSMZ for further studies to the scientific community.

Lagar Customs Office

Genetic Resources Access and Benefit Sharing Directorate
 Addis Ababa

9.A.4. 30726

4hh 011-6-613722 7.A.t. Fax 011-6-612542 P.O.Box

ስዲስ አበባ Addis Abab ስ.ትዮጵያ Ethiopia

Tel, 011-6-612244 011-6-512023 011-6-615607 011-6-616643

E-Mail:info@ibc.gov.et

AGO 07364A7 28 NORTH TAST EAST OFF FRANCE Please quote our Ref. No. when replying



# 3. Spain – taxonomic purposes only Effective date: March 15, 2017

Strain can be utilized for TAXONOMIC PURPOSES ONLY.

For all other non-commercial or commercial purposes, please contact the Spanish competent national authority for a permit. For more information, please see the Spanish FAQs (<a href="http://www.mapama.gob.es/es/biodiversidad/temas/recursos-geneticos/protocolo-de-nagoya/FAQ">http://www.mapama.gob.es/es/biodiversidad/temas/recursos-geneticos/protocolo-de-nagoya/FAQ</a> Autorizaciones.aspx) on access and benefit sharing.

The translation of the definition of exclusively taxonomic purposes that is established in the Spanish ABS bylaw is: "Application of principles and methods for identification, delimitation and classification of living beings, which requires the study of their phylogenetic relationships as well as the evolutionary and ecological processes that have generated biodiversity using morphological, physiological, genetics, behavioral and environmental data".

A mail box to answer questions on Spanish access legislation is set up: bzn-protocolonagoya@mapama.es

# Before user purchases a strain, she must commit to Nagoya restrictions

I have read and accept the DSMZ GmbH "Terms & Conditions" (or AGB in German, see https://www.dsmz.de/terms.html) and understand all of the obligations therein including:

If present, I will adhere to the requirements listed in the documents in the product's Nagoya protocol restrictions section of the online catalog and download and save the documents for 20 years after the last use of the product.

I will not distribute or share products with third parties or use products for commercial purposes. (Note: For some microbial strains, commercial use can be considered on a case-by-case basis. Please email <a href="mailto:sales@dsmz.de">sales@dsmz.de</a>. For plant virus diagnostic purposes, commercial use is permitted. See "Terms & Conditions"/AGB.)

#### **Pros & Cons of Registration**

#### Pros:

- 1. Market advantage: Increase in sales? Requires user awareness
- 2. Political visibility & strategic engagement
- 3. Increased trust with provider countries

#### Cons:

- 1. Time & Money (1.5 yrs + 30k IT one-time, 100k€ annually)
- 2. Practical (no standard forms, lots of legalese)
- 3. Decrease in deposits
- 4. Adminstrative: work with depositors & provider countries,

#### **Day-to-day challenges**

- 1. The ABS-CH has limited utility. Very few IRCCs.
- 2. Marine regions are legally challenging
  - International waters
  - EEZ vs coastal territory
  - Continental shelf vs. Water column
  - http://www.marineregions.org/eezsearch.php
- 3. Commercial use vs. commercial user
  - A collection is NOT the ABS police!
- 4. Working with users "after the fact"
  - Non-commercial use
  - deposit in the collection allowed
  - subsequent distribution

# What is different about the DSMZ compared to other collections?

- 1. Very significant, permanent public funding
- 2. Income stream from sales
- 3. Motivated scientists that MUST deposit in order to describe a new species
- 4. Engaged, informed leadership
- 5. Leibniz Association (7-year review process)



Website Search
to product search >>

Management

Portrait of the DSMZ

Nagoya Protocol

Due Dilligence

Registered Collection

Legal background

**DSMZ Staff** 

Strain Deposit

Mitglied der Leibniz

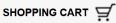
About us > Nagoya Protocol

#### Nagoya Protocol and the utilisation of biological resources

The Nagoya Protocol regulates the collection and use of biological resources worldwide. This means that each country now has sovereign rights over its biological resources and can thus prevent so-called "biopiracy". But, as a result, the collection of bacteria, fungi or other microorganisms (as well as microorganisms) has become much more complicated since the Protocol came into force in 2014. At present, many scientists are uncertain about what they are and are not allowed to do and what permits are required and how to obtain them.

#### The DSMZ has compiled information to give you a better overview:

- A central aspect of the European Nagoya Protocol regulation is the so-called due diligence
  declaration. Scientists are required to exercise due care to determine whether their use of
  biological resources is legal and must make an unsolicited declaration to the national authority
  in connection with a funded research project. Here you will find an overview of how to
  proceed... »
- DSMZ, as the first Registered Collection certifies for its customers that the resources
  purchased from us are "Nagoya compliant" and provides the initial information needed for the
  EU due diligence declaration. No other collection in the world can offer this... »
- As a depositor, you must determine whether in the country where you intend to collect the
  genetic resources permits need to be issued in the form of a PIC, MAT, an IRCC or similar
  documentation. If this is the case you must obtain permits from the country of origin or local
  authority responsible before collecting genetic (microbial or other biological) resources or any

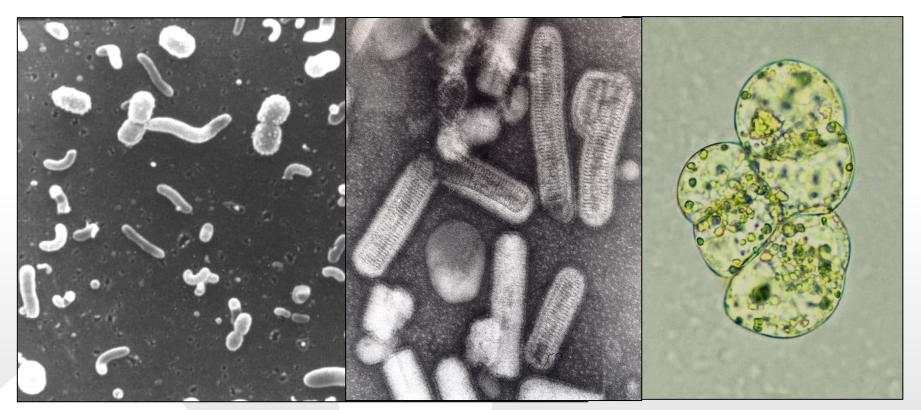


Please login!

To Shopping Cart »
To Login/Logout »







Thank you

amber.h.scholz@dsmz.de



#### The DSMZ MTA (Terms & Conditions)

By agreeing to our MTA, the user has committed to the following:

Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), Internationally Recognised Certificate of Compliance (IRCC) and/or an additional (depositor-originated) Material Transfer Agreement (MTA) may exist for specific products. Where applicable, the corresponding files are available as free downloads in the DSMZ GmbH catalogue. The customer pledges to download these documents, adhere to the provisions defined therein, and to retain the documents for 20 years after they are last used. If there are subsequent users on a case-by-case basis (see Section 2), the documents must be transferred to them by the customer in full. Violating this obligation constitutes a summary offence that is punishable with a fine of up to fifty thousand Euros (Section 4 des Gesetzes zur Umsetzung der Verpflichtungen nach dem Nagoya-Protokoll und zur Durchführung der Verordnung (EU) Nr. 511/2014 (EU) No. 511/2014; "Nagoya Protocol Implementation Act").

## The DSMZ MTA (Terms & Conditions)

Any commercial use of the material is excluded. Commercial use of products that are not regulated by the Nagoya Protocol is when the products are used directly for the purpose of profit generation. Products of the plant viruses department intended for virus diagnostics and consisting of antibodies, serological positive controls or nucleic acid extracts are exempt. For orders of microorganisms or plant viruses, commercial use is possible on a case-by-case basis with the consent of DSMZ GmbH management. For material regulated by the Nagoya Protocol, the customer is required to adhere to the conditions in the (PIC/MAT) document associated with the material. See paragraphs 1 and 6 of this section for related restrictions and fines. The customer pledges to pay a contract penalty in case of intentional culpable or unapproved commercial use. The contract penalty is EUR 1,000 corresponding to the full cost price of own isolation. DSMZ GmbH has the right to assert possible additional claims for damages. In this case the contract penalty is offset against the asserted claim for damages. The customer has the right to provide proof that no violation has occurred.

#### Why do scientists put microbes in a collection?

- Validly publish a new species & identify biodiversity:
  - 1. Deposited in two internationally recognized collections
  - 2. Validated with a certificate of deposit from collection
  - 3. Available to scientific community "without restrictions"
- Plant, animal, fungal taxonomy follow similar systems

- Scientific integrity & reproducibility: \$10B lost annually due to incorrect "biological reagents and reference materials"
- Redundancy, security, quality control
- Reduce "friendly" requests



#### The DSMZ's finances

- Non-profit publicly-funded research infrastructure
- €15 Mio. Budget
  - Sales revenue: 4.5 Mil.
  - Federal/state: 10.5 Mil
- Do we make a profit?
  - €9,836 to cultivate a new fastidious strain
  - Deposit:
    - free for depositor
    - Costs the DSMZ €918
  - Average strain sells for €85
  - To be cost-neutral, strains would cost €900.
- Take home message:
   The collection fills a public good for the scientific community.



#### A year and a half journey to registration....

- Aug-Nov 2016: 5 pages of questions for BfN and in-person visit
- Aug-Oct 2017: preparation of application
  - Hired a lawyer (~100.000 €/yr)
  - 2nd set of questions
  - Two draft applications exchanged with BfN & review of supporting docs
- Nov 2017: submitted final application
  - First application in Germany
  - Jan-Feb 2018: follow-up questions from BfN
- March 18, 2018: approval by BfN of the application



# Overview: What did we need to change?

Art 5(2) Application	Art 5(3)a Standardized procedures	Art 5(3)b NP Compliance	Art 5 (3)c Country, date, NP documents
<ul> <li>Application itself (14 p.)</li> <li>Supplied 11 supporting documents</li> </ul>	<ul><li>SOPs</li><li>DSMZ MTA</li><li>Webshop</li></ul>	<ul> <li>New programming</li> <li>AF</li> <li>DB</li> <li>Legal check</li> </ul>	<ul> <li>Database review process</li> <li>Expand info in our online catalog: <ul> <li>Country of origin</li> <li>Date of sampling</li> <li>PIC/MAT/MTA documents downloadable</li> </ul> </li> </ul>



## Unique identifiers: Art. 5(3)(b)

- Since the founding of the collection, each biological resource receives a unique ID upon acceptance
  - DSM### = microorganisms
  - PV ### = plant viruses
  - ACC### = (human) & animal cell lines
- Nagoya documents associated to unique ID
- Publications refer to unique ID



#### Microbial diversity @ DSMZ

- Research infrastructure
- 200 employees, €15 Mil. budget
- 1969: 7 microbial collections merged together
- 1990s: 4 other collections added
- 80% of all bacterial species
- Plant viruses certified for quarantine
- 140 publications/year
- Sequencing center
- Cited by 12,000 publications
  - 63% outside systematics







# Assignment of a DSM #

Leibniz-Institut DSMZ-Deutsche Sar von Mikroorganism Zellkulturen GmbH Inhoffenstrasse 7b 38124 Braunschwei Germany Tel.: +49 (09)531-26	nmlung en und	rinted and signed version of th the package that cont ACCESSION F for deposit in the o acteria, Archaea, F	ORM  open collection	DSMZ
Depositors of PLEASE NOTE Depositors of international	F- Nummer  strains are requested: THE DSMZ ONLY AC Risk Group 2 strains	nd they MUST inform the DSM	SM-Nummer	To be completed by DSMZ state 1.062007  DSM-Nr. 1062007  Date 12 M N
Organism Type	Bacteria	Author(s) of the species description	Zhi Tian	
Genus (or other higher taxonomic designation)	Cellulomonas	Species epithet	sp.	
Subspecies epithet	sp.	Variety, forma, race		
Gram staining		posed) type strain e species / subspecies yes	Strain designation us the depositor for the	

