IN - INDIA

MICROBIAL CULTURE COLLECTION (MCC)

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1. <u>Requirements for Deposit</u>

(a) Kinds of Microorganisms that May Be Deposited

The MCC will at present accept bacteria, fungi, yeasts and plasmids in a host and/or as isolated DNA preparations belonging to Hazards Group 1 and 2 as per classification of the Indian Authority.

Genetically manipulated microorganisms and isolated DNA will be accepted if they can be processed in BSL-1 or BSL-2 facility or conform to Group 1 or 2 organisms.

The MCC reserves the right to refuse to accept a deposit if, in its view, the deposit may be an unacceptable hazard or the MCC may not be in a position to process it. Deposit of bacteria and fungi pathogenic to plants and animals will be accepted from other countries only if cleared by the appropriate authority in India.

The deposited material will generally be preserved by freeze-drying or storage in liquid nitrogen or by other method(s) of long-term preservation.

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

(i) Form and Quantity

Materials for deposit should be pure (uncontaminated) and should be sent in the following form:

Bacteria and fungi (including yeasts): two active cultures on slants Plasmids 5 x 20 micrograms of isolated and purified DNA preparations. Suitable host of the plasmid and host harbouring the plasmid also need to be deposited in active form (2 slants each). The deposit should be accompanied by appropriate forms duly completed by the depositor. These forms can be obtained from the MCC. Separate forms need to be used for bacteria, fungi (including yeasts) and plasmids. A fee for storage (Rule 12.1(a) (i) of the Regulations under the Budapest Treaty) must be paid for each deposit.

(ii) <u>Time Required for Viability Testing</u>

The MCC will test viability as quickly as possible. Since growth rate of microorganisms vary the time required for viability testing for different microorganisms may accordingly vary. The average time that will be required for viability testing is indicated below:

Bacteria, yeast and plasmids	4 days to 3 weeks
Actinomycetes, fungi	7 days to 4 weeks

(iii) Depositor Checks and Renewal of Stocks

The MCC may prepare, as and when it finds necessary, new batch(es) of glycerol stocks, lyophilized and frozen (in liquid nitrogen) culture by subculturing available materials. The MCC will send samples of the new batch and the depositor is required to check the authenticity of such microorganisms.

(c) Administrative Requirements and Procedures

(i) <u>General</u>

Language. The language of communication of the MCC and of the forms will be English. Communication in Hindi is also acceptable. However, in case of any dispute, the English version will prevail.

Contract.

The MCC does not enter into any written contract with the depositor defining the liabilities of either party, but by signing the MCC deposit form the depositor accepts general terms and conditions and surrenders any right to withdraw his deposit during the required storage period. He also accepts that the organism will be distributed according to the relevant patent requirement.

Import and/or Quarantine Regulations. Cultures of microorganisms from outside India may require import clearance and/or be subjected to quarantine regulations. The depositor from outside India should communicate with the MCC regarding such deposits before dispatching cultures.

(ii) <u>Making the Original Deposit</u>

Requirements to Be Met by the Depositor. A depositor will be required to send a complete BP/1 form which is the accession for a deposit under the Budapest Treaty. For amendments to the scientific description or taxonomic designation a depositor will be required to send a completed BP/7 form.

Official Notifications to the Depositor. The receipt and viability statement will be issued in English on the mandatory "international forms" BP/4 and BP/9, respectively. The attestation of receipt of an amendment to the scientific description or taxonomic designation will be issued on BP/8 form. The notification of furnishing a sample to third parties will be issued on BP/14 form.

Unofficial Notifications to the Depositor. If requested, the MCC may communicate the date of deposit and accession number before the official receipt is issued only after the viability test is completed and a positive result is obtained.

Supply of Information to a Patent Agent. If required by the depositor, the MCC will send copies of the receipt and viability statement to both the depositor and his/her patent agent.

(iii) Converting a Previous Deposit

In case of a deposit made in the MCC earlier, outside the provisions of the Budapest Treaty, the original depositor may convert the same to a Budapest Treaty deposit. However, if the original deposit was in the general category and is listed in the MCC catalogue (printed or electronic) and had no restriction for distribution by the MCC, the depositor will be requested to authorize the MCC not to restrict distribution of such a deposit and waive his/her right to notification of release of the sample. If this condition is not acceptable then a fresh deposit of the material under the Budapest Treaty will be required. Deposit previously made with MCC for patent procedure or for safekeeping also can be converted to deposits under the Budapest Treaty.

Administrative requirements and fees for conversion will be the same as for the original deposit under the Budapest Treaty.

(iv) Making a new Deposit

For making a new deposit the completed BP/2 form will be required along with the relevant documents as required under rule 6.2. A receipt and viability statement for such a deposit will be issued on BP/5 and BP/9 forms respectively.

2. <u>Furnishing of Samples</u>

(a) <u>Requests for Samples</u>

The MCC will follow procedure as provisions of the Budapest Treaty for furnishing samples to third parties. For proof of entitlement BP/12 form and for request BP/13 form will be used in furnishing samples. For hazardous microorganisms the requesting party has to provide evidence that proper facility for handling such microorganisms is available and he/she has the requisite permission to work on such organisms.

A requesting party from outside India also has to provide an import permit if it is required for that country.

The MCC will furnish samples prepared by it from the deposited sample(s).

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

A depositor will be notified on BP/14 form when samples of their deposit have been furnished to third parties.

(c) <u>Cataloguing of Budapest Treaty Deposits</u>

Materials deposited under the Budapest Treaty will not be published in the MCC catalogue (printed or electronic) or displayed on the internet.

3. <u>Schedule of Fees</u>

Bacteria, fungi, yeast and plasmids	Indian Rupees
(a) Storage under rule 12.1 (a)(i)	20,000
(b) Conversion of deposit	20,000
(c) Extension of duration storage beyond that provided by Rule 9 (per year)	2,000
(d) Issue of viability statement on the basis of test	3,000
(e) Issue of viability statement on the basis of last viability test	1,000
(f) Furnishing of samples	3,000
(g) Communication of information under Rule 7.6	1,000
(h) Attestation referred to in Rule 8.2	1,000

4. Guidance for Depositors

The MCC will be happy to provide written notes or advice to prospective depositors.

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