

CN – CHINA

CHINA CENTER FOR TYPE CULTURE COLLECTION (CCTCC)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal viruses, animal cell cultures, bacteria, bacteriophages, eukaryotic DNA, fungi, human cell cultures, stem cells, hybridomas, molds, mycoplasma, nematodes, oncogenes, plant cell cultures and plant seeds, plant viruses, plasmids, protozoa (non-parasitic) and yeasts are generally accepted by CCTCC for deposit. However, if the microorganism is a dangerous pathogen, the depositor should consult CCTCC in advance, which will decide whether or not the CCTCC can accept the biological material for deposit. The CCTCC does not accept for deposit pathogenic microorganisms of Risk Group 1 & 2 (Chinese classification).

In addition, the CCTCC does not accept for deposit biological material which is restricted from import according to Chinese law or whose conservation involves hazards deemed to be excessive. It also rejects applications which ask the CCTCC to supply biological material that is restricted from export according to Chinese law.

At present, the CCTCC does not accept for deposit embryos, parasitic and pathogenic protozoa and RNA preparations.

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

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, molds, yeasts, algae and viruses must be submitted for deposit as lyophilized preparations. However, agar stab or slant cultures are also acceptable. Viruses that cannot be lyophilized should be frozen. Plasmids or other vectors in the form of an isolated DNA preparation must be furnished in freeze-dried form or precipitated in alcohol.

All kinds of viruses and plasmids need to be sent together with a suitable host if the host is not available in the public collection of the CCTCC. Plant cell cultures can only be

deposited in the form of callus or suspension cultures with non-differentiated growth. Animal cell cultures are accepted in the form of frozen cultures. The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the CCTCC, animal cell cultures must be examined to ensure that they are free from viruses.

All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

The minimum number of replicates that must be provided by the depositor when making his deposit is as follows:

Algae, bacteria, molds, plant viruses, yeasts	6 lyophilized or on culture media
Bacteriophages (at least 10^8 pfu/ml) 5 X 0,5 ml (free-cell lysate)	11
Animal cell lines, animal viruses, hybridomas, plasmids (DNA at least 20 meg/tube)	11
Seeds	2,500

(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 CCTCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria	3 days (or up to 14 days)
Algae, molds, yeasts	5 days (or up to 20 days)
Animal cell lines, hybridomas, bacteriophages, plasmids	7 days (or up to 14 days)
Animal viruses, plant cell cultures, seeds	21 days (or up to 30 days)
Plant viruses	no period of time as yet

(iii) Depositor Checks and Renewal of Stocks

The CCTCC prepares its own depositing batches in lyophilized or frozen form from the original material supplied by the depositor. The deposits could also be made by subculturing the microorganisms from the original material at the request of the depositor. The CCTCC generally does not prepare its own batches of animal and plant viruses, plasmids, seeds, and some animal cell lines, hybridomas and plant tissue cultures. When stocks of material are depleted by the furnishing of samples, the CCTCC will ask the depositor to make a new deposit.

(c) Administrative Requirements and Procedures

(i) General

Language. The working languages of the CCTCC are Chinese and English.

Contract. The CCTCC 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 CCTCC deposit forms and pay necessary fees, the depositor should supply all the necessary information requested by the CCTCC, surrender the right to withdraw his deposit during the required storage period and recognize that the deposits may be distributed according to the relevant regulation of the Budapest Treaty.

Import and/or Quarantine Regulations. Overseas depositors must contact the CCTCC 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 CCTCC will apply the import license and/or quarantine to the concerned organizations in China. Obtaining such a permit usually takes one or two weeks. After obtaining it, the CCTCC will inform the depositor or depositor's patent agent when the import permit was obtained.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the application and accession form used by the CCTCC for deposits under the Budapest Treaty, which is model form BP/1. 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 CCTCC has received such information, the depositor must complete the equivalent of 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 equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Individual correspondence is used rather than standards forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CCTCC will telephone or telefax the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CCTCC will similarly communicate the result of the viability test before the viability statement is issued, but only after the viability test has been done and has given a positive result.

Supply of Information to a Patent Agent. The CCTCC routinely asks the depositor to give the name and address of his patent agent. If requested, the CCTCC will supply copies of the receipt, the viability statement and any other information 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 CCTCC 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 CCTCC 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 CCTCC will withhold samples of organisms 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 CCTCC must obtain an export permit from the concerned organizations in China, and assumes that the requesting party has met the import requirements of his own country.

Except for animal viruses, plasmids, seeds, and some animal cell lines, hybridomas and plant tissue cultures, the samples of microorganisms furnished by the CCTCC are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the CCTCC to make samples of a microorganism available to anyone, that organism is listed in the next published CCTCC catalog. All microorganisms that are the subject of granted and published Chinese patents are listed in the CCTCC 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
(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 CCTCC has published a leaflet describing its overall activities and it is available to possible depositors to provide detailed information by email, telephone, telefax, or letter.