CN - CHINA

GUANGDONG MICROBIAL CULTURE COLLECTION CENTER (GDMCC)

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1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

The GDMCC will accept for deposit: bacteria and archaea (including those containing plasmids), fungi (including molds and yeasts), bacteriophages, plasmids (both isolated and in hosts), deoxyribonucleic acids (DNAs), unicellular algae, plant cell cultures (including undifferentiated cell cultures, embryogenic plant cell cultures and tissues, *in-vitro* shoot cultures), human and animal cell cultures (including hybridomas).

At present, the GDMCC does not accept deposits of embryos, parasitic and pathogenic protozoa, animal viruses, plant viruses, and RNA preparations.

The GDMCC do not accept for deposit pathogenic microorganisms of Risk Group 1 & 2 (Chinese classification) and other microorganisms restricted or prohibited by Chinese law or administrative regulations.

As a general rule, the GDMCC will only accept the deposited materials that can be preserved by lyophilization or storage in liquid nitrogen or by some other method of long-term preservation without significant changes in their characteristics.

Exceptionally, the GDMCC may accept deposits which can only be maintained in active culture, but acceptance of such deposits, and relevant fees, must be decided on a case-by-case basis by prior negotiation with the prospective depositor.

The GDMCC reserves the right to refuse to accept a deposit if, in its view, the deposit may be an unacceptable hazard or the deposit may be technically too difficult to process.

(b) <u>Technical Requirements and Procedures</u>

(i) Form and Quantity

Bacteria, archaea, fungi (including molds and yeasts), unicellular algae and plasmids in hosts should, where possible, be deposited in the form of five actively growing cultures. However, lyophilized or frozen cultures can be occasionally accepted.

Bacteriophages should be deposited in minimum quantities of 10×5 ml having a minimum titre of 1×10^9 pfu per ml.

Plasmids as isolated DNA preparations should be in a minimum quantity of 10 x 10 [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 GDMCC.

Plant materials can be deposited in the form of undifferentiated plant cell cultures, embryogenic plant cell cultures and tissues, and as *in-vitro* shoot cultures. 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 15 ampoules (all from the same batch), each containing at least 5×10^6 cells per ampoule (cells growing in suspension) or 2×10^6 cells per ampoule (adherent cells).

The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the GDMCC, animal and human cell cultures must be examined to ensure they are free from viruses.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of biological materials accepted by the GDMCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets.

Archea, Bacteria

Fungi, Yeasts

Algae

Plasmids

Bacteriophages

Plant Cell Cultures

Human and Animal Cell Lines

3 days (or up to 14 days)
5 days (or up to 20 days)
7 days (or up to 14 days)
7 days (or up to 14 days)
7 days (or up to 30 days)
7 days (or up to 20 days)

(iii) Depositor Checks and Renewal of Stocks

The GDMCC prepares its own depositing batches in lyophilized or frozen form at the time of deposit by subculturing microorganisms supplied by the depositor. The deposits could also be made from the original materials at the request of the depositor. However, the GDMCC generally does not prepare its own batches of isolated plasmids, bacteriophages,

DNA, plant cell cultures and human and animal cell lines. When stocks of biological material are depleted by the furnishing of samples, the GDMCC will ask the depositor to make a new deposit.

The depositor may request a sample from lyophilized or frozen batches of their deposit, which have been prepared by GDMCC, for an authenticity check.

(c) Administrative Requirements and Procedures

(i) General

Language. The working languages of the GDMCC are Chinese. However, communications in English are also accepted.

Contract. The GDMCC does not enter into a written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by signing the GDMCC deposit forms and pay necessary fees, the depositor should supply all the necessary information requested by the GDMCC, surrender the right to withdraw his deposit during the required storage period, and recognize that the deposits may be distributed according to the relevant regulations of the Budapest Treaty.

Import and/or Quarantine Regulations. Overseas depositors must contact the GDMCC in advance for advice about the shipping of their microorganisms. The microorganisms are all subject to the Chinese import and/or quarantine regulations. In such cases, the prospective depositor must supply the species name of the microorganisms, whereupon the GDMCC will apply the import license and/or quarantine to the concerned organizations in China. Obtaining such a permit usually takes one or two weeks. The depositor or depositor's patent agent will be informed when the GDMCC has obtained the import permit.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. In accordance with Rule 6.3(a) of the Regulations of the Budapest Treaty, the GDMCC requires the followings before it could accept microorganisms for deposit:

- that the deposit of a microorganism be in appropriate form and in a quantity that enables the GDMCC to fulfill its obligations under the Regulations;
- that the form established by the GDMCC and duly completed by the depositor for the purposes of the administrative procedure be furnished;
- that the written statement referred to in Rule 6.1.(a) or 6.2.(a) be properly completed in English or Chinese;
- that the fee for storage referred to in Rule 12.1(a) be paid;
- that the depositors obtain all necessary permits for the transportation of the deposit.

Depositors are required to complete the application and accession form GDMCC-BP/1 (equivalent to model form BP/1) for deposits under the Budapest Treaty. 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 GDMCC has received such information, the depositor must complete the form GDMCC-BP/7 (equivalent to model form BP/7).

Official Notifications to the Depositor. The receipt and viability statements are issued on mandatory "international forms" BP/4 and BP/9, respectively. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the form BP/8. Notification of the furnishing of samples to third parties is issued on the form BP/14. Individual correspondence is used rather than standards forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the GDMCC will email or telephone the date of deposit and accession number after the biological materials have been received, but before the official receipt is issued. The result of the viability test can be communicated before the issue of a viability statement by email or telephone.

Supply of Information to a Patent Agent. The GDMCC does not routinely asks the depositor to give the name and address of his patent agent. However, if requested, the GDMCC will supply 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 deposited for patent purposes. However, any deposits previously made free of charge are subject, on conversion, to storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

The depositor is 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 of the Regulations under the Budapest Treaty. The receipt and viability statements for a new deposit are issued on mandatory "international forms" BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The GDMCC 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 GDMCC 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).

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the GDMCC will withhold samples of biological materials that are subject to health and safety regulations until the requesting party has shown that he has a permit to work

with such organisms. When responding to a request from overseas, the GDMCC assumes that the requesting party has met the import requirements of his own country.

The samples of biological materials furnished by the GDMCC are generally from batches of its own preparations. But for isolated plasmids, bacteriophages, DNAs, plant cell cultures and human and animal cell lines, the GDMCC uses the original deposit materials for furnishing.

(b) <u>Notification to the Depositor</u>

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

(c) Cataloguing of Budapest Treaty Deposits

In accordance with Rule 9.2 of the Treaty, the GDMCC usually does not list Budapest Treaty deposits in its published catalogue. If the depositor or a competent patent office instructs the GDMCC to make samples of a deposit available to the public, then that deposit will be listed in the next GDMCC catalog.

3. Schedule of Fees

		RMB
(a)	Storage	3.000
(b)	Issuance of a viability statement	500
(c)	Furnishing of a sample	500
(d)	Communication of information	200
(e)	Application for the import or export license	Depends on individual
		situation

Other currencies will be converted into RMB (Chinese Yuan) according to the exchange rate of the Bank of China.

4. Guidance for Depositors

The GDMCC provides a brochure giving details of its requirements and practices for the deposit of cultures for patent purposes, and is always ready to give advice by telephone or by email.