DE – GERMANY

LEIBNIZ-INSTITUT DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH (DSMZ)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including mycoplasma) and archaea (both including those containing plasmids), fungi (including yeasts), bacteriophages, plasmid DNAs, plant viruses, plant cell cultures (undifferentiated plant cell cultures, embryogenic plant cell cultures and tissues, *in-vitro* shoot cultures), human and animal cell cultures (including hybridomas).

The DSMZ accepts for deposit only those microorganisms which, pursuant to the Directive 2000/541EC on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work (OJ No. L262, pp. 21-45 of September 18, 2000) or the respective German Law (*Biostoffverordnung* (BGBI. 1pp. 2514 as of July 15, 2014)) belong to risk group 1 or 2.

Genetically manipulated organisms and isolated DNA must be processable in accordance with Class 1 or 2 of Directive 98/8 1/EC on the contained use of genetically modified microorganisms (OJ No. L330, pp. 13-31 of December 5, 1998) or safety level S1 or S2 of the German Law Regulating Genetic Engineering (BGBI. 1, pp. 2066-2083 of December 21, 1993, last changed by Art. 2 abs. 27 and Art. 4 Abs 14 G of August 7, 2013, I 3154).

The biological material indicated above cannot be accepted if it is contaminated by foreign organisms.

Mixtures of microbial cultures of more than two components will not be accepted. Mixtures of two components will only be accepted if these a) cannot be cultivated separately as pure cultures and b) can easily be distinguished macroscopically and/or microscopically.

Plant viruses which cannot be multiplied through mechanical infection of plants cannot be accepted for deposit.

The DSMZ reserves the right to refuse to accept for deposit material which in its view represents an unacceptable hazard or which it is not in a position to process.

In all instances, it must be possible to preserve the deposited material by lyophilization or storage in liquid nitrogen or by some other method of long-term preservation without significant change.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The DSMZ has the following special requirements for the form in which the microorganisms should be submitted for deposit.

- Bacteria, archaea and fungi should, where possible, be deposited in the form of two actively growing cultures. Lyophilized cultures are also accepted.

- Bacteriophages should be deposited in minimum quantities of 2 x 5 ml having a minimum titre of 1 x 10^9 pfu pro ml.

- Plasmids as isolated DNA preparations should be in a minimum quantity of 2 x 20 [micro] g.

- Bacteriophages and plasmids need to be sent together with a suitable host, if such a host is not available in the public collection of the DSMZ.

- Plant viruses should be deposited in the form of dried or frozen material along with the host's seeds, unless the host is generally available. 100 [micro] l of serum suitable for immunoelectron microscopy should also be deposited for the purity and identity test.

- Plant material can be deposited in the form of undifferentiated plant cell cultures, embryogenic plant cell cultures and tissues. For deposit 25 frozen ampoules are required. In the case of cryopreserved shoot tips or meristems these ampoules should contain a total of at least 100 surviving apices resp. meristems.

- Animal and human cell cultures should be deposited as frozen cultures in 12 ampoules (all prepared at the same time), each containing at least 5 x 10^6 cells per ampoule (cells growing in suspension) or 2 x 10^6 cells per ampoule (adherent cells).

The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the DSMZ, animal and human cell cultures must be examined to ensure they are free from viruses. Cultures should be sent in appropriate containers.

(ii) Time Required for Viability Testing

The average time required for testing the viability of the various kinds of microorganisms accepted by the DSMZ is given below, but depositors should realize that in some cases, especially with slow growing microorganisms, viability testing may take longer, as indicated by the figures in brackets:

Bacteria, archaea, yeasts, bacteriophages and plasmids	2 days (or up to 3 weeks)
Fungi	3 days (or up to 3 weeks)
Plant viruses	2 weeks
Plant cell cultures	3 to 4 weeks (or up to 6 months)
Human and animal cell cultures (including test for contamination with mycoplasma)	2 weeks

(iii) Depositor Checks and Renewal of Stocks

The DSMZ prepares its own lyophilized and/or frozen batches of bacteria, archae, fungi and yeasts at the time of deposit by subculturing material supplied by the depositor (but not from plasmids, bacteriophages, plant cell cultures, plant viruses or animal and human cell cultures). New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the DSMZ.

Despite the methods used for preparing batches of samples for distribution, the DSMZ nevertheless stores a portion of the original material supplied by the depositor, if the culture supplied allows this.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the DSMZ is German. Communications are also accepted in English. Correspondence in French is accepted, except in the case of forms.

Contract. The DSMZ does not enter into a written contract with the depositor defining the liabilities of either party but, by signing the DSMZ deposit form, the depositor accepts the General Terms and Conditions of the DSMZ and surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. In very few cases import regulations apply to the kinds of microorganisms accepted by the DSMZ. In such cases, the depositor must supply the species name of the microorganism, whereupon the DSMZ will apply to obtain the necessary permit. The kinds of microorganisms accepted by the DSMZ are not subject to quarantine regulations. Further information about import requirements may be obtained from: Bundesminister für Ernährung, Landwirtschaft und Verbraucherschutz, Wilhelmstr. 64, 10117 Berlin, Germany.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete form DSMZ-BP/1 (the equivalent of model form BP/1) which is the deposition form used for Budapest Treaty deposits. The DSMZ uses separate forms for the deposit of bacteria, archaea or fungi, bacteriophages, plasmids, plant viruses, plant cell cultures and animal and human cell cultures. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the DSMZ has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, both in German and English. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The DSMZ will communicate by e-mail the date of deposit and deposition number before the official statements of receipt and viability are issued, but only after the viability and purity test has been done and has given a positive result.

Supply of Information to a Patent Agent. The DSMZ does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the DSMZ will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally made for patent purposes. However, in the case of deposits previously made for scientific purposes and which are already generally available from the DSMZ, the depositor is requested to authorize the DSMZ to continue to make them so available and to waive his right to be notified of the release of samples. If the depositor is unwilling to accede to this request, he must make another deposit of the same organism under the Budapest Treaty. These constraints do not apply to deposits previously made for patent purposes or to deposits made confidentially for safekeeping. Any deposit previously made free of charge is subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. With the exceptions noted above, the administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is requested to complete the equivalent of model form BP/2 when making a new deposit, and to supply copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on mandatory "international forms" BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The DSMZ advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the DSMZ will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

Model request form BP/13 is used in connection with requests for deposited microorganisms where the responsible patent office has communicated lists of the accession numbers given by the IDA to deposits of microorganisms referred to in the said patents.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the DSMZ will withhold samples of potentially hazardous microorganisms until the requesting party has provided evidence that he is allowed to work with such organism. When responding to requests from overseas, the DSMZ will ask the requesting party to provide an import permit if it knows that one is required for that particular country.

All samples of bacteria, archaea and fungi furnished by the DSMZ are from batches of its own preparations of the microorganism.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

In accordance with Rule 9.2 of the Treaty, the DSMZ does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

	EUR
I.1	
(a) Storage according to Rule 12.1 (a)(i) of the Regulations under the Budapest Treaty (comprising the initial viability check, the preservation and the storage of the biological material)	
- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses	1.050
- plant cell cultures, human and animal cell cultures	2.000
(b) Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty	
- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses	1.050
- plant cell cultures, human and animal cell cultures	2.000
(c) Prolongation of the duration of the storage over the one provided by Rule 9 of the Regulations under the Budapest Treaty, per year	70
I.2 Issuance of a viability statement according to Rule 12.1(a)(iii) of the Regulations under the Budapest Treaty	
(a) where a viability test is requested	160
(b) on the basis of the most recent viability test	80
I.3 Furnishing of a sample according to Rule 12.1(a)(iv) of the Regulations under the Budapest Treaty (plus current freight costs)	160
I.4 Communication of information under Rule 7.6 of the Regulations under the Budapest Treaty	60
I.5 Attestation referred to in Rule 8.2 of the Regulations under the Budapest Treaty	60

For the customers within Germany the fees are subject to VAT, currently at the rate of 7 %. Turnover tax, again currently at the rate of 7 %, must be charged on EU orders not quoting a VAT registration number.

A processing fee of 5-30 Euros to cover handling and bank charges is payable on all invoices

4. Guidance for Depositors

The DSMZ provides specific written notes for the guidance of prospective depositors on its home page (www.dsmz.de). In addition, it is always ready to give advice by telephone or by e-mail.