

PL – POLAND

COLLECTION OF PLASMIDS AND MICROORGANISMS (KPD)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, archaea, genetically modified microorganisms, microbial consortia, and plasmids in a host and/or as isolated DNA preparations.

KPD accepts microorganisms, microbial consortia, and plasmids in a host and/or as isolated DNA preparations, which can be handled under containment levels 1 and 2. Pathogens belonging to a hazard group higher than Risk group 2 according to the EU directive 2000/54/EC and its updates are excluded.

Class 2 genetically modified microorganisms may be accepted for deposit; however, the period for completion of a deposit will be longer to allow for the sufficient time needed to meet regulatory requirements.

In the case of microbial consortia or mixtures of microorganisms, KPD recommends that the depositor separates the different components and deposits them individually. In such cases, the depositor is charged for each separate deposit. Exceptionally, KPD may also accept deposits of defined mixtures of microorganisms on the conditions that (i) it is possible to ensure that the mixture can be preserved without losing one of the components, (ii) the individual components can easily be distinguished macroscopically, and (iii) it is possible to test the viability of each of the organisms in the mixture individually. However, KPD is not responsible for changes in the characteristics of the properties of the consortium once it has been deposited. The acceptance of mixtures of microorganisms is subject to the KPD curator's decision, and the fees related thereto must be fixed individually by prior negotiation with the prospective depositor.

Contaminated cultures, undefined, unidentifiable microorganisms, strains with no scientific description and/or proposed taxonomic designation whose identity cannot be verified will not be accepted.

All deposits should be able to withstand preservation by either freeze-drying or freezing over liquid nitrogen, or by some other method of long-term preservation without any significant change to their properties.

The KPD reserves the right to refuse to accept for deposit material that is technically or legally too difficult to manage, or which in its view represents an unacceptable hazard, or it is not in a position to process.

(b) Technical Requirements and Procedures

(i) Form and Quantity

- Bacteria and Archaea

Microorganisms should be submitted for deposit as lyophilised preparations.

The depositor must supply 25 ampoules of freeze-dried cells of the same batch. The freeze-dried cells of one or more of these ampoules will be subjected to a viability test.

- Plasmids in a bacterial host

The depositor must supply 5 active or 25 freeze-dried cultures of the same batch, of which one or more will be subjected to a viability test and subsequently serve for the preparation of a stock of cryopreserved cells.

- Plasmids as isolated DNA

The minimum amount of isolated DNA that must be supplied by the depositor when making their deposit is 12 microtubes of 20 micrograms of freeze-dried or ethanol-precipitated DNA. The plasmid DNA must have a sufficient degree of purity and integrity to ensure a successful transformation.

Plasmids need to be sent together with a suitable host if such a host is not available in the public KPD collection. The non-publicly available host provided by the depositor must be deposited separately in the public KPD collection or as a separate deposit under the Regulations of the Budapest Treaty.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of microorganisms accepted by the KPD is as follows (however, depositors should be aware that the viability test may take longer for certain types of microorganisms):

Bacteria, archaea	4 days (up to 21 days)
Plasmids in hosts or purified DNA	2 weeks

(iii) Depositor Checks and Renewal of Stocks

The KPD prepares its own lyophilized and/or frozen batches of bacteria, archaea and plasmid DNA at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter to renew diminishing stocks. The depositor is required to test for authenticity samples from all batches of their microorganism prepared by the KPD.

Whichever method is used for preparing batches of samples for distribution, KPD nevertheless freezes and stores a portion of the original material supplied by the depositor, wherever possible.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the KPD is English. Communications are also accepted in Polish.

Contract. The KPD form, which the depositor is required to complete, constitutes a contract by which the depositor is bound:

- to provide all necessary information requested by the KPD;
- to obtain necessary permission for transportation and deposit;
- to pay all necessary fees;
- not to withdraw their deposit during the required storage period;
- to replace the microorganism at the depositor's expense if the KPD is no longer able to furnish samples of it;
- to indemnify the KPD or University of Gdansk against any claims which may be brought against them as a consequence of the release of samples, unless such claims result from negligence on the part of the KPD;
- to authorize the KPD to furnish samples according to the applicable patent requirements.

Import and/or Quarantine Regulations. Most of the kinds of microorganisms accepted by KPD are not subject to import regulations. Prospective depositors of pathogenic microorganisms should contact KPD in advance so that the necessary arrangements can be made. The kinds of microorganisms accepted by the KPD are not subject to quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete form KPD/BP/1 (the equivalent of model form BP/1) which is the deposition form used for Budapest Treaty deposits and the KPD accession form including a GMO risk assessment (if applicable) for each microorganism or plasmids deposited. The KPD uses separate forms for the deposit of bacteria, archaea or plasmids. 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 KPD 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, in English. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the KPD equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on the KPD equivalent model form BP/14.

Unofficial Notifications to the Depositor. The KPD will inform the depositor via e-mail about 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. KPD requests the depositor to communicate to them, in the interest of all concerned, the name and address of their patent agent. The depositor has to request KPD to send copies of the receipt and viability statement to their 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. Any earlier deposit - even if made free of charge - is subject, at the time of conversion, to the storage fee normally charged for deposits made under the Budapest Treaty. The administrative requirements for conversion are the same as those that must be met for an original deposit made under the Budapest Treaty. Both the date of deposit and the date of receipt of the request for conversion are stated on the "international form" BP/4.

(iv) Making a New Deposit

The depositor will be required to complete 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 the 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

KPD advises third parties of the procedure to be followed in order to make a valid request. In the case of requests requiring proof of entitlement, KPD will provide requesting parties with copies equivalent of model form BP/12.

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 KPD will withhold samples of potentially hazardous microorganisms until the requesting party has provided evidence that they are allowed to work with the such organism. In any case of requests, the requesting party has to comply with its own country's requirements regarding the import, handling of biological material and biosafety regulations.

Samples furnished by KPD are from material supplied by the depositor or from batches prepared by the KPD.

(b) Notification of the Depositor

The depositor will be notified by KPD when a sample of the deposited microorganism will be furnished to third parties on the KPD equivalent of model form BP/14.

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

In PLN	
Preservation	
Storage according to Rule 12.1 (a)(i) (comprising of the initial viability check, the preservation and storage of biological material):	1200
Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty (comprising of the initial viability check, the preservation and storage of biological material):	1200
Prolongation of the duration of the storage over the one provided by Rule 9 of the Regulations under the Budapest Treaty, per year	100
Issuance of a viability statement according to Rule 12.1(a)(iii) of the Regulations under the Budapest Treaty	
where a viability test is requested	150
based on the most recent viability test	50
Furnishing of samples:	

To the depositor, according to Rule 11.2 (i) of the Regulation under the Budapest Treaty	200
To a third party according to Rule 11.2 (ii) and 11.3 of the Regulations under the Budapest Treaty	200
Communications and attestations	
Communication of information under Rule 7.6 of the Regulations under the Budapest Treaty	50
Attestation referred to in Rule 8.2 of the Regulations under the Budapest Treaty	50

Fees (in Polish zloty) do not include shipping costs or bank fees, or Value-added tax (VAT). (For customers outside Europe, no VAT will be added).

4. Guidance for Depositors

The KPD provides information about the patent deposit process on its home page. The details of the deposit procedure may also be requested by mail or phone from the KPD.