

CN – CHINA

**CHINA GENERAL MICROBIOLOGICAL CULTURE COLLECTION CENTER
(CGMCC)**

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

With the exception of pathogenic microorganisms of Risk Group I (Chinese classification): Archaea, bacteria (including actinomycetes), yeasts, filamentous fungi, anaerobic microorganisms, single cell algae, animal cell lines, plant cell lines, plant seeds, mycoplasma, viruses, bacteriophages, plasmids. The CGMCC will accept deposits consisting of or containing recombinant DNA molecules, the highest acceptable physical containment level is P2.

At present, the CGMCC does not accept temporarily the following biological material for deposit: protozoa.

As a general rule, the CGMCC will accept only strains that can be placed in a culture under conditions technically feasible for the collection concerned and conserved, other than in continuous vegetative activity, without inducing significant changes in the characteristics.

Exceptionally, the CGMCC may accept deposits that cannot be conserved other than by active culture, but acceptance of such a deposit will have to be decided, and the relevant fee determined, on a case-by-case basis, after prior negotiation with the potential depositor.

The CGMCC reserves the right to refuse a deposit of biological material under Article 5 of the Budapest Treaty:

- which is restricted from import according to Chinese law;
- whose conservation involves hazards deemed to be excessive.

Notwithstanding the foregoing, the CGMCC reserves the right to reject or accept for deposit any material which, in the opinion of the Director, represents a risk that is either unacceptable or is too difficult to handle.

The CGMCC also reserves the right to refuse an application which asks the CGMCC to supply biological material that is restricted from export according to Chinese law.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of microorganisms are accepted by the CGMCC in any form. The minimum number of replicates that must be provided by the depositor when making his deposit is as follows:

Archaea, bacteria, actinomycetes, yeasts, filamentous fungi, mycoplasma, single cell algae	5
Viruses, phages, plasmids (not cloned into a host), animal cell lines, plant cell lines	15
Plant seeds	2,000

(ii) Time Required for Viability Testing

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

Archaea, bacteria, yeasts	3 days (or up to 20 days)
Actinomycetes, filamentous fungi, mycoplasma	6 days (or up to 30 days)
Phages, single cell algae, animal cell lines	7 days (or up to 14 days)
Plasmids ¹	8 days (or up to 14 days)
Animal viruses, plant cell lines, plant seeds	21 days (or up to 30 days)
Plant viruses	no date as yet

¹ For plasmids, "viability" testing consists in inserting the plasmid into a host. If the host is transformed, the "viability test" is regarded as positive.

(iii) Depositor Checks and Renewal of Stocks

The CGMCC prepares its own lyophilized and/or frozen batches at the time of deposit of archaea, bacteria, actinomycetes, yeasts, filamentous fungi, phages, single cell algae and cell lines, and in some cases, viruses, by subculture of, or directly from, active material supplied by the depositor. New batches are prepared as necessary for the renewal of diminishing stocks. The CGMCC stores and distributes lyophilized material supplied by the depositor, if this is his wish. The CGMCC generally does not prepare its own batches of plant seeds, animal viruses and plasmids. In such cases, when stocks of material are depleted by the furnishing of samples, the CGMCC will ask the depositor to make a new deposit.

The CGMCC requires the depositor to check the authenticity of its lyophilized preparations. The viability statement issued by the CGMCC contains a section in which the depositor can record the result of this test. If the depositor does not inform the CGMCC of the results of this test within three months, the CGMCC assumes that its preparations are equivalent to the depositor's original deposit.

Whichever method is used for preparing batches of samples for distribution, the CGMCC stores a portion of the original prepared and deposited material.

(c) Administrative Requirements and Procedures

(i) General

Language. The working languages of CGMCC are Chinese and English.

Contract. The CGMCC does not enter into any 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,

- to supply all the necessary information requested by the CGMCC;
- to pay all the necessary fees;
- not to withdraw the deposit during the required storage period;
- to authorize the CGMCC to supply samples in accordance with the requirements of the patent procedure applicable at the time.

Import and/or Quarantine Regulations. For the deposit from abroad, the CGMCC must obtain an import permit from the Chinese departments concerned for the import of microorganisms into China, which takes about seven days (or up to 14 days). The CGMCC will notify the depositor or depositor's patent agent when it gets the import permit. Depositors must pay for quarantine.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete CGMCC form BP/1 "Budapest Treaty Deposits" in all cases. The CGMCC does not require a special form to be completed in the event of a later indication or amendment of the

scientific description and/or proposed taxonomic designation, or for a request for attestation that the CGMCC has received such information.

Official Notifications to the Depositor. The receipt and viability statements are issued on mandatory “international forms” BP/4 and BP/9, respectively. Notification of release of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CGMCC will telephone or email the date of deposit and accession number after the microorganisms have been received, but before the official receipt is issued. The CGMCC similarly will telephone or email the result of the viability test before the official viability statement is issued. A fee of \$10 is charged for this service by telephone.

Supply of Information to a Patent Agent. If requested, the CGMCC will supply copies of the receipt and viability statements to the depositor’s 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 the storage fees 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 Budapest Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

The CGMCC may accept a new deposit under Article 4 of the Budapest Treaty and Rule 6.2 of the Regulations under the Treaty. The CGMCC does not require the depositor to complete a standard form when making a new deposit, but he is asked to supply an acknowledgment that the new deposit is the same as the original deposit (Article 4), and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The CGMCC will furnish samples to interested industrial property offices, to the depositor or parties with the authorization of the depositor, to parties legally entitled under Rule 11.3 of the Regulations under the Budapest Treaty.

The CGMCC advises third parties of the correct procedures to be followed in making a valid request. In the case of requesters requiring proof of entitlement, the CGMCC provides them with copies of model request form BP/12.

The CGMCC will withhold samples of organisms that are subject to health and safety regulations until it has confirmed that the requesting party can comply with such regulations.

Also, in some cases a permit from the Chinese departments concerned is required to work with certain organisms considered potentially very dangerous in China, and a requesting party in China must obtain such a permit before he can receive a sample.

When requests are received from abroad, the CGMCC presumes that the individual concerned is familiar with his country's import requirements.

Except for animal viruses and plasmids, the CGMCC furnishes samples of its own preparations of the deposited microorganism.

(b) Notification of the Depositor

Unless he has waived his right to be so notified, the CGMCC notifies the depositor on CGMCC form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the CGMCC to make samples of a microorganism available to anyone, that organism is listed in the next published CGMCC catalog. All microorganisms that are the subject of patents granted and published by the Patent Office of the People's Republic of China are listed in the CGMCC catalog.

3. Schedule of Fees

	<u>RMB</u>
(a) Storage	3.000
(b) Issuance of a viability statement	500
(c) Furnishing of a sample	500
(d) Communication of information	200

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

4. Guidance for Depositors

The CGMCC publishes a brochure giving details of its requirements and practices for the deposit of cultures for patent purposes.