

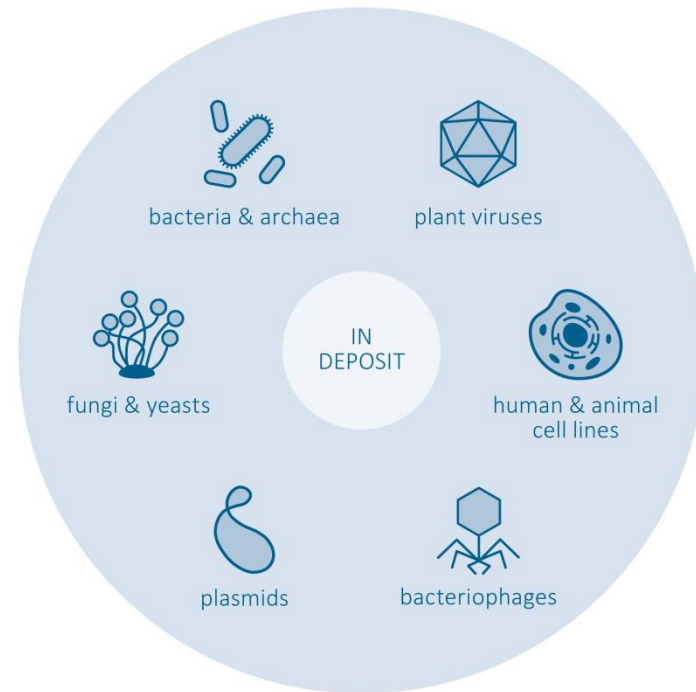
Topic 2: Requirements of International Depository Authorities (IDAs)

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The DSMZ acts as Patent Depository > 45 years

- First patent strain in 1972
- Recognized as **IDA** according to the *Budapest Treaty* since 1981
- In 2019 – 328 patent deposits
- Total - > 9000 patent deposits



Requirements of International Depository Authorities (IDAs)

- 48 depository institutions in 26 countries
- **Deposit** of microorganisms and the **furnishing** of samples under the Budapest Treaty

Tasks of an IDA

- Compliance with the demand of secrecy about deposited strains
- Impartiality and objectivity

1. Requirements for Deposit

- Kinds of biological Material that May Be Deposited
- Viability testing of the biological material
- Storage of the biological material in a genetically unchanged way
- Administrative Requirements and Procedures

2. Furnishing of Samples

- Release of samples for trials and examinations to authorized parties

Kinds of material that May Be Deposited (10 out of 48 IDAs)

Country	Kind of material accepted	IDA
Belgium	Animal cell cultures, Bacteria , Fungi , Human cell cultures*, Hybridomas, Plasmids (in hosts and not in hosts), RNA, Yeasts Contaminant level: 2	Belgian Coordinated Collections of Microorganisms (BCCM)
China	Algae,Animal cell cultures,Animal viruses,Bacteria ,Bacteriophages,Eukaryotic DNA,Fungi ,Human cell cultures,Hybridomas,Molds,Mycoplasma,Nematodes,Oncogenes,Plant cell cultures,Plant viruses,Plasmids (in hosts and not in hosts),Protozoa (non-parasitic),Seeds,Yeasts Contaminant level: 2	China Center for Type Culture Collection (CCTCC)
China	Algae,Animal cell cultures,Animal viruses,Bacteria ,Bacteriophages,Eukaryotic DNA,Fungi ,Mycoplasma,Plant cell cultures,Plant viruses,Plasmids (in hosts and not in hosts),Seeds,Yeasts Contaminant level: 1, recombinant DNA: 2	China General Microbiological Culture Collection Center (CGMCC)
Germany	Animal cell cultures,Bacteria ,Bacteriophages,Fungi ,Human cell cultures,Hybridomas,Mycoplasma,Plant cell cultures,Plant viruses,Plasmids (in hosts and not in hosts),Yeasts Contaminant level: 2	Leibniz-Institut DSMZ - Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)
Mexico	Algae,Animal cell cultures,Animal viruses,Bacteria ,Bacteriophages,Embryos,Eukaryotic DNA,Fungi,Human cell cultures,Hybridomas,Mycoplasma,Nematodes,Plant cell cultures,Plant viruses,Plasmids (in hosts and not in hosts),Protozoa (non-parasitic),RNA,Yeasts (non-pathogenic), Contaminant level: 1	Colección de Microorganismos del CNRG (CM-CNRG)
Morocco	Bacteria ,Fungi ,Yeasts Contaminant level: 2	Collections Coordonnées Marocaines de Microorganismes (CCMM)
Netherlands	Bacteria,Bacteriophages,Fungi,Plasmids (in hosts and not in hosts),Yeasts Contaminant level: 3, 2 for GEMs (WHO pathogenic group I and II)	Westerdijk Fungal Biodiversity Institute (CBS)
Republic of Korea	Algae,Animal cell cultures,Animal viruses,Bacteria (non-pathogenic),Bacteriophages,Embryos,Eukaryotic DNA,Fungi (non-pathogenic),Human cell cultures,Hybridomas,Molds,Murine embryos,Plant cell cultures,Plant viruses,Plasmids (in hosts and not in hosts),Protozoa (non-parasitic),RNA,Seeds,Yeasts Contaminant level: 1	Korean Collection for Type Cultures (KCTC)
UK	Bacteria,Bacteriophages,Fungi (non-pathogenic),Plant cell cultures,Plasmids (in hosts and not in hosts),Seeds,Yeasts (non-pathogenic) Contaminant level: 2	National Collections of Industrial, Food and Marine Bacteria (NCIMB)
USA	Algae,Animal cell cultures,Animal viruses,Bacteria,Bacteriophages,Embryos,Eukaryotic DNA,Fungi,Human cell cultures,Hybridomas,Molds,Murine embryos,Mycoplasma,Oncogenes,Plant cell cultures,Plant viruses,Plasmids (in hosts and not in hosts),Protozoa (parasitic and non-parasitic),Protozoa (pathogenic),RNA,Seeds,Yeasts Contaminant level: 3	American Type Culture Collection (ATCC)

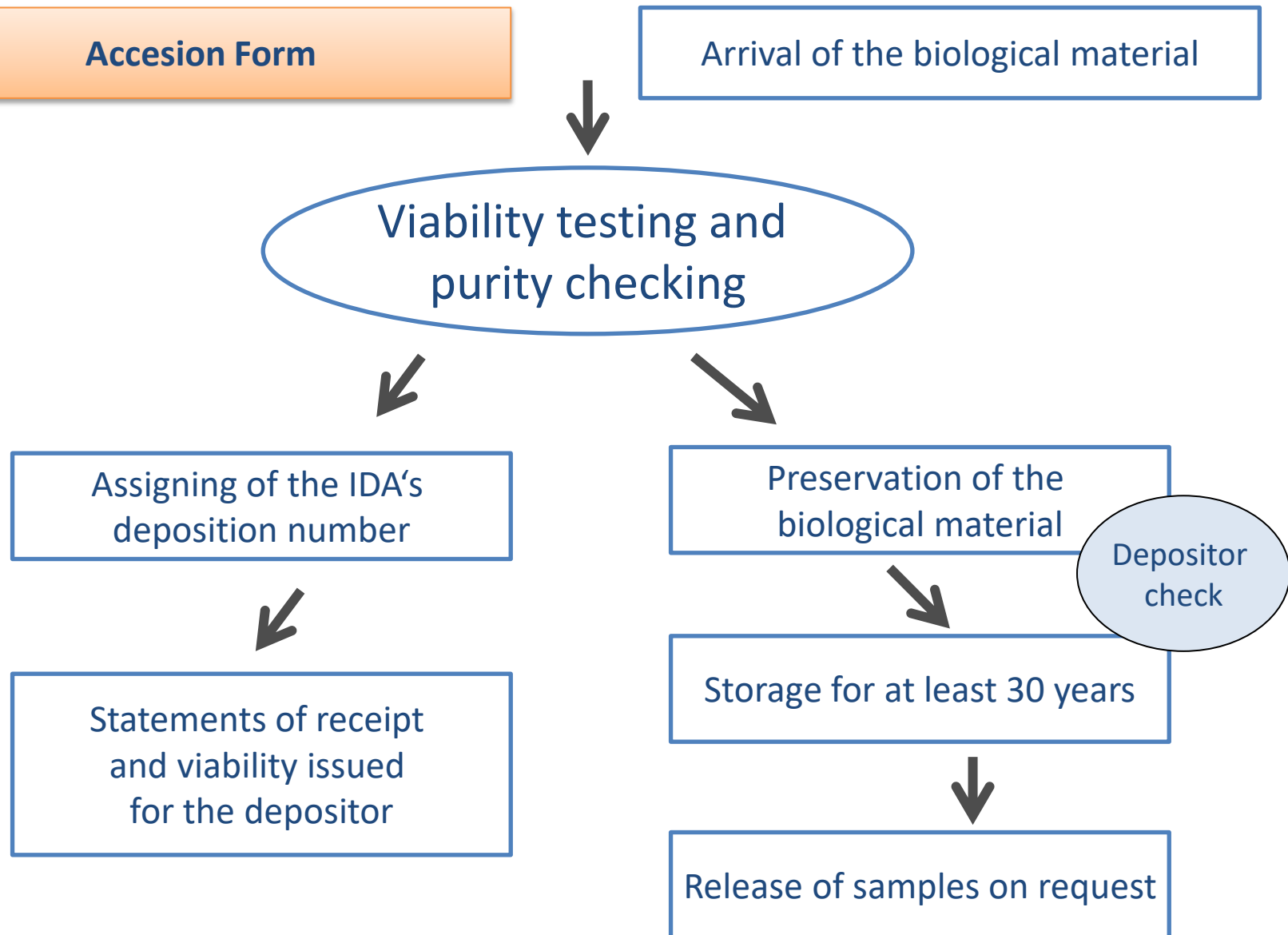
Technical Requirements and Procedures

- Form and Quantity

at the DSMZ

Biological Material	Form and Amount of the Material
Archaea, Bacteria	dried or frozen material (glycerol stocks) or actively growing cultures: two separate preparations
Fungi, Yeasts	actively growing cultures: two separate preparations
Plasmid DNA	isolated DNA preparations in a minimum quantity of 2 x 20 µg
Bacteriophages	minimum quantities of 2 x 5 ml with a minimal titre of 1 x 10 ⁹ pfu per ml
Plant Viruses	dried or frozen material along with the host's seeds (minimum 1 g of leaf material or infectious plant sap)
Human and Animal Cell Lines	frozen on dry ice in a quantity of 12 cryoampoules (all prepared at the same time) containing 5 x 10 ⁶ cells per ampoule (suspension culture) and 2 x 10 ⁶ cells per ampoule (adherent cells).
Plant Cell Lines	cultures in the form of undifferentiated plant cell cultures, embryogenic plant cell cultures and tissues, or as in-vitro shoot cultures; at least 25 frozen ampoules

Procedure of a Patent Deposit



Administrative Requirements and Procedures: Accession form for Bacteria and FungiBP 1

FOR PATENT DEPOSIT PURPOSES ONLY!
Not for safe deposit or public deposit!



BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

STATEMENT IN THE CASE OF AN ORIGINAL DEPOSIT
pursuant to Rule 6.1

To
LEIBNIZ-INSTITUT DSMZ-DEUTSCHE SAMMLUNG
VON MIKROORGANISMEN UND ZELLKULTUREN GmbH
Inhoffenstr. 7 B
D-38124 Braunschweig
GERMANY

To be filled in by the Depositary Authority

DSMZ-Accession Number: _____

Date culture received: _____

BACTERIA/ARCHAEA/FUNGI¹

THE UNDERSIGNED HEREBY DEPOSITS UNDER THE [BUDAPEST TREATY](#) THE MICROORGANISM IDENTIFIED HEREUN
UNDERTAKES NOT TO WITHDRAW THE DEPOSIT FOR THE PERIOD SPECIFIED IN RULE 9.1.²

I. IDENTIFICATION OF THE MICROORGANISM¹

Identification reference³: _____ The culture to be deposited is :

() a pure culture

Taxonomic designation⁴: _____ () a mixture of microorganisms

(not more than two components)

II. CONDITIONS FOR CULTIVATION ()⁵

Medium: _____ pH before sterilisation: _____

Sterilisation _____ min at _____ °C

pH after sterilisation: _____

Oxygen relationship:
() aerobic
() microaerophilic
() obligate anaerobic
Specific gaseous requirements: _____

Incubation temperature: _____ °C

Incubation time: _____

Short term storage at: _____ °C

Interval of transfer: _____

III. CONDITIONS FOR LONG TERM STORAGE ()⁵

IV. CONDITIONS FOR TESTING VIABILITY ()⁵

V. COMPONENTS OF MIXED CULTURES (WHEN APPLICABLE) ()⁵

Description of components: (not more than two components)

Method(s) for checking presence of components:

VI. PROPERTIES DANGEROUS TO HEALTH OR ENVIRONMENT ()⁵

RISK GROUP of the microorganism¹:

() risk group 1 () risk group 2

CLASSIFICATION in case the microorganism is genetically engineered¹:

() Class 1/S1 () Class 2/S2

THE STRAIN HAS TO BE HANDLED UNDER LABORATORY CONTAINMENT LEVEL¹:

() L1 () L2

IS THIS STRAIN DANGEROUS TO HEALTH OR THE ENVIRONMENT ?

() YES () NO

if yes, please specify:

() the undersigned is not aware of such properties

Administrative Requirements and Procedures: Accession form for Bacteria and FungiBP 1

VII. IF THE MICROORGANISM IS GENETICALLY MANIPULATED ()⁵
Please absolutely give complete answers!

1. DATA CONCERNING THE HOST ORGANISM

designation: _____

risk group¹: _____ () risk group 1 () risk group 2

sensitivities: _____
resistances: _____
auxotrophies: _____

special properties:
(e.g. restriction/modification system, general genetic recombination) _____

2. DATA CONCERNING THE DONOR ORGANISM

designation: _____

risk group¹: _____ () risk group 1 () risk group 2 () risk group 3

description of the **cloned DNA fragment**:

cloned information: _____

size of the cloned DNA (in bp): _____
() complete genome () cDNA
() subgenomic () subgenic () synthetic

potential risk of the cloned DNA:
() no potential risk () pathogenic () tumorigenic
() toxigenic () allergenic

3. DATA CONCERNING THE VECTOR

designation: _____

derivative of: _____

host specificity: _____

resistances: _____

plasmid size (in kb): without insert: _____ with insert: _____

promoters: _____

additional reading frames: _____

own infectivity: () yes () no
mobilisable plasmid: () yes () no
own transfer system: () yes () no
transfer by endogenous viruses: () yes () no

4. DATA CONCERNING THE GENETICALLY MANIPULATED ORGANISM

special properties:
(e.g. production of ...; use as ...-vector etc.) _____

foreign DNA: () chromosomally integrated () episomal

potential risk: () pathogenic () tumorigenic
() toxigenic () allergenic

() no potential risk
please indicate why: _____

According to the regulations of the [German Law Regulating Genetic Engineering](#) the DSMZ can only accept genetically manipulated, potentially pathogenic organisms for deposition when a copy of the permit issued by the competent authority (or by an equivalent national biological safety commission) for work on the organisms accompanies the deposition form.

VIII. SCIENTIFIC DESCRIPTION⁶ ()⁵

IX. ADDITIONAL DATA⁷ ()⁸

X. FATE OF THE CULTURE AFTER THE PRESCRIBED DURATION OF STORAGE⁹

a) The culture is to be transferred into the publicly available collection of the DSMZ () yes () no

b) Extension of the deposit against a fee () yes () no

XI. DEPOSITOR¹⁰

Institution/ legal entity: _____

Phone: _____

Fax: _____

E-Mail: _____

Invoice Address: _____

Department: _____

Contact Person: _____

Delivery Address for Depositor's Check:

Contact Person _____

E-Mail: _____

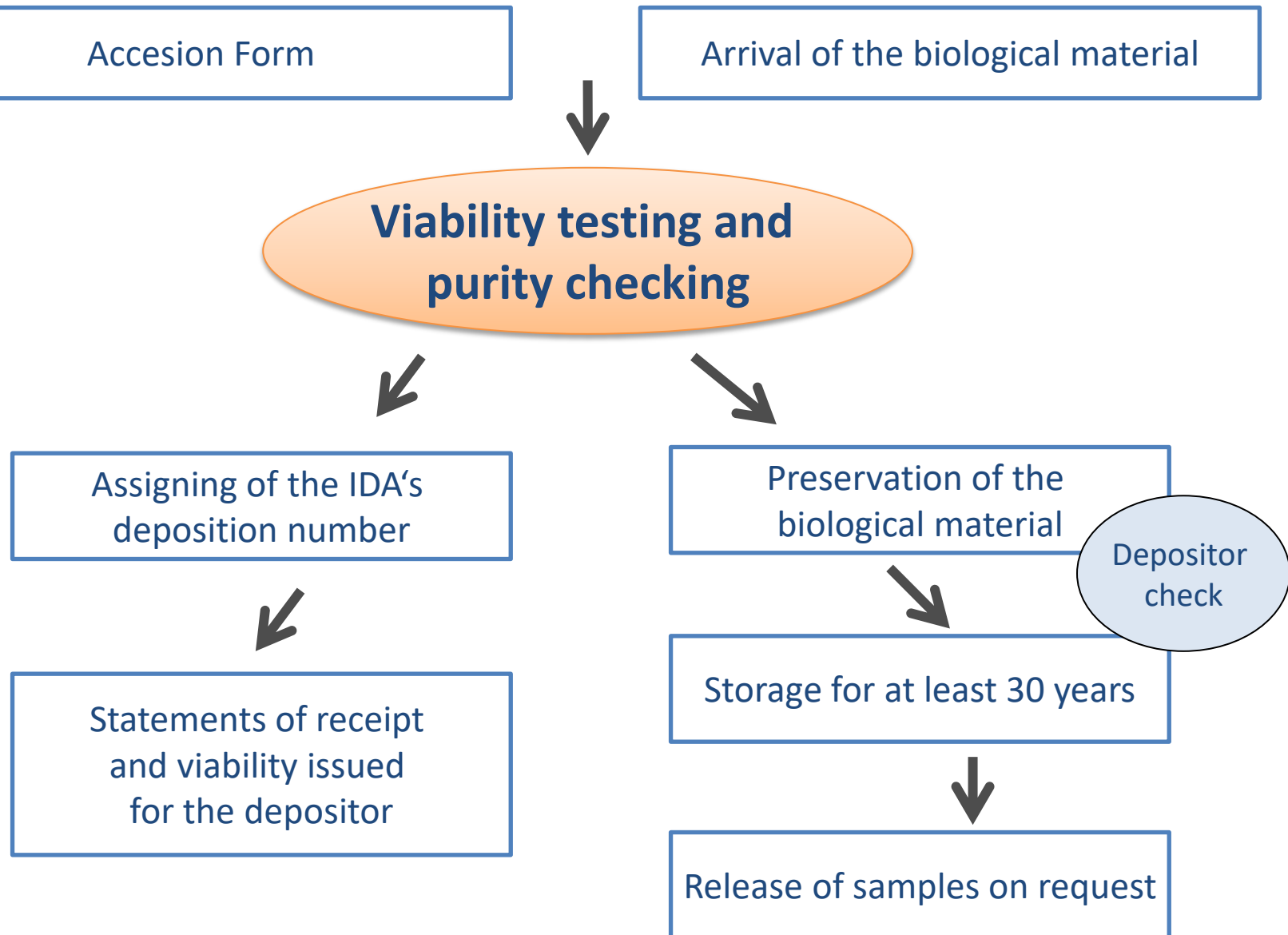
Phone: _____

Name of signing person(s) (typewritten): _____

The signing person(s) deposit(s): () on behalf of the legal entity
() as private depositor(s)

Signature(s): _____ Date: _____

Procedure of a Patent Deposit



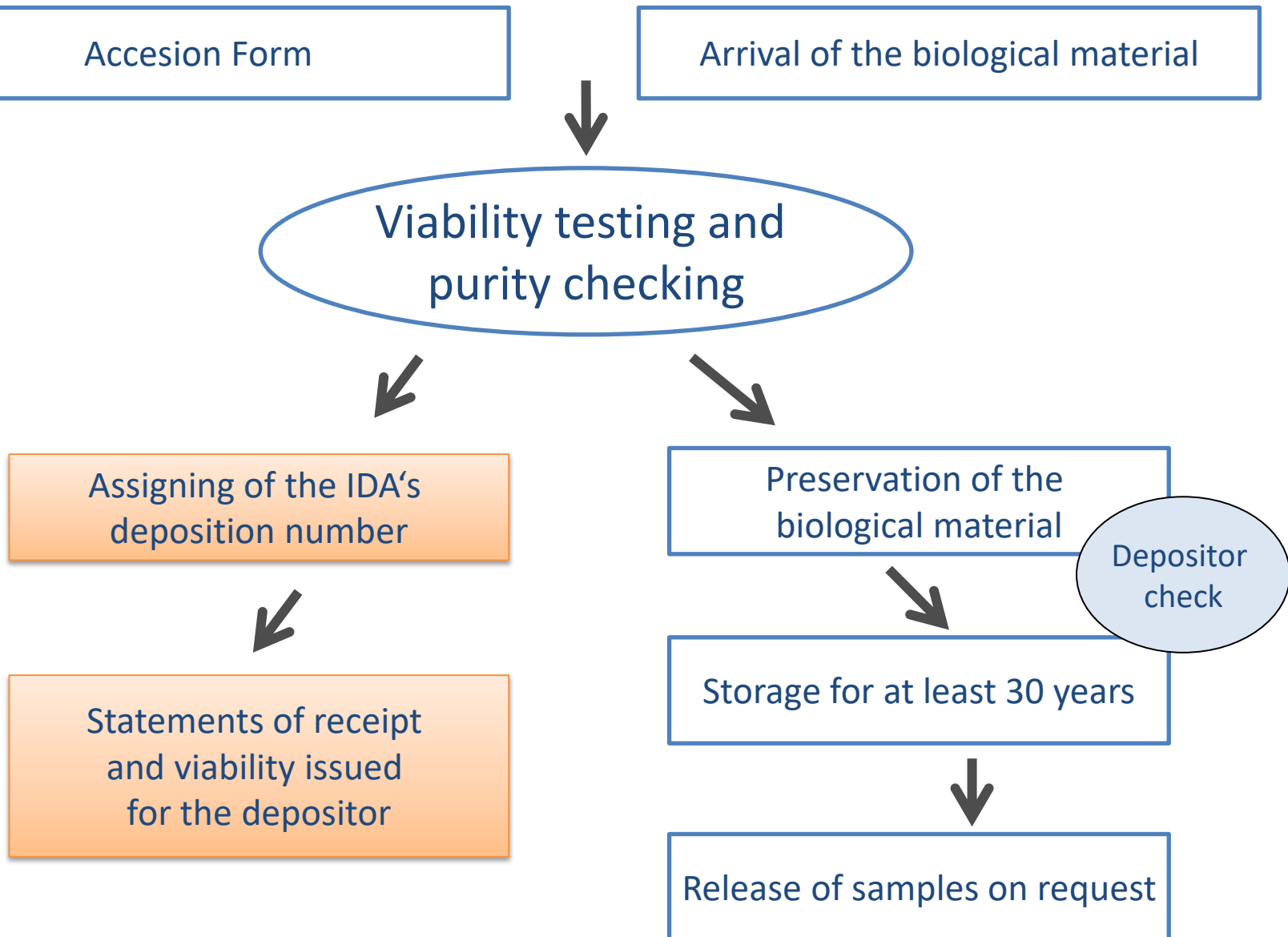
Viability Testing and Time Required for Testing

<i>Kind of biological material</i>	<i>Recommended method for viability testing</i>	<i>Average duration</i>
Bacteria	Growth and purity controlled macroscopically and microscopically on the medium indicated by the depositor	2 days
Fungi, yeasts	Growth and purity controlled macroscopically and microscopically on the medium indicated by the depositor	2-3 days
Plasmid bearing (genetically manipulated) bacteria	Inoculation of the indicated medium containing and not containing an antibiotic; growth and purity confirmed macroscopically and microscopically	1-2 days
Plasmid DNAs	Presence proven by showing the plasmid in an agarose gel; 'viability' tested by transforming the plasmid into the suitable host	2-3 days
Bacteriophages	Proof of its infectiosity (lysis of host cells, formation of plaques)	2-3 days
Plant cell cultures	Ability of the cells to divide	4-8 weeks
Plant viruses	Proof of its infectiosity to the host plant	2 weeks
Human and animal cell cultures	Ability of the cells to divide; test for contamination with mycoplasmas	7-10 days

Additional Testing

<i>Kind of biological material</i>	<i>Recommended method for viability testing</i>	<i>Additional tests</i>
Bacteria	Growth and purity controlled macroscopically and microscopically on the medium indicated by the depositor	Api, MALDI-TOF, sequencing
Fungi, yeasts	Growth and purity controlled macroscopically and microscopically on the medium indicated by the depositor	
Plasmid bearing (genetically modified) bacteria	Inoculation of the indicated medium containing and not containing an antibiotic; growth and purity confirmed macroscopically and microscopically	Plasmid isolation, U3 phage infection, Api
Plasmid DNAs	Presence proven by showing the plasmid in an agarose gel; 'viability' tested by transforming the plasmid into the suitable host	
Bacteriophages	Proof of its infectiosity (lysis of host cells, formation of plaques)	
Plant cell cultures	Ability of the cells to divide	TTC test
Plant viruses	Proof of its infectiosity to the host plant	Electron microspcopy
Human and animal cell cultures	Ability of the cells to divide; test for contamination with mycoplasmas	

Procedure of a Patent Deposit



Administrative Requirements and Procedures



INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

Statement of Receipt BP4

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: _____ _____	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: DSM _____
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I. above was accompanied by: <input type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable).	
III. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on _____ (Date of the original deposit).	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depositary Authority on _____ (date of original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on _____ (date of receipt of request for conversion).	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Address: Inhoffenstr. 7 B D-38124 Braunschweig	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: _____



Administrative Requirements and Procedures

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE



INTERNATIONAL FORM

VIABILITY STATEMENT
 issued pursuant to Rule 10.2 by the
 INTERNATIONAL DEPOSITARY AUTHORITY
 identified at the bottom of this page

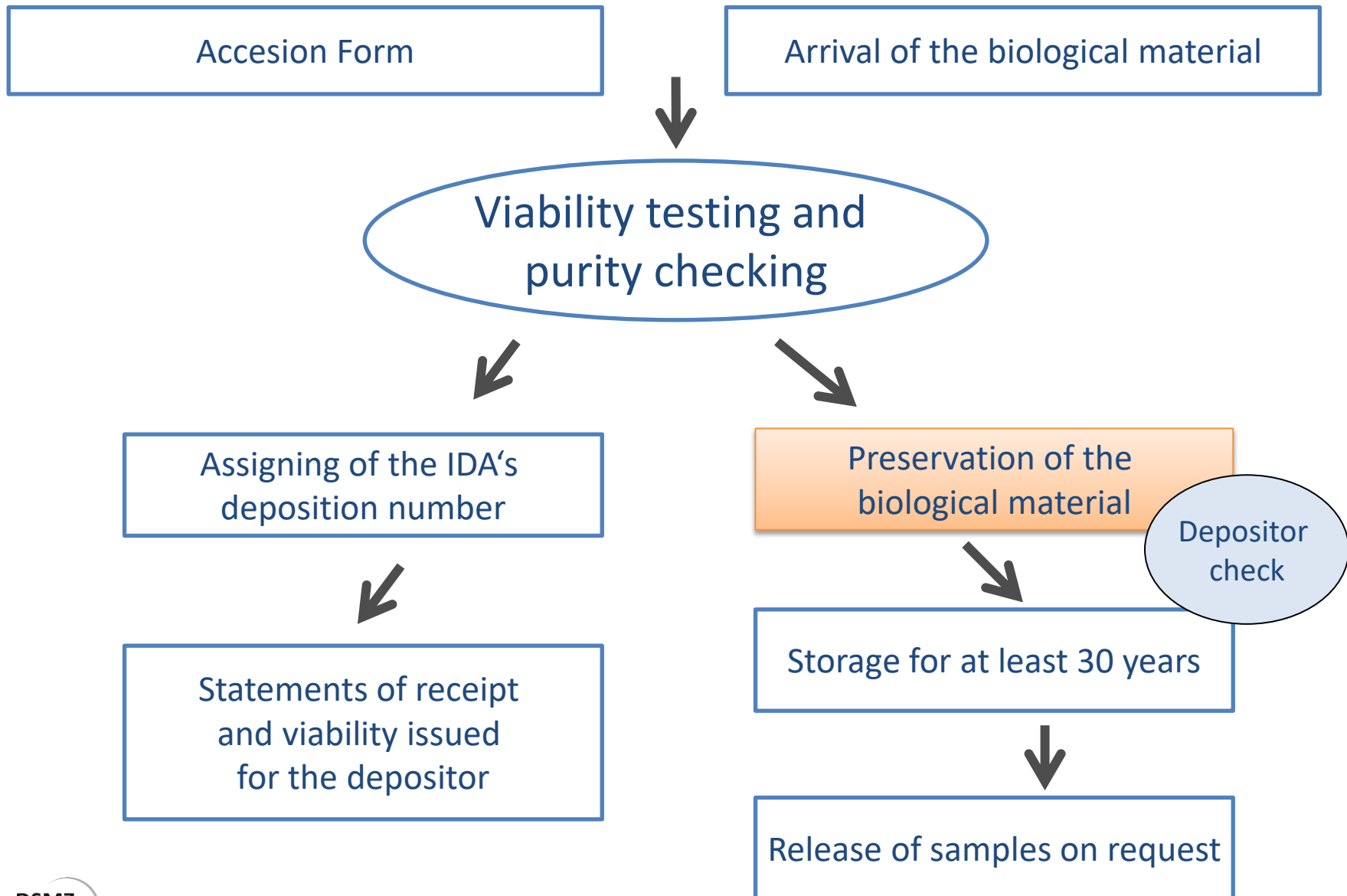
Statement of Viability BP9

I. DEPOSITOR		II. IDENTIFICATION OF THE MICROORGANISM	
Name:	_____	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:	
Address:	_____ _____ _____	DSM _____	
		Date of the deposit or the transfer ¹ : _____	
III. VIABILITY STATEMENT			
The viability of the microorganism identified under II above was tested on _____ ² . On that date, the said microorganism was			
<input checked="" type="checkbox"/> ³ viable <input type="checkbox"/> ³ no longer viable			
IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED ⁴			
_____ _____ _____			
V. INTERNATIONAL DEPOSITARY AUTHORITY			
Name:	Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):	
Address:	Inhoffenstr. 7 B D-38124 Braunschweig	Date: _____	

¹ Indicate the date of original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
² In the cases referred to in Rule 10.2(a) (ii) and (iii), refer to the most recent viability test.
³ Mark with a cross the applicable box.
⁴ Fill in if the information has been requested and if the results of the test were negative.



Procedure of a Patent Deposit



Tasks of an IDA

- Compliance with the demand of secrecy about deposited strains
- Impartiality and objectivity

1. Requirements for Deposit

- Kinds of Microorganisms that May Be Deposited
- Viability testing of the biological material
- **Storage of the biological material in a genetically unchanged way**
- Administrative Requirements and Procedures

2. Furnishing of Samples

- Release of samples for trials and examinations to authorized parties

Principles of Preservation



Reduction of the microbial metabolism



Sustain viability of the cells

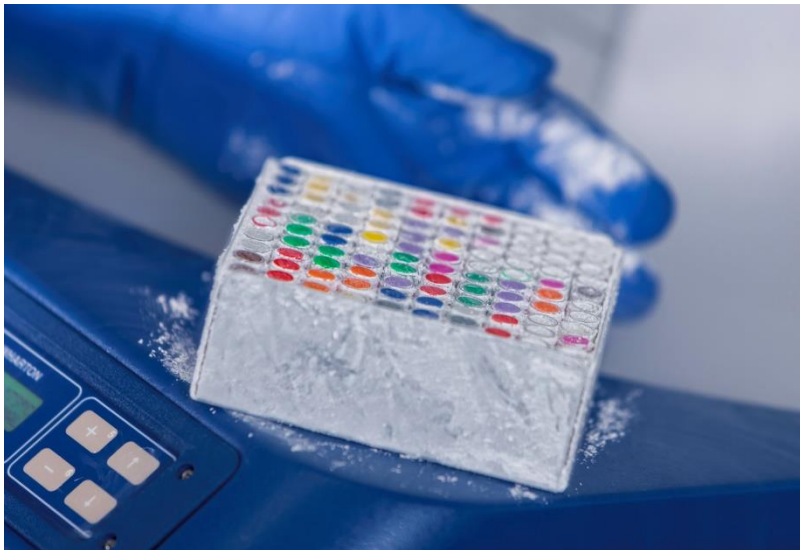


Lowering the temperature
(storage in liquid nitrogen)



Depriving the cells of water
(freeze drying)

Storage of capillaries or cryotubes in Liquid Nitrogen



Storage in Liquid Nitrogen: Production of glass capillaries



Liquid nitrogen storage tanks

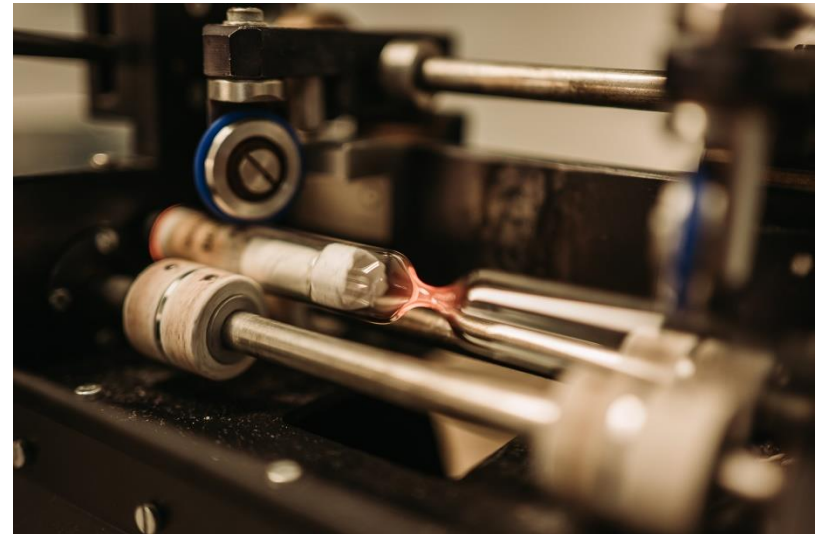
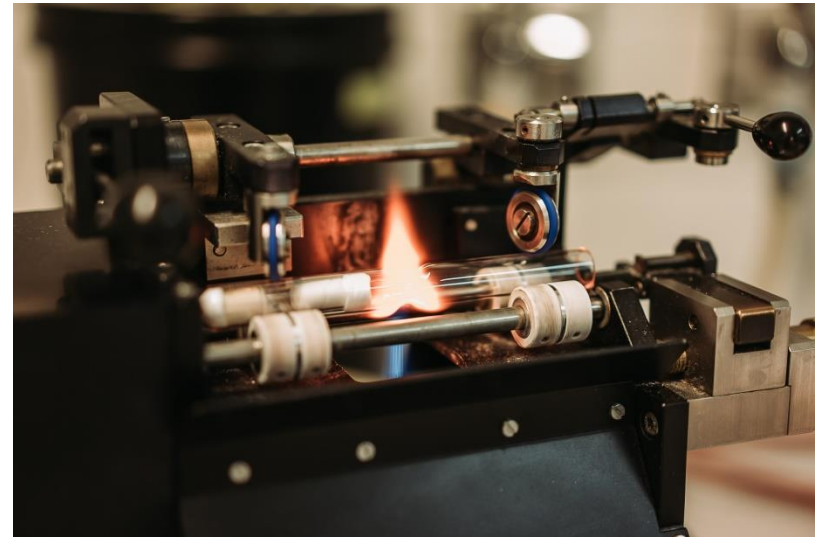


Drying of Microorganisms

Production of ampoules



Constrictors to melt glass ware



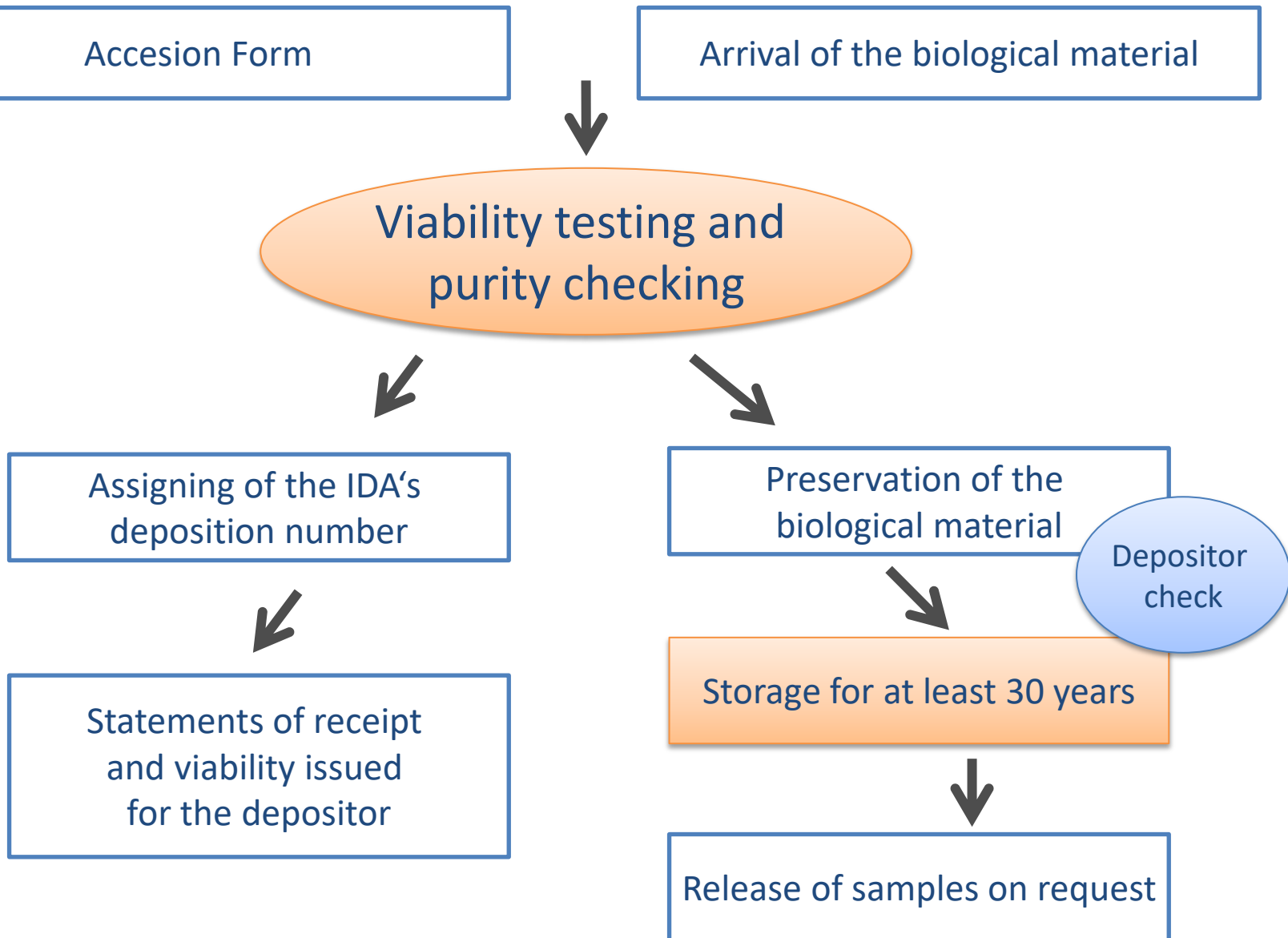
Drying of Microorganisms: Freeze Drying machine



Storage of Dried Cultures



Procedure of a Patent Deposit



Storage of Biological Material

Viability and purity testing of the stored material

Ideal time schedule:

year 0	initial testing after preservation
year 1	1. further testing
year 5	2. further testing
year 15	3. further testing
(year 25	4. further testing)

Fees for the Patent Deposit of Biological Material at the DSMZ

<i>Kind of Service</i>	<i>EUR</i>	<i>USD</i>
Accession of: bacteria fungi plasmid DNA bacteriophages plant viruses	800	960
Accession of: animal and human cell cultures plant cell cultures	1.400	1.670
Furnishing of a sample under Rule 11 of the Budapest Treaty	120	140

Tasks of an IDA

- Compliance with the demand of secrecy about deposited strains
- Impartiality and objectivity

1. Requirements for Deposit

- Kinds of Microorganisms that May Be Deposited
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2. Furnishing of Samples

- Release of samples for trials and examinations to authorized parties

2. Furnishing of Samples acc. to the Budapest Treaty

When
?

11.1 To Interested Industrial Property Offices

At any time

When
?

**11.2 To the depositor or with the authorization of
the depositor to 3rd parties**

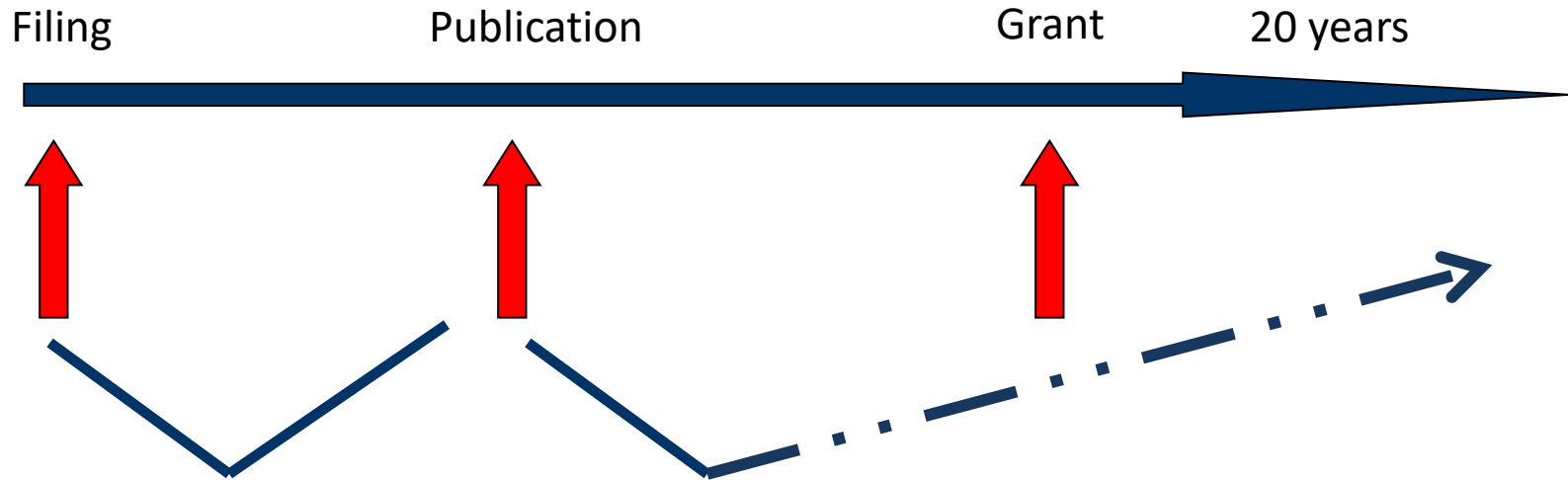
At any time on request to the IDA

When
?

11.3 To Parties Legally Entitled

By confirmation of the request by the
responsible Patent Office

Furnishing of Samples - When ? To Whom ?



Available for:

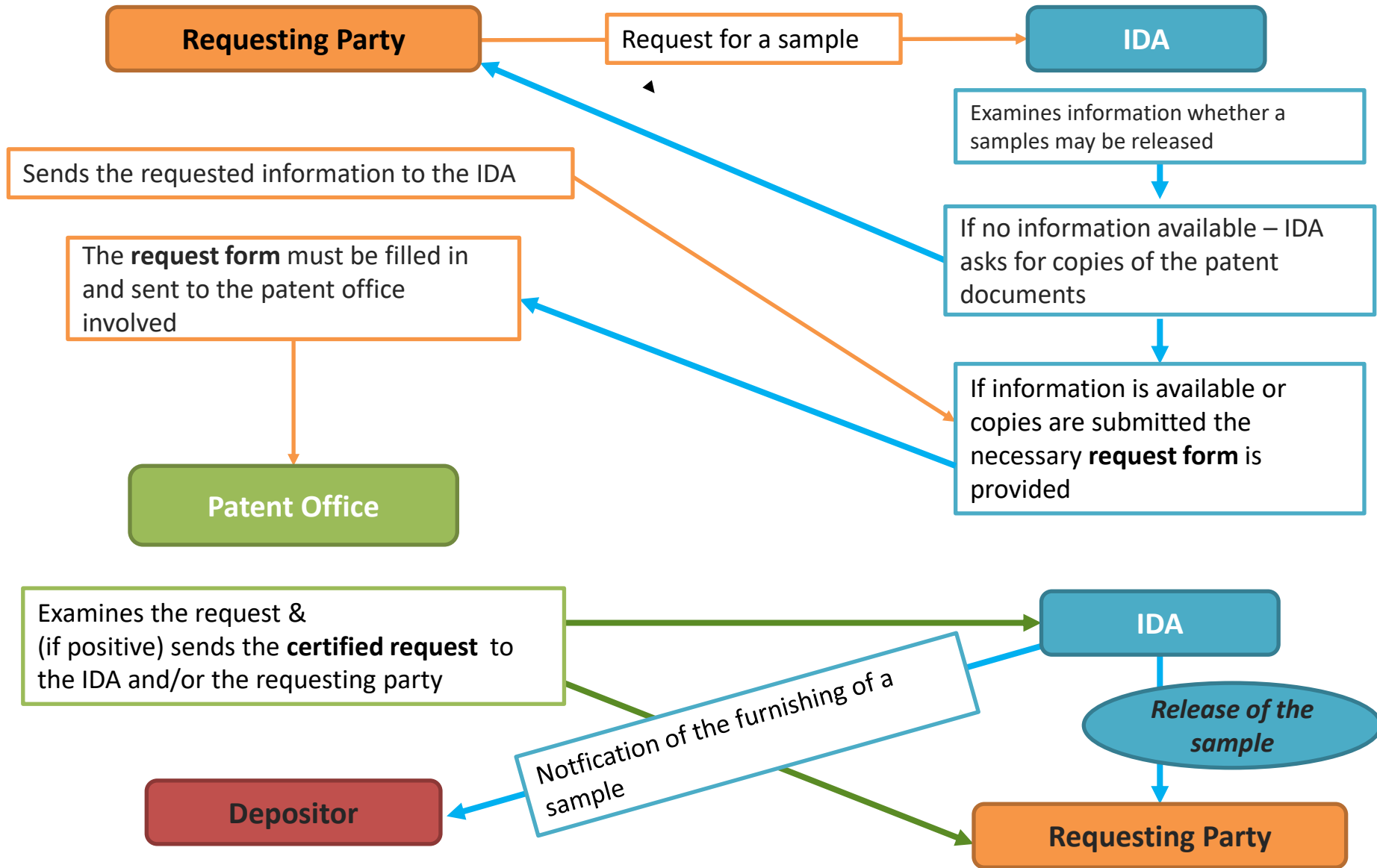
-Patent Office
-Depositor
-Authorized 3rd Party

-Patent Office
-Depositor
-Authorized 3rd Party



-Certified 3rd Party

Release of Patent Samples to Certified Third Parties



Restrictions for the Shipment – Import/Export

- Import or quarantine restrictions
- Directives restricting ex-/import of plant pathogens
- Directives restricting ex-/import of epidemics of animals
- Dual-use trade controls
- War Weapons Control Act

Transport of Biological Material

Pathogenic material

➤ menace or danger during transportation for:

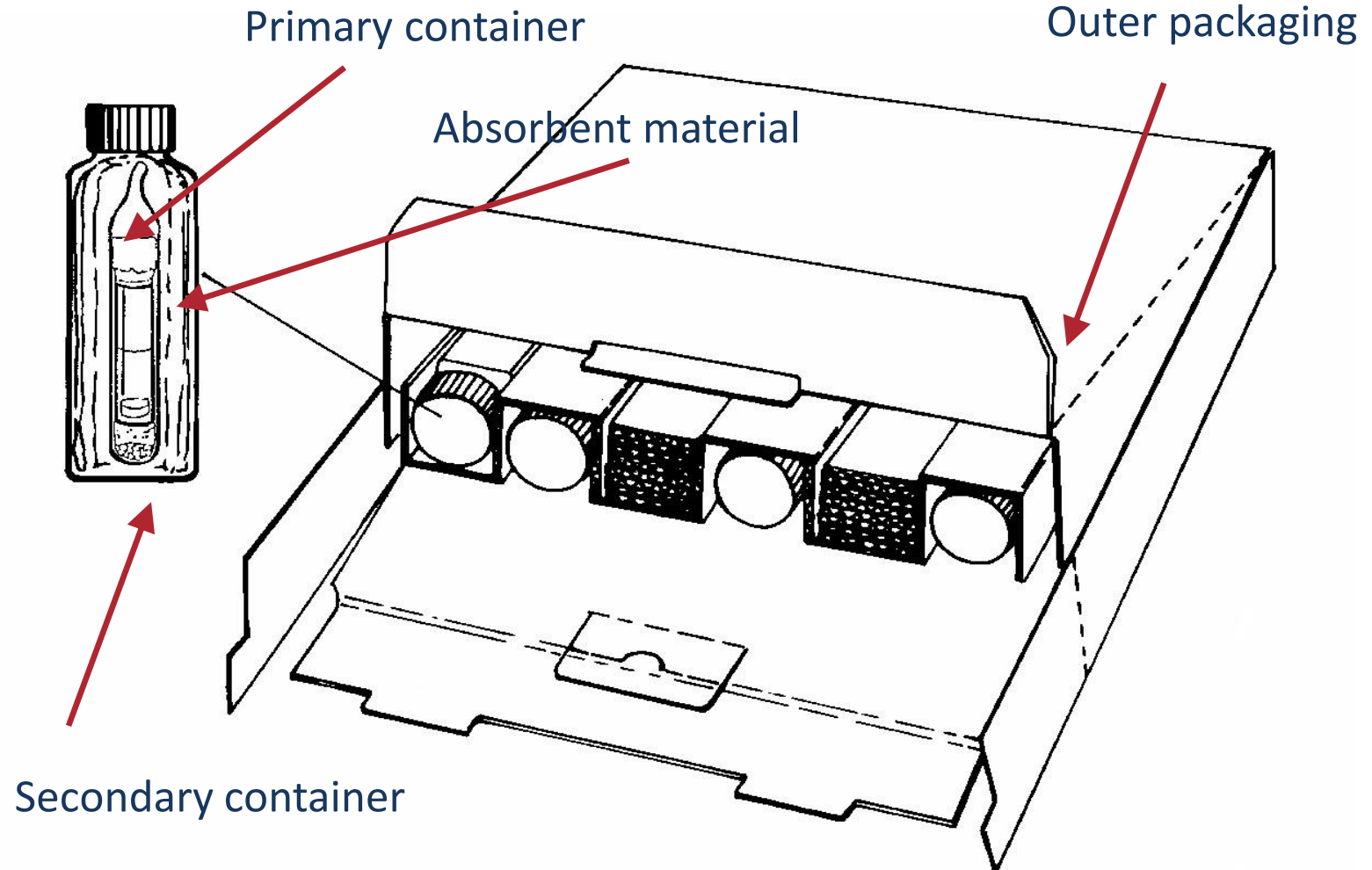
Postal employees,
airport personnel,
secretaries and
others

who could be exposed hazardously



National and international laws and regulations to reduce the possibility of an inadvertent release of microorganisms

Triple Packaging for Non-Infectious Substances



Some more ethical issues

BTWC - Biological and Toxin Weapons Convention

- bans the development, production, stockpiling, acquisition and retention of microbial or other biological agents or toxins

CITES – Convention on International Trade in Endangered Species of Wild Fauna and Flora

- ensures that international trade in specimens of wild animals and plants does not threaten their survival

CBD - Convention on Biological Diversity (in particular the Nagoya Protocol)

- aims at *the conservation of biological diversity*, sustainable use of its components, *fair and equitable sharing of the benefits* arising out of the utilization of genetic resources, including by appropriate *access* to genetic resources

Keywords: ABS (access and benefit sharing) , Cartagena Protocol (transboundary movement), Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (prior informed consent)

Budapest Treaty and the Nagoya Protocol (NP)

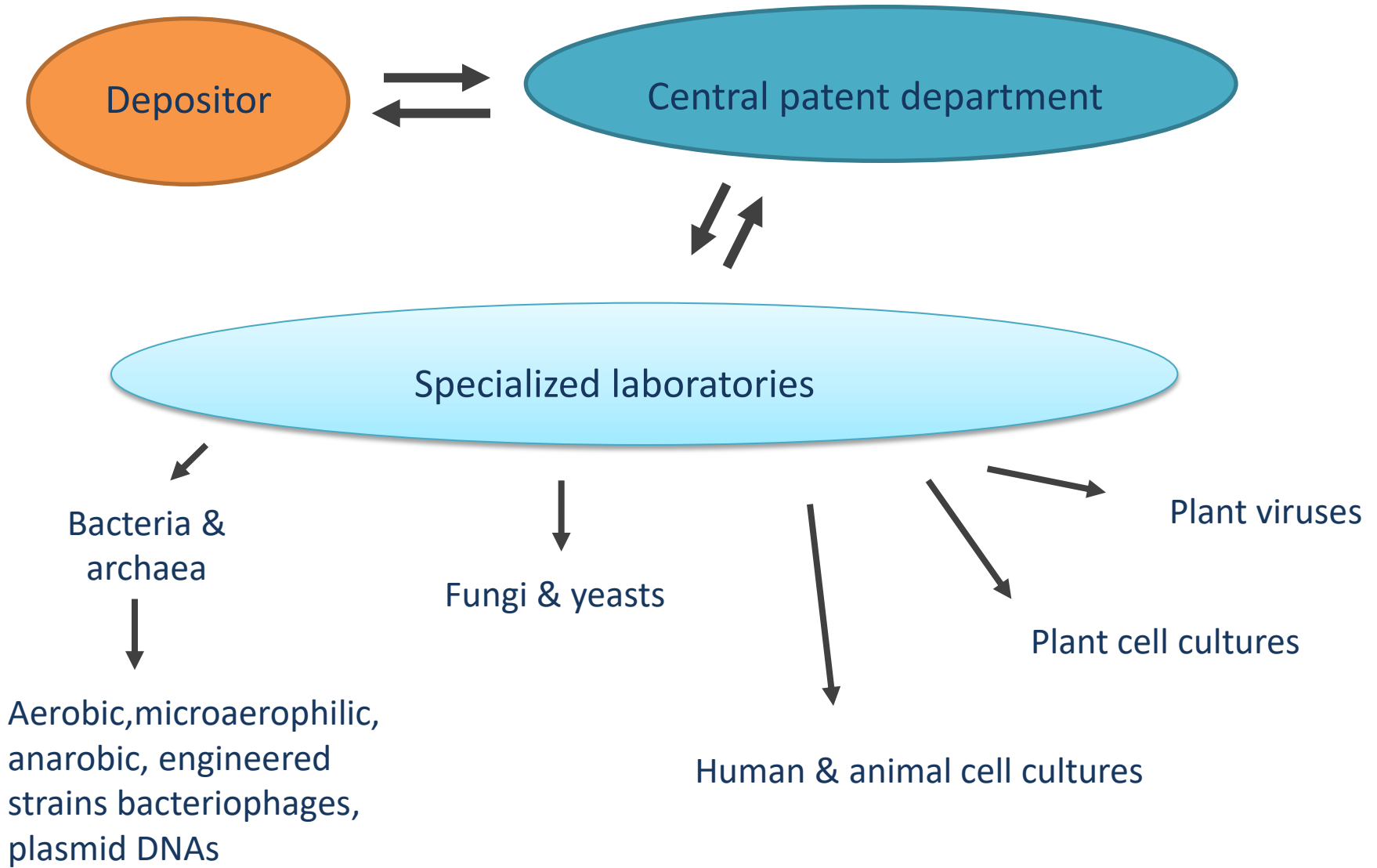
- Fears: **valuable biological material** of a given country of origin could be **released** to third parties **in an uncontrolled manner**
- Solution: Under the CBD, and in particular the Nagoya Protocol, an attempt is being made to provide countries of origin with instruments enabling them to **share in the benefits arising from their resources**.
- The **users** of the resources **are responsible** for compliance with the NP. The IDA is only a depository and therefore not a user.
- BT supports the spirit of CBD that **biological material must be traceable** by the given control mechanisms (Rule 11.4 (g))
 - information of the depositor

Budapest Treaty and the NP II

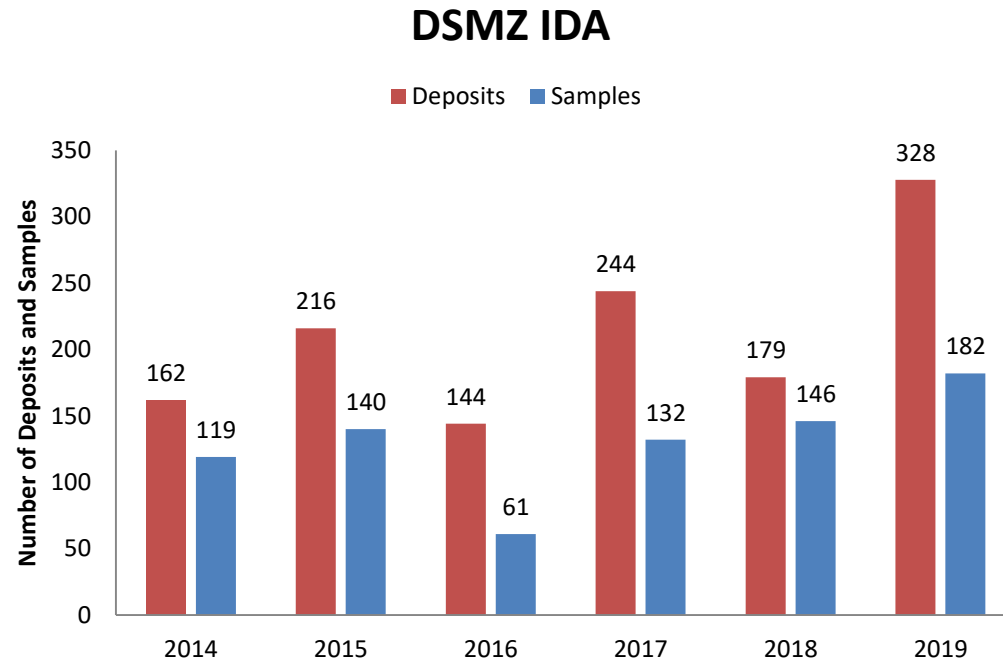
Example

- A strain is collected with the necessary NP documentation in Ethiopia (in the Nagoya Protocol the documents are called PIC/MAT or MTA).
- The scientist may only use the material in accordance with the documents (commercial use and therefore a patent application is often excluded) and may only pass on the strain together with these documents.
 - **Traceability is given**
- In case this strain is deposited with an IDA the depositor/scientist will be informed about each release and has to pass on the NP-Documents to the (new) user.
 - **Traceability is given**
- **Uganda** is a signatory of the Nagoya Protocol and has national regulations and guidelines to assist the compliance with the Nagoya protocol. PIC, MAT should be in place.

The DSMZ as IDA: Organization Scheme



The DSMZ as IDA



DSMZ – in numbers

~ 200 employees



The DSMZ IDA Team

2 scientists (group leader)

3 technical assistants

1 secretary



Thank You for Your Attention



Do you have questions?

Dr. Felizitas Bajerski
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Leibniz-Institut • DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH