

Safe and fair deposit of microorganisms: the Budapest treaty and Nagoya protocol



Depositing Biological Material in a Culture Collection

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SIRAM-PRIMA Project
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DSMZ - German Collection of Microorganisms and Cell Cultures GmbH



- DSMZ = both
 - **Research infrastructure (active collection)** used by science and industry for non-commercial purposes
 - **Research institution** in the field of biodiversity research
- The most **diverse biological resource center** in the world
- One of the largest **collections of microorganisms and cell cultures** worldwide
- DSMZ was the first "**Registered Collection**" under the EU Regulation 511/2014 for the **Nagoya Protocol**
- The only recognized **international depositary authority** under the **Budapest Treaty** in Germany

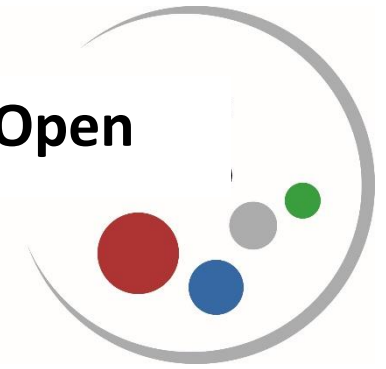


Forms of Deposit

Open collection



Open

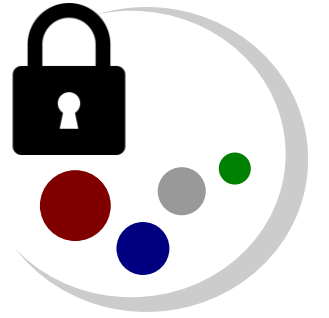


- **Public collection** = available to the international scientific community in both academic and industrial institution, without fee
- Biological material of applied, biotechnological, educational, taxonomic, and general interest
- Should have been used in work already **published** or prepared for publication
- DSMZ, as a **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



Forms of Deposit

Restricted Collection – Providing Safe Storage and Controlled Access



- **Safe deposit**
 - Handled strictly confidentially
 - Available only for the depositor (annual fee to be paid)
 - Not suitable for patent purposes or scientific purposes like the valid description of type strains
- **Patent deposit**
 - For patent purposes according the Budapest Treaty
 - The deposit will be recognized internationally
 - The material and all information concerning it will be handled strictly confidentially

Ownership, Property & Possession (law)

Ownership

- State or fact of legal **possession** and **control over property**
- Involve **multiple rights**
- May be separated and held by different parties

Possession

- The control a person intentionally exercises toward a thing
- Like ownership, the possession of anything is commonly regulated under the **property law**
- To possess something, a person must have an intention to possess it as well as access to it and control over it.
- A person **may be in possession** of some piece **of property without being its owner**.

Property

- **System of rights** that gives people legal control of valuable things
- Owner has the **right to properly use** it under the **granted property rights**
 - consume, alter, share, redefine, rent, mortgage, pawn, sell, exchange, transfer, give away, or destroy it, or to exclude others from doing these things

Modified content from:

<https://en.wikipedia.org/wiki/Ownership>

[https://en.wikipedia.org/wiki/Possession_\(law\)](https://en.wikipedia.org/wiki/Possession_(law))

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Ownership, Property & Possession (law)

Who „owns“ biological material (microorganisms)?

- Not clearly regulated by law
- Definition of **rights of use**

DSMZ terms of use (Public Collection)

- Any commercial use of the material is excluded
- Research purposes only
- No distribution
- Nagoya Protocol compliance
- Future publications

(Patents Deposits)

- For European Patents: Use that material for experimental purposes only (EPC form 1140: Request for the issue of a sample of deposited biological material v. 07.24)



Patents



What is an invention?

- An invention is a **product or a process** that provides a **new way of doing something** or offers a **new technical solution** to a problem that surpasses trivial solutions.

What is a patent?

- A **patent** is an exclusive right granted for an **invention**.
- **Patents** benefit inventors by providing them with **legal protection** of their inventions.
- Patents benefit the society by providing **public access to technical information** about these inventions



What is patented (referring to microorganisms)?

- “Process by which biological material is produced or processed or in which it is used”
 - Usually not the material itself
 - Different regulations by countries

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Needs of a Patent

- ✓ **New** or **novel** and **non-obvious**
- ✓ **Useful** purpose (commercial applicability)
- ✓ Must be **disclosed** in the application in a manner sufficiently clear and complete for an expert to be able to carry it out
- Disclosure by depositing microorganism with a specialized institution
- 1977: Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure



Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

- Adopted in 1977
- Contracting Parties Budapest Treaty: 89 members
 - Last accession: Rwanda in 2023
 - Spain: 1977, ratified in 1980
 - Portugal: 1997, IDA University of Coimbra Bacteria Culture Collection (UCCCB) 2024
- 51 depositary institutions in 27 countries
- **Deposit** of microorganisms and the **furnishing** of samples under the Budapest Treaty

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Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

The main facts for a deposit according to the Budapest Treaty are as follows:

- **A single deposit with one IDA** (e.g. the DSMZ) is recognised as valid by all Contracting States of the Budapest Union.
- The storage time is **at least 30 years**.
- After deposition the culture cannot be claimed back. **The deposit remains valid**.
- The depositor is advised to keep samples of the culture for the same period of time so that in the case the culture is for any reason no longer available from the Depository Authority he can replenish the stock.
- The Depository Authority (the DSMZ) **maintains secrecy about the details of a deposit** and the nature of the deposited material. All material and information is **handled strictly confidentially**

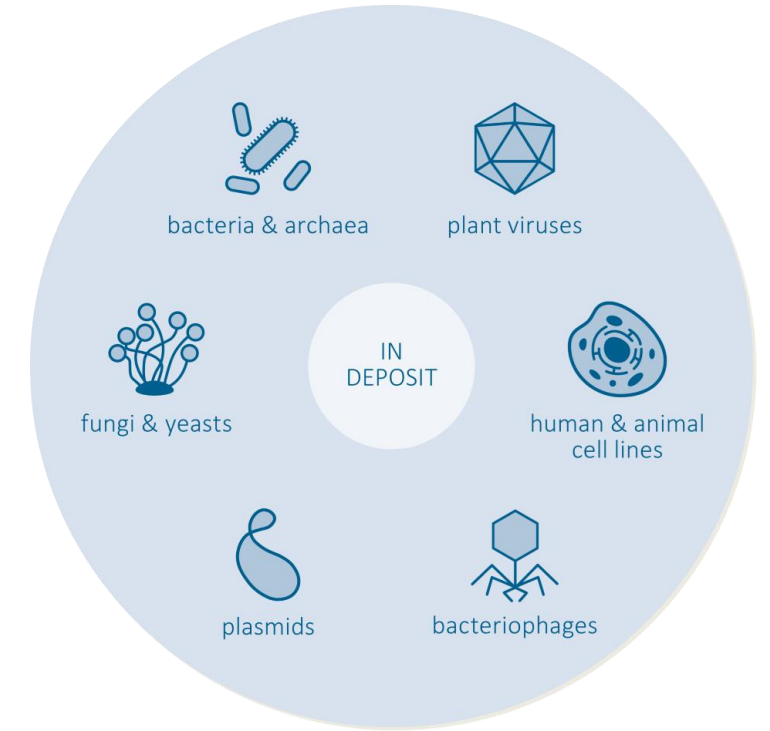
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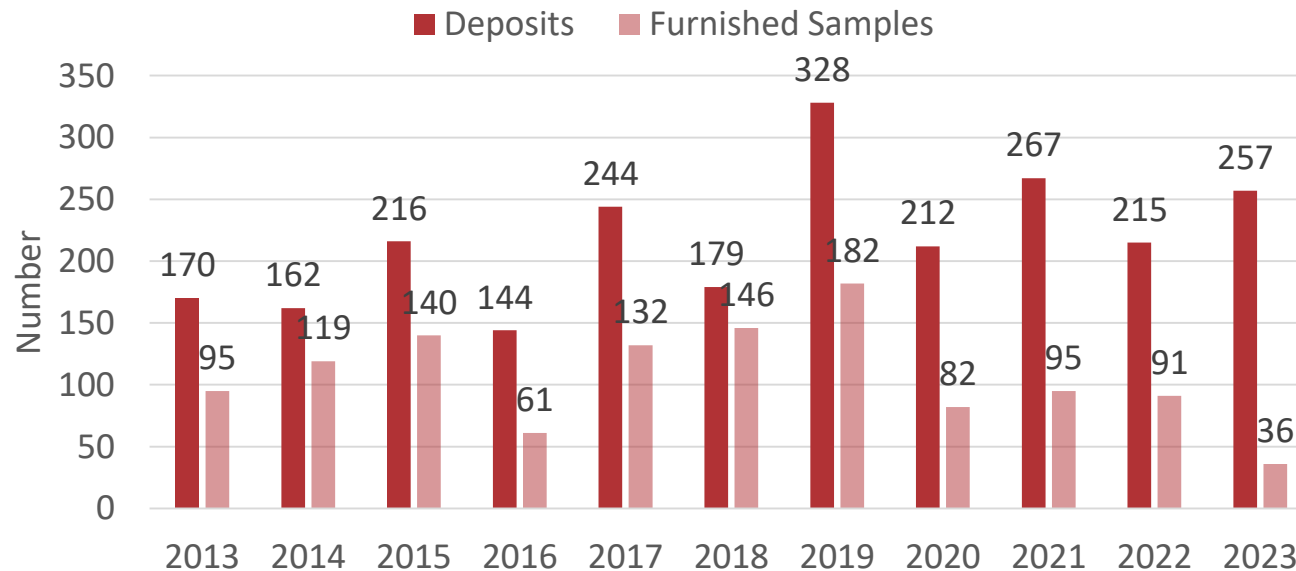
Providing Safe Storage and Controlled Access

DSMZ as Patent Depository

- > 45 years
- First patent strain in 1972
- Recognized as **International Depository Authority (IDA)** according to the Budapest Treaty **since 1981**
- Total > 9000 patent deposits



Patent Deposit in Numbers



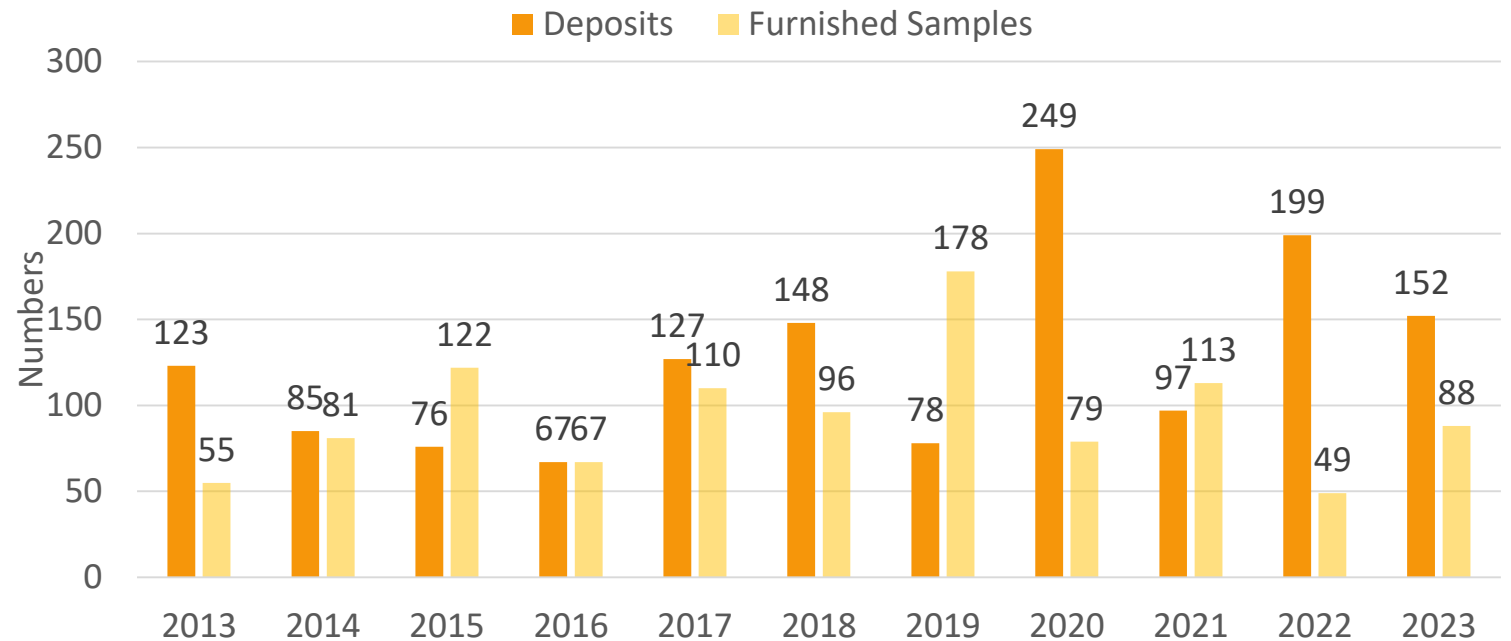
Providing Safe Storage and Controlled Access

Safe Deposit

DSMZ as Safe for Microorganisms

- ✓ **Safe Deposit** as a special service for the **long-term preservation** and **safe storage**
- ✓ Not included in the DSMZ catalogue
- ✓ Only passed on with a written request by the depositor

Safe Deposit in Numbers



Providing Safe Storage and Controlled Access

Safe Deposit

Biobanking

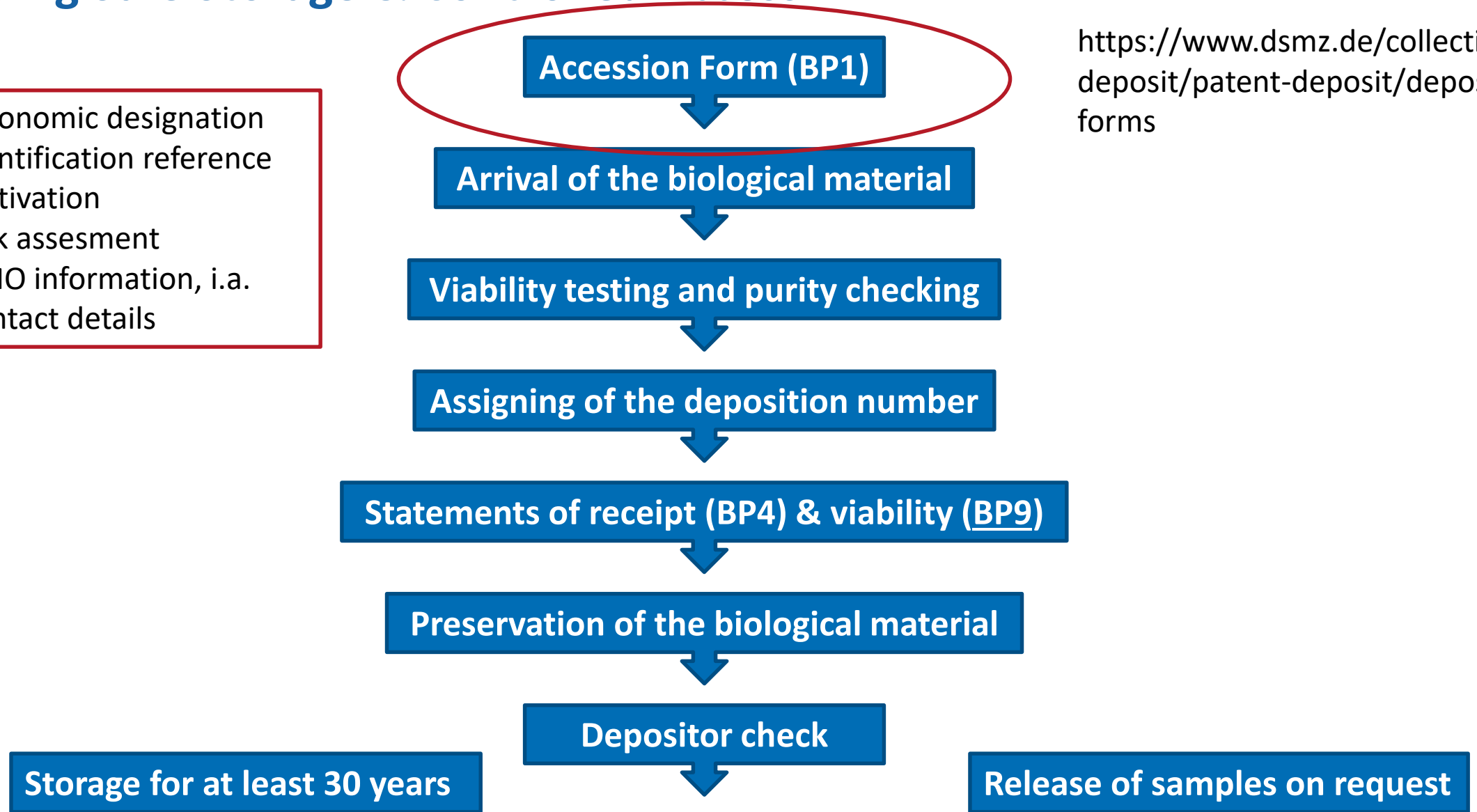
- **Maintain valuable biological resources** for future research, public health and the bioeconomy
- Potential **risks**: pandemic situations as recently experienced during the Covid-19 outbreak, crisis, disasters
- Aim: **Avoid** the loss of material via staff shortage, infrastructure-related supply problems and disasters
- Spatially separated **back-up** solutions strongly recommended and often mandatory for biobanks
- Used for official registration processes such as for the European Food Safety Authority
 - E.g. Feed additive applications



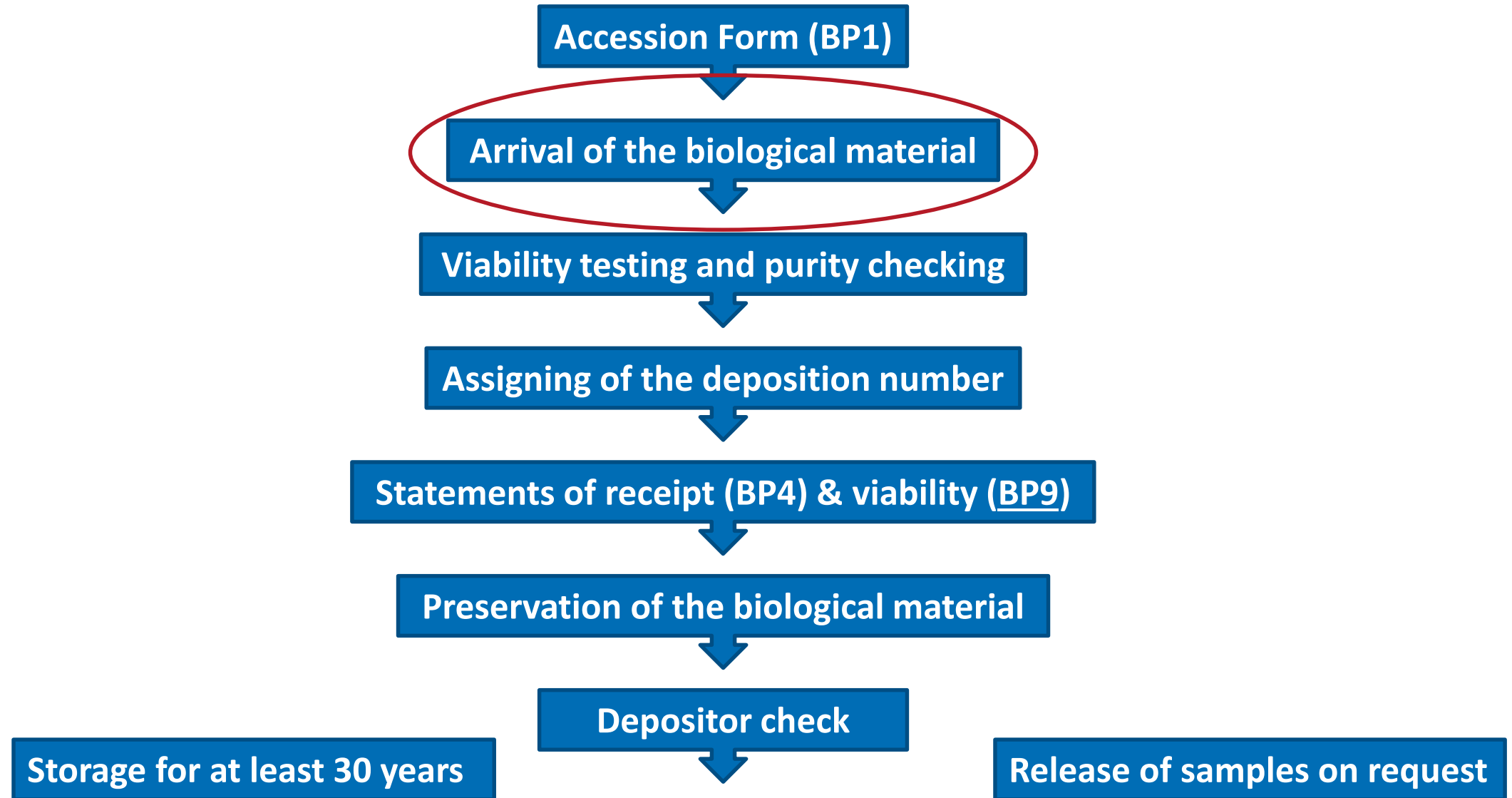
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- Taxonomic designation
- Identification reference
- Cultivation
- Risk assesment
- GMO information, i.a.
- Contact details

<https://www.dsmz.de/collection/deposit/patent-deposit/deposit-forms>



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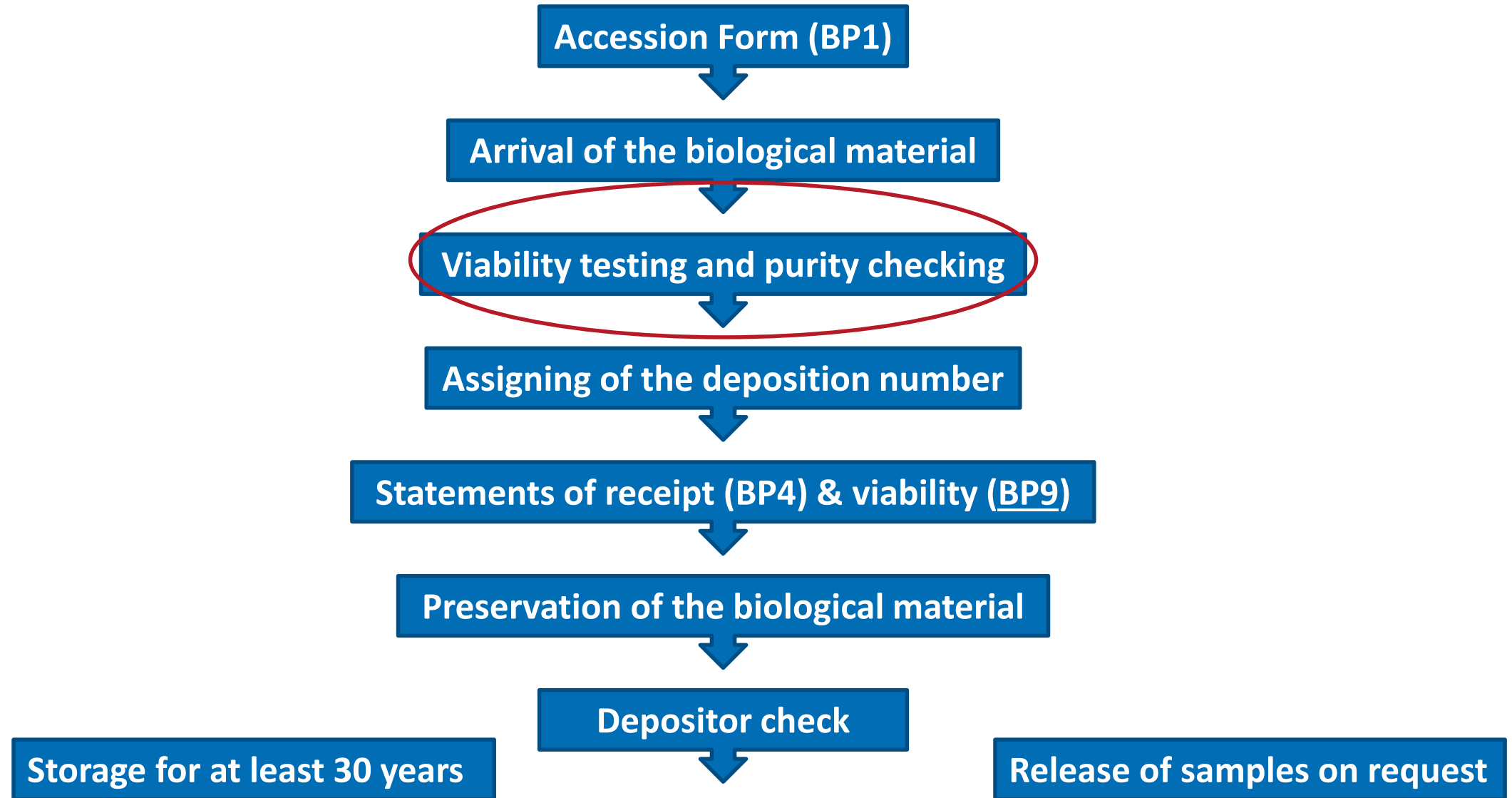
Technical Requirements and Procedures Form and Quantity at the DSMZ

- ✓ risk group 1 or 2
- ✓ genetically engineered material, safety level S1 or S2 or class 1 or 2

Biological Material	Form and Amount of the Material
Archaea, Bacteria	dried or frozen material (glycerol stocks) or actively growing cultures: two separate preparations; requirement for anaerobes: active culture as two or more preparations with a minimum total volume of 5 ml
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



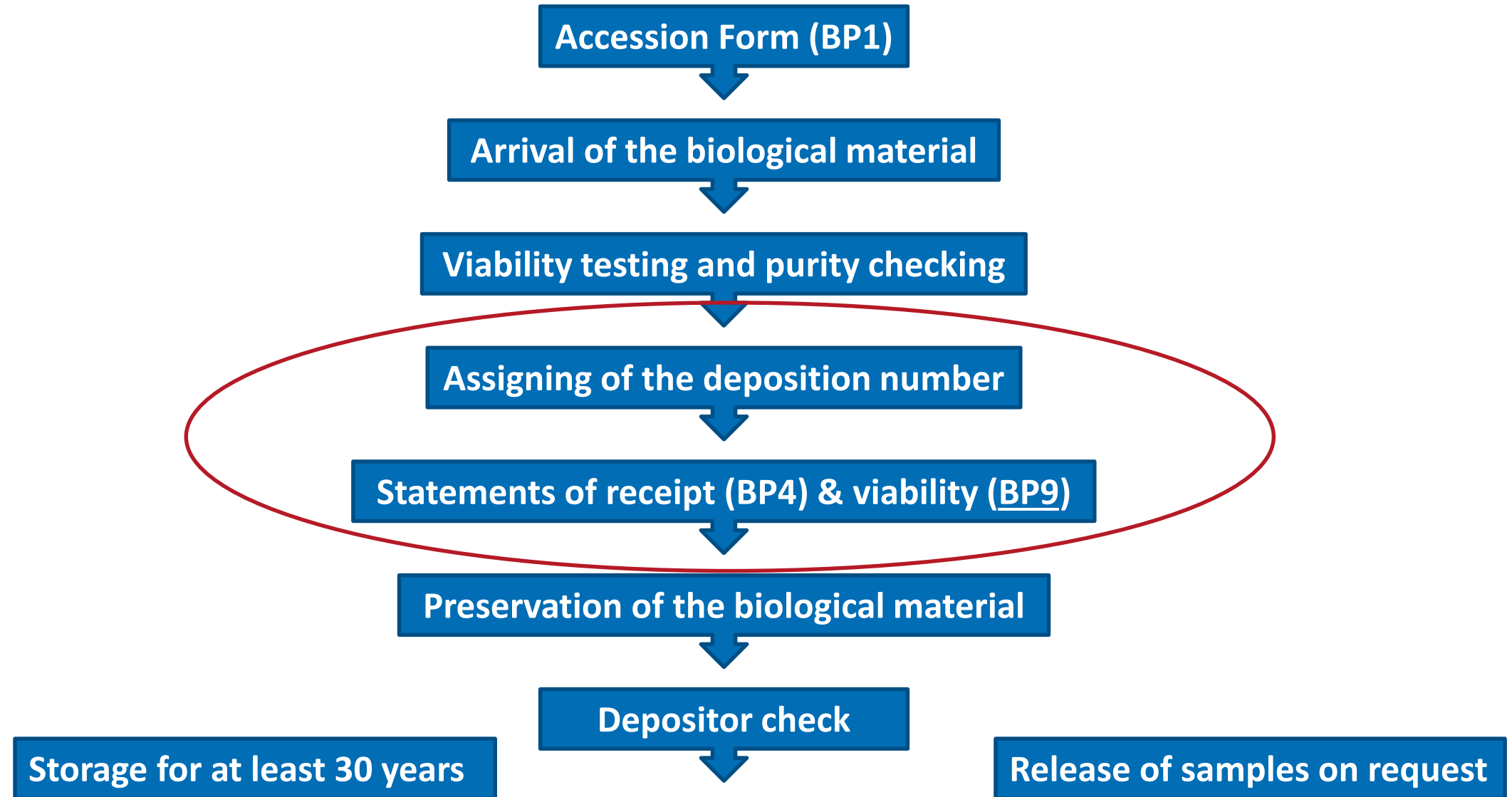
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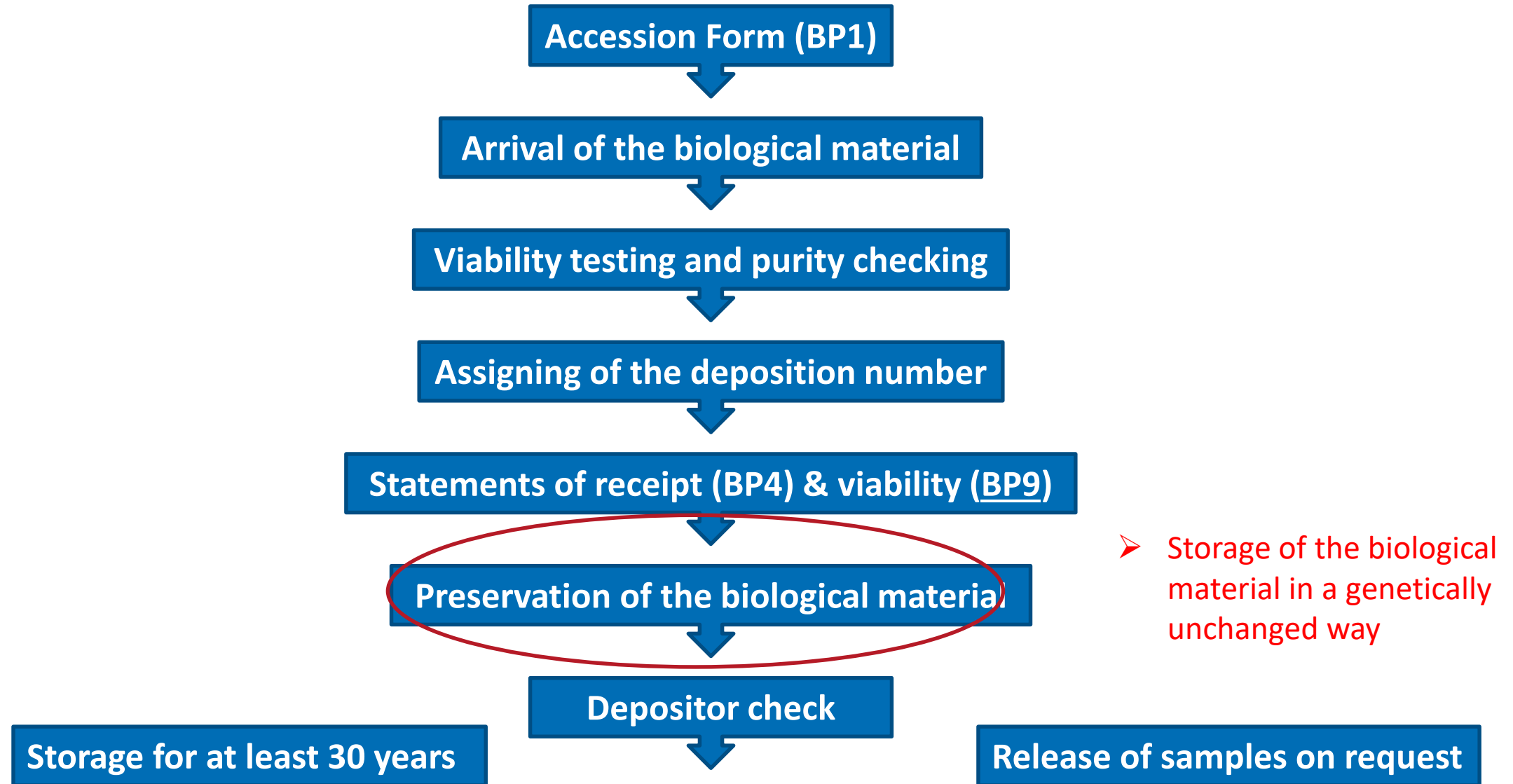
Viability Testing and Time Required for Testing

<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

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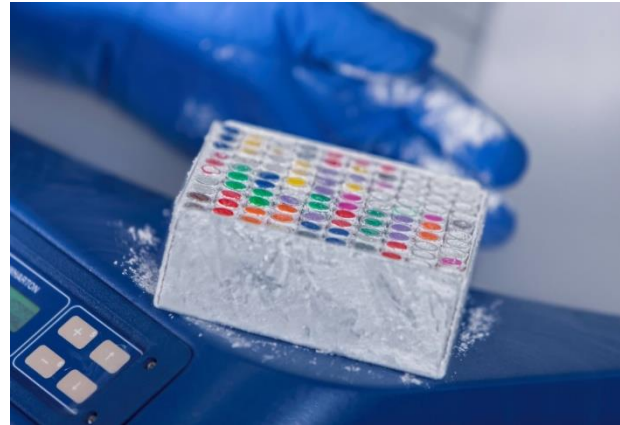


Providing Safe Storage & Controlled Access



Preservation of the biological material in Liquid Nitrogen

Cryotubes in LN tanks (cell lines and phages)



Production of glass capillaries



Glass capillaries in LN tanks (bacteria)

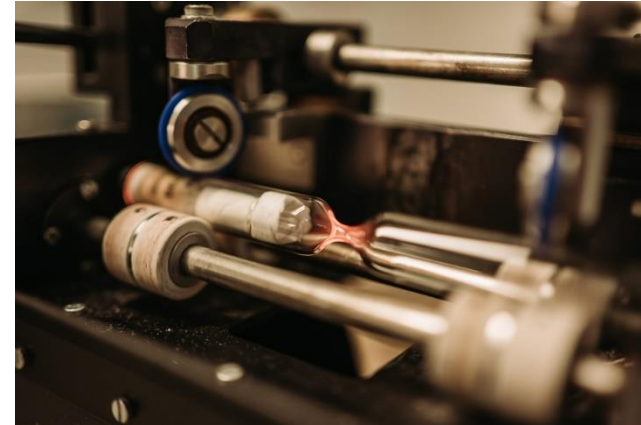
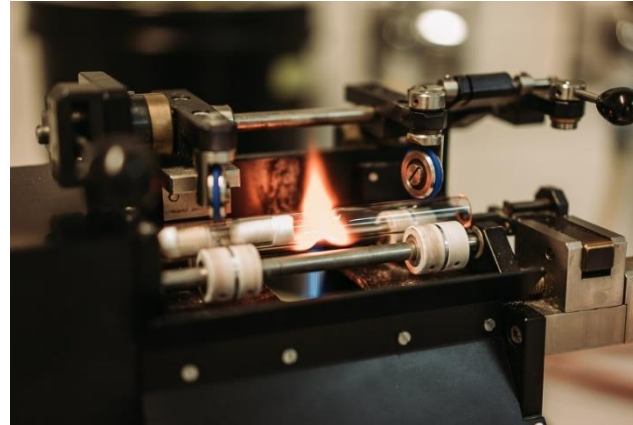


Drying of Microorganisms

Production of ampoules



Constrictors to melt glass ware



Freeze drying machine



Storage of the biological material for at least 30 years

Storage in liquid nitrogen storage tanks

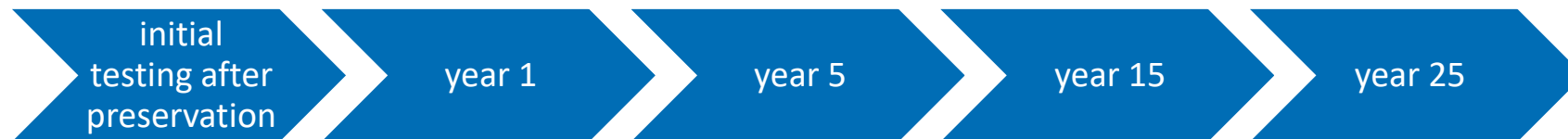


Storage of Dried Cultures



Viability and purity testing of the stored material

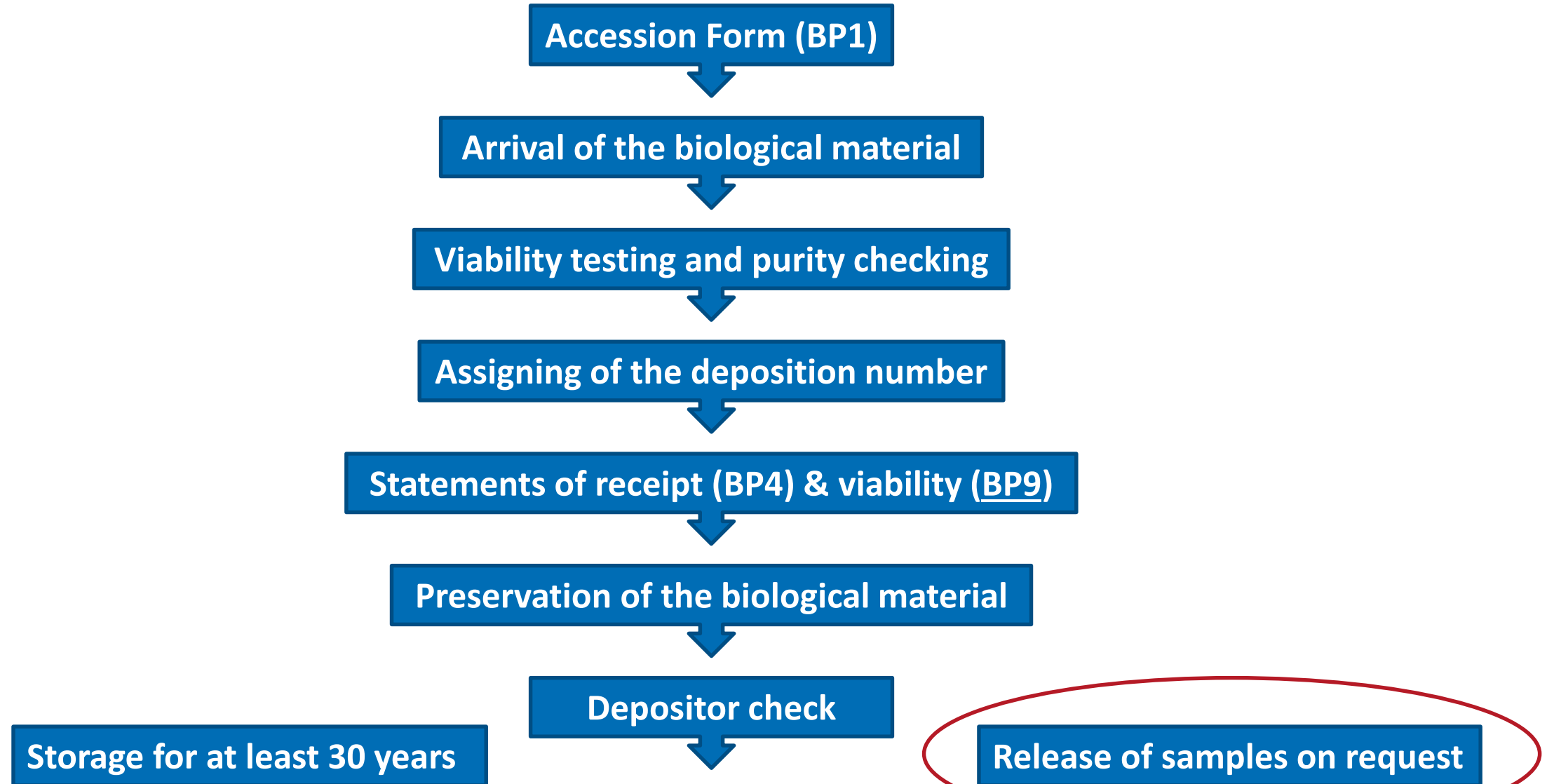
Ideal time schedule:



Fees for the Patent Deposit of Biological Material at the DSMZ

<i>Kind of Service</i>	<i>EUR</i>
Accession of: bacteria fungi plasmid DNA bacteriophages plant viruses	900
Accession of: animal and human cell cultures plant cell cultures	1.600
Furnishing of a sample under Rule 11 of the Budapest Treaty	140

Providing Safe Storage & Controlled Access



Furnishing of Samples – When? To Whom?

Budapest Treaty Rule 11

11.1 To Interested **industrial property offices**

When?

- At **any time** on request to the DSMZ

11.2 To **Depositor** and with the authorisation of the depositor to third parties

When?

- At **any time** on request to the DSMZ

11.3 To Parties **legally entitled**

When?

- A) By **confirmation** of the request **by** the responsible **patent office**
- B) In respect of **patents granted** and **published** by any industrial property office



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Thank You for Your Attention



Do you have questions?

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