Section D: Requirements of International Depositary Authorities (IDAs)

(a) Culture Collections Currently Holding IDA Status

The following 48 depositary institutions in 26 countries have acquired the status of IDA:

**Australia** (AU)
Lady Mary Fairfax CellBank Australia (CBA)
The National Measurement Institute (NMI)

**Belgium** (BE)
Belgian Coordinated Collections of Microorganisms (BCCM™)

**Bulgaria** (BG)
National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)

**Canada** (CA)
International Depositary Authority of Canada (IDAC)

**Chile** (CL)
Colección Chilena de Recursos Genéticos Microbianos (CChRGM)

**China** (CN)
China Center for Type Culture Collection (CCTCC)
China General Microbiological Culture Collection Center (CGMCC)
Guangdong Microbial Culture Collection Center (GDMCC)

**Czech Republic** (CZ)
Czech Collection of Microorganisms (CCM)

**Finland** (FI)
VTT Culture Collection (VTTCC)

**France** (FR)
Collection Nationale de Cultures de Micro-organismes (CNCM)

**Germany** (DE)
Leibniz-Institut DSMZ – Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)

**Hungary** (HU)
National Collection of Agricultural and Industrial Microorganisms (NCAIM)
India (IN)
Microbial Culture Collection (MCC)
Microbial Type Culture Collection and Gene Bank (MTCC)
National Agriculturally Important Microbial Culture Collection (NAIMCC)

Italy (IT)
Ospedale Policlinico San Martino IRCCS
Collection of Industrial Yeasts (DBVPG)
Istituto Zooprofilattico Sperimentale della Lombardia e dell’Emilia Romagna “Bruno Ubertini” (IZSLER)

Japan (JP)
International Patent Organism Depositary (IPOD), National Institute of Technology and Evaluation (NITE)
National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD)

Latvia (LV)
Microbial Strain Collection of Latvia (MSCL)

Mexico (MX)
Colección de Microorganismos del Centro Nacional de Recursos Genéticos (CM-CNRG)

Morocco
Moroccan Coordinated Collections of Microorganisms (CCMM)

Netherlands (NL)
Westerdijk Fungal Biodiversity Institute (CBS)

Poland (PL)
IAFB Collection of Industrial Microorganisms
Polish Collection of Microorganisms (PCM)

Republic of Korea (KR)
Korean Agricultural Culture Collection (KACC)
Korean Cell Line Research Foundation (KCLRKF)
Korean Collection for Type Cultures (KCTC)
Korean Culture Center of Microorganisms (KCCM)

Russian Federation (RU)
All-Russian National Collection of Industrial Microorganisms (VKPM)
Russian Collection of Microorganisms (VKM)

Slovakia (SK)
Culture Collection of Yeasts (CCY)

Spain (ES)
Banco Español de Algas (BEA)
Colección Española de Cultivos Tipo (CECT)

Switzerland (CH)
Culture Collection of Switzerland (CCOS)
United Kingdom (GB)
CABI Bioscience, UK Centre (IMI)
Culture Collection of Algae and Protozoa (CCAP)
European Collection of Cell Cultures (ECACC)
National Collection of Type Cultures (NCTC)
National Collection of Yeast Cultures (NCYC)
National Collections of Industrial, Food and Marine Bacteria (NCIMB)
National Institute for Biological Standards and Control (NIBSC)

United States of America (US)
Agricultural Research Service Culture Collection (NRRL)
American Type Culture Collection (ATCC)
Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA)
(b) List of Kinds of Microorganisms Accepted by IDAs*

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* For information purposes only. For the up-to-date list of microorganisms accepted by IDAs pursuant to Rule 13.2(a) of the Regulations under the Budapest Treaty, please refer to “Information on Kinds of Microorganisms Accepted and Amount of Fees Charged by IDAs” on the Budapest Treaty website (http://www.wipo.int/budapest).
### List of Kinds of Microorganisms Accepted by IDAs (continued)

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(c) Detailed Requirements and Practices of IDAs

(i) General

This subsection describes in detail the requirements and practices of each IDA as they relate to the deposit of microorganisms and the furnishing of samples under the Budapest Treaty. Information is based on communications and notifications published on WIPO’s website (http://www.wipo.int/budapest), and on the replies to letters sent to all IDAs by WIPO. The IDAs are listed alphabetically by country and the information on each is arranged in the format given in (ii), below. Reference to “model forms” and “international forms” means those forms designed by the International Bureau of WIPO, published in WIPO documents BP/A/II/12 (1981) and BP/A/VIII/1 (1990), and which are reproduced in Appendix 3.

(ii) Information on IDAs

For each IDA, information is arranged as follows:

country, name of international depositary authority and acronym, address, telephone and fax numbers, electronic and Internet addresses, if any.

IDAs are listed according to the two-letter country code in accordance with WIPO Standard ST.3.

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The different types of biological entities accepted for deposit and any specific exclusions are given. The maximum hazard rating and/or physical containment requirements acceptable to the IDA in respect of microorganisms that may be deposited are stated.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The state in which cultures must be submitted is given, e.g., lyophilized, frozen, liquid suspension, agar slant, etc. The minimum number of replicates that must be supplied by the depositor and the minimum titre of each culture (where appropriate) are stated.

(ii) Time Required for Viability Testing

The average and maximum length of time (in days) needed by the IDA to carry out viability tests is given for each kind of microorganism accepted.
(iii) **Depositor Checks and Renewal of Stocks**

Information is given whether the IDA subcultures material supplied by the depositor to provide stocks of samples for storage; whether it stores samples originally supplied by the depositor; how it replenishes diminishing stocks; and whether it requires the depositor to test for authenticity samples of its own preparations.

(c) **Administrative Requirements and Procedures**

(i) **General**

Language. The official language(s) and any other language(s) in which the IDA accepts communications are given.

Contract. Information is given about the kind of contract (if any) that the IDA enters into with the depositor.

Import and/or Quarantine Regulations. Information is given whether any of the microorganisms accepted by the IDA are subject to import and/or quarantine regulations; the requirements for compliance with such regulations; and the government departments where further advice may be obtained.

(ii) **Making the Original Deposit**

Requirements to Be Met by the Depositor. Reference is made to any forms that must be completed; any information that must be given to the IDA in advance of deposit; and any special transport and/or delivery arrangements.

Official Notifications to the Depositor. Reference is made to any forms that the IDA uses to issue official notifications to the depositor.

Unofficial Notifications to the Depositor. An indication is given whether the IDA will communicate information to the depositor in advance of any official notifications.

Supply of Information to a Patent Agent. An indication is given whether the IDA will supply copies of documents to the depositor’s patent agent.

(iii) **Converting a Previous Deposit**

Information is given about the requirements of the IDA that the depositor must meet and the extent to which he is permitted to convert a deposit previously made outside the Budapest Treaty to one made under the Treaty.

(iv) **Making a New Deposit**

Any requirements of the IDA additional to those that must be met when making an original deposit are indicated.
2. Furnishing of Samples

(a) Requests for Samples

Information is given whether the IDA advises third parties of the correct procedures to follow in order to make a valid request; whether the IDA supplies the requesting party with the appropriate forms; whether the requesting party must meet any health and safety requirements; whether samples furnished by the IDA are from its own preparations or from those supplied by the depositor.

(b) Notification of the Depositor

The means whereby the IDA notifies the depositor of the furnishing of samples is given.

(c) Cataloguing of Budapest Treaty Deposits

It is stated whether, and under what conditions, the IDA lists deposits under the Budapest Treaty in its published catalogs.

3. Schedule of Fees

The fees payable to the IDA for procedures carried out under the Budapest Treaty are listed.

4. Guidance for Depositors

Reference is made to any publications that the IDA makes available for the guidance of prospective depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

CBA will accept for deposit, human and animal cell lines and hybridomas that can be preserved in liquid nitrogen vapour without significant damage to or loss of their properties or viability.

CBA will not at this time accept for deposit, genetically modified organisms requiring physical containment level 3 or 4 (PC3 or PC4). Deposits should be accompanied by a favourable Biohazard Risk Assessment statement.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Human and animal cell lines and hybridoma must be submitted to CBA for deposit in the form of frozen cultures. CBA may refuse deposits that have not been packed in sufficient dry ice to keep them frozen during transit.

The minimum number of replicates that must be provided by the depositor when making the deposit is 12. All hybridoma, human and animal cell cultures must contain at least 4 x 10^6 cells/ampoule.

Any requests to deposit human embryo stem cell lines will be subject to current Australian Government regulations and guidelines.
Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by CBA is given below, but depositors should realize that, in some cases, viability testing might take longer. Customers will be advised of this prior to deposit being accepted.

- Animal cell cultures: 10 days (or up to 15 days)
- Human cell cultures: 10 days (or up to 15 days)
- Hybridoma cultures: 10 days (or up to 15 days)

Depositor Checks and Renewal of Stocks

CBA generally does not prepare its own batches of the deposited organisms, and when the furnishing of samples depletes stocks, the depositor will be asked to make a new deposit. The depositor is asked to check the authenticity of samples prepared by CBA.

Administrative Requirements and Procedures

(i) General

Language. The official language of CBA is English. Communications in any other language are not accepted.

Contract. The CBA application form, which the depositor is required to complete, binds the depositor:

- to provide material only in the required form and quantity;
- to provide a biohazard statement;
- to pay all necessary fees including all charges for the transportation of deposits to CBA;
- to observe the terms and conditions of the Budapest Treaty;
- to accept the terms and conditions of deposit of samples in CBA.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. The customer will be advised to obtain the regulatory documentation once CBA has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the CBA application form referred to in (i), above, the depositor must complete a CBA deposit form and biohazard statement (available on the CBA website).

At least 48 hours before the microorganism is dispatched, CBA must be informed of the number of ampoules being sent, the method of transportation and the estimated time of arrival. If dispatch is by air, CBA must be told the flight number and destination, waybill number and handling agent for delivery.
CBA 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 CBA has received such information.

**Official Notifications to the Depositor.** The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

**Unofficial Notifications to the Depositor.** If requested, CBA will telephone, fax or email the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

**Supply of Information to a Patent Agent.** CBA does not routinely ask the depositor for the name and address of his or her patent attorney. However, if requested, it will send copies of the receipt and viability statement to both the depositor and the patent attorney.

(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 are subject, on conversion, to the 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, except that requirements relating to shipping procedures do not apply.

(iv) **Making a New Deposit**

The depositor is required to complete the CBA deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform to the procedures mentioned previously in respect of shipping requirements.

2. **Furnishing of Samples**

(a) **Requests for Samples**

CBA does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant intellectual property office.
Notwithstanding any entitlement of third parties to receive samples under patent regulations or by written authorization of the depositor, CBA will withhold samples of potentially hazardous microorganisms until the requesting party has confirmed that it has the appropriate containment facilities to handle such organisms.

When responding to requests from overseas, CBA assumes that the requesting party has met the import requirements of their own country, and the customer is responsible for provision of the relevant documentation to do so.

Samples furnished by CBA are usually from preparations supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

CBA does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

1. Cell lines

   Australian dollars
   
   For the storage of the microorganism in accordance with the Treaty, including certification and viability statement 2,600
   
   Issuance of a new or updated viability statement 170

2. General

   Furnishing of a sample (excluding shipping costs) 210
   
   Issuance of (new or amended) certification 110
   
   Administration fee for amendments 110

Fees plus GST, where applicable, are payable to CellBank Australia.

4. Guidance for Depositors

Guidance for depositors is provided on the CBA application form and CBA website (www.cellbankaustralia.com)
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes), yeasts and fungi other than known human and animal pathogens, that can be preserved without significant change to their properties by the methods of preservation in use (freezing and freeze-drying).

Nucleic acid preparations and phages may be accepted if the depositor certifies that they pose no hazard when handled by normal laboratory procedures and the depositor supplies suitable material for preservation.

At present, the NMI does not accept for deposit animal, plant, algal and protozoal cultures, cultures of viral, rickettsial and chlamydial agents, microorganisms which may require, in the view of the curator, special attention to handling and preparation for storage.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms must be submitted for deposit as lyophilized preparations or on culture media. The minimum number of replicates that must be provided by the depositor when making his deposit and the form in which they must be submitted are as follows:

- Bacteria, fungi and yeasts: 6 lyophilized or on culture media
- Phages and plasmids: sufficient quantity and titre for preservation

(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 NMI is given below:

- Bacteria: 5 days
- Fungi: 10 days
- Yeasts: 10 days
The NMI prepares its own batches of bacteria, fungi and yeasts by subculturing material supplied by the depositor. New batches are prepared by asking the depositor to make a new deposit under Article 4, by subculturing NMI’s own preparation with the approval of the depositor, or by subculturing material originally supplied by the depositor. The depositor is asked to check the authenticity of batches prepared by the NMI from material supplied by him at the time of deposit and thereafter. The NMI stores original material supplied by the depositor.

(c) Administrative Requirements and Procedure

(i) General

Language. The official language of the NMI is English.

Contract. At present, the NMI does not enter into a written contract with the depositor defining the liabilities of either party.

Import and/or Quarantine Regulations. Certain kinds of microorganisms accepted for deposit by the NMI are subject to import and quarantine regulations. The NMI will arrange the necessary permits for importation of biological materials and clearing any quarantine requirements. The depositor must contact the NMI before depositing any microorganisms. The time required to obtain the permit may vary depending on the kinds of microorganisms to be deposited. Further information may be obtained from the Australian Quarantine Inspection Service, GPO Box 858, Canberra, A.C.T., 2601 Australia. (ii)

Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is requested to complete model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued, respectively, on mandatory “international forms” BP/4 and BP/9. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification to the depositor that a sample of the deposited microorganism has been furnished to an entitled party is issued on model form BP/14. Standard forms are not used for other notifications.

Unofficial Notifications to the Depositor. If requested, the NMI will telephone or email the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. Similarly, the NMI will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NMI asks the depositor at the time of deposit to supply the name and address of his patent agent and, if requested, it will send copies of the receipt and the 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 to deposits under the Budapest Treaty, whether or not they were originally deposited for patent purposes. In addition to the administrative requirements for conversion, which are the same as those to be met in respect of an original deposit under the Budapest Treaty, the NMI requests the depositor to verify the authenticity of his deposited material at the time of conversion.
(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to supply copies of the documents specified under Rule 6.2; otherwise, the procedure is similar to that when making an original deposit.

2. Furnishing of samples

(a) Requests for Samples

The NMI advises requesting parties of the correct procedure to follow to make a valid request. In the case of requests requiring proof of entitlement, the NMI will provide requesting parties with copies of model request form BP/12 and/or requests forms used by individual industrial property offices. It will also advise requesting parties on the requirements provided for under the Australian Patent Act.

The NMI furnishes a sample of a dangerous microorganism only after having received confirmation that the requesting party is capable of handling the microorganism safely.

(b) Notification of the Depositor

Depositors are notified when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

At present, the NMI does not publish a catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Service</th>
<th>AUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage</td>
<td>1,000</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement on an existing deposit</td>
<td>270</td>
</tr>
<tr>
<td>(c) Furnishing of a sample</td>
<td>270</td>
</tr>
</tbody>
</table>

4. Guidance for Depositors

Guidance notes for prospective depositors are in preparation.
BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS (BCCM™)

BCCM™ is a consortium of complementary service collections. The headquarters and the component collections that accept deposits under the Budapest Treaty are listed hereunder. All applications and/or deposits are to be addressed directly to the appropriate BCCM™ collection.

The Quality Management System of the BCCM™ consortium has been certified according to the ISO 9001 standard for, among others, the following activities:

“Accession, control, preservation, storage and supply of biological material and related information in the frame of public deposits, safe deposits and patent deposits under the Budapest Treaty”.

Headquarters
BCCM Coordination Cell
Federal Public Planning Service Science Policy
231, avenue Louise
1050 Brussels

Telephone: (32-2) 238 36 07
Facsimile: (32-2) 230 59 12
E-mail: bccm.coordination@belspo.be

Collections

BCCM/IHEM Biomedical fungi and yeasts collection
Scientific Institute of Public Health
Service Mycology and Aerobiology
Rue J. Wytsmanstraat, 14
1050 Brussels

Telephone: (32-2) 642 55 18
Facsimile: (32-2) 642 55 19
E-mail: bccm.ihem@wiv-isp.be

BCCM/GeneCorner Plasmid Collection
Department of Biomedical Molecular Biology
Ghent University
Technologiepark, 927
9052 Zwijnaarde

Telephone: (32-9) 331 38 43
Facsimile: (32-9) 331 35 04
E-mail: bccm.genecorner@dmbr.UGent.be
1. Requirements for Deposit

(a) **Kinds of Microorganisms that May Be Deposited**

    **BCCM/IHEM**: filamentous fungi and yeasts, including pathogenic fungi and yeasts that cause mycosis in man and animals, and actinomycetes.

    **BCCM/LMBP**: genetic material, recombinant or not, cloned in a host or as isolated material (e.g. plasmids); natural or genetically modified human and animal cell lines, including hybridomas. Deposits of genetically modified microorganisms should not exceed containment level 2 as defined by the EU directive 2009/41/EC and its updates concerning the contained use of genetically modified organisms.

    **BCCM/LMG**: bacteria, including actinomycetes, but excepting pathogens belonging to a hazard group higher than Risk group 2 according to the EU directive 2000/54/EC and its updates.

    **BCCM/MUCL**: filamentous fungi, yeasts and arbuscular mycorrhizal fungi, including plant pathogens, but excluding pathogenic fungi causing mycosis in man and animals belonging to a hazard group higher than Risk group 2 according to the EU directive 2000/54/EC and its updates.

    As a general rule, the BCCM™ collections accept only samples that can be cultured and preserved under conditions technically feasible for the collection concerned and that can be conserved, other than in continuous vegetative activity, without inducing significant changes in their characteristics.
Exceptionally, the various BCCMTM collections may accept deposits of microorganisms that cannot be conserved other than by active culture. Acceptance as well as the costs of such a deposit will be negotiated case by case with the potential depositor. Exceptionally and following the same case-by-case negotiation procedure, they may also accept deposits of mixtures of microorganisms.

The BCCMTM collections also reserve their right to refuse a deposit of biological material whose manipulation or conservation involves hazards deemed to be excessive, or if they receive the material in a bad condition.

All deposits should be addressed directly to the appropriate BCCMTM collection.

(b) Technical Requirements and Procedures

(i) Form and Quantity

- Bacteria, filamentous fungi, yeasts, actinomycetes:

The depositor must supply 23 ampoules with 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 and subsequently serve for the preparation of a stock of 20 cryopreserved samples.

In case the depositor is not able to provide the required 23 ampoules, he must supply at least 3 ampoules of freeze-dried cells of the same batch.

In case the depositor is not able to provide the microorganism under freeze-dried form, he must supply 3 “vials” of frozen cultures, or 3 active cultures, each of the same batch.

The freeze-dried cells of one or more ampoules or the frozen cells of one or more vials, or one or more of the active cultures will be subjected to a viability test and subsequently serve for the preparation of a stock of 20 samples of cryopreserved cells. BCCMTM will prepare a batch of 20 samples of freeze-dried cells for an additional fee.

- Arbuscular mycorrhizal fungi:

Optimally, the depositor must supply 2 in vitro (monoxenic) cultures of the same batch.

Otherwise, he must supply an “inoculum” containing propagules (i.e. spores and/or mycorrhizal root fragments) from an in vitro culture or from a trap plant, or a trap plant culture containing spores\(^1\). It is mandatory that the “inoculum” is derived from a single monosporal culture. However, a mixture of propagules from more than one culture may also be accepted if the material is derived from the same mother monosporal culture.

Upon request of the depositor, BCCM/MUCL could attempt to grow the arbuscular mycorrhizal fungus under in vitro (monoxenic) culture for an additional fee.

\(^{1}\) Note that in trap plant culture, purity can only be assessed within the Glomeromycota phylum since the trap plant culture are generally not produced in aseptic conditions.
- Plasmids in a bacterial host:

The depositor must supply three active, freeze-dried or frozen 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 material:

Samples must be supplied in freeze-dried or frozen form or precipitated in alcohol. A minimum of 2 x 20 micrograms must be furnished.

The plasmid DNA must have a sufficient degree of purity to ensure successful transformation. The recommended bacterial host strain must be stated and - if not available at the depositary - also be furnished without the plasmid concerned. In the latter case, the storage of the appropriate host strain for the period of at least 30 years will be charged separately.

- Human and animal cells, hybridomas:

The animal and human cell cultures or hybridomas must be checked for contaminants before submitting the mass frozen cultures (containing at least 4 x 10^6 viable cells/vial). BCCM/LMBP may refuse the deposit when cultures are thawed upon arrival. At least 12 samples of the same batch in well-sealed and clearly and durably marked 1-2 ml cryotubes of ± 12 mm diameter must be supplied, of which one or more will be subjected to a viability test.

- Other genetic material: contact BCCM/LMBP.

(ii) Time required for Viability Testing

The minimum periods required by BCCM™ to test the viability of various types of microorganisms are as follows (however, depositors should be aware that the viability test may take longer for certain types of microorganisms):

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td>3 days</td>
</tr>
<tr>
<td>Filamentous fungi</td>
<td>3 days</td>
</tr>
<tr>
<td>Yeasts</td>
<td>2 days</td>
</tr>
<tr>
<td>Arbuscular mycorrhizal fungi</td>
<td>30 days</td>
</tr>
<tr>
<td>Plasmids^2</td>
<td>± 1 week</td>
</tr>
<tr>
<td>Human and animal cell cultures, hybridomas^3</td>
<td>± 3 weeks</td>
</tr>
<tr>
<td>Other genetic material</td>
<td>Contact BCCM/LMBP</td>
</tr>
</tbody>
</table>

(iii) Depositor Checks and Renewal of Stocks

At the time of deposit, BCCM™ prepare their own cryopreserved batch and, depending on the form and quantity in which the microorganisms have been supplied, their own freeze-dried batch. From this cryopreserved or freeze-dried batch, the depositor is

^2 The “viability test” includes the preparation of plasmid DNA and restriction enzyme analysis by gel electrophoresis. For genetic material deposited as isolated material, the “viability test” obviously implies the transformation of the suitable host first. If the theoretically expected fragments can be experimentally confirmed, the “viability test” is deemed positive.

^3 The “viability test” includes testing for mycoplasma contamination.
provided with 1 sample with the request to check the authenticity of this sample of his microorganism prepared by BCCMTM and to inform them of the result of his checking.

Also, to renew depleted stocks, BCCMTM will prepare, as needed, new batches starting from one sample of the previous batch.

Only for the renewed freeze-dried batches, and for the cultures maintained by regular sub-cultivation (i.e. the Glomeromycota), the depositor is again asked to check the authenticity.

In general, BCCMTM do not prepare their own batches of animal and human cell lines or hybridomas. Consequently, when stocks of material are depleted following furnishing of samples, they request the depositor to make a new deposit.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of BCCMTM is English. Communications are also accepted in German, French and Dutch.

Contract. The application form BCCMTM/acron/DBT1, which must be completed by the depositor, constitutes a contract under which the depositor is required:

- to communicate all information requested by BCCMTM;
- to pay all required fees;
- not to withdraw his deposit during the required conservation period;
- to authorize BCCMTM to furnish samples in accordance with the requirements applicable to patents;
- to make a new deposit in the event of BCCMTM not being in a position to supply samples;
- not to make BCCMTM liable for any deterioration of samples during conservation if all the precautions he has described for that conservation have been taken by BCCMTM;
- to compensate BCCMTM for any prejudice they may incur as a result of the handling of the microorganism for which they are responsible if all the precautions he has described with respect to such handling have been taken by BCCMTM;
- to compensate BCCMTM for any court action that may be taken against them following the supply of samples, unless such action is based on negligence on the part of BCCMTM.

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4 All the forms used by BCCMTM bear a reference number of the type BCCM/acron/num; “acron” is replaced by the acronym (IHEM, LMBP, LMG, MUCL) of the Collection concerned; “num” is replaced by the individual number of the form. Numbering of the type “BP/..” indicates that it is a compulsory international form or another standard form.
Once the deposit and acceptance procedure has been completed, the depositor receives a form BCCM/acron/DBT2 to remind him that he is bound by the contract thus concluded. Belgian law applies to any dispute.

**Import and/or Quarantine Regulations.** Certain types of microorganisms accepted by BCCMTM are subject to import or quarantine regulations. Where that is the case, the depositor must communicate the name of the species of the microorganism to BCCMTM to enable the necessary measures to be taken.

(ii) **Making the Original Deposit**

**Requirements to Be Met by the Depositor.** The depositor is required to complete, in addition to the application form BCCM/acron/DBT1 (see (i) above), a form BCCM/acron/BP/1, which is the deposit form required by the Budapest Treaty.

Preferentially, these two forms are to be sent to the appropriate BCCMTM collection before sending the biological material. The BCCMTM collections reserve the right to refuse a deposit of biological material if these two forms are not filled out correctly.

In the event of a subsequent communication or modification of the scientific description or the proposed taxonomic designation and also for any request for attestation that BCCMTM have received such information, the depositor should preferably complete the form BCCM/acron/BP/7.

**Official Notifications to the Depositor.** The attestation of receipt and the viability statement are issued on the compulsory “international forms” BCCM/acron/BP/4 and BCCM/acron/BP/9, respectively.

The attestation of receipt of communication or subsequent amendment of the scientific description and/or the proposed taxonomic designation is issued on the form BCCM/acron/BP/8.

The notification on the furnishing of samples to third parties is issued on form BCCM/acron/BP/14.

**Unofficial Notifications to the Depositor.** Although BCCMTM confirm receipt of the microorganisms sent to them, this does not mean that they have accepted them for deposit. If the viability test gives a positive result, BCCMTM communicate the result, on request, unofficially, together with the deposit number of the microorganism before issuing the official attestations on receipt and viability.

**Supply of Information to a Patent Agent.** BCCMTM request the depositor to communicate to them, in the interest of all concerned, the name and address of his patent agent. On request, they will provide to the patent agent a copy of the attestation of receipt and of the viability statement.

(iii) **Converting a Previous Deposit**

Deposits that were not made under the Budapest Treaty may be converted by the original depositor into deposits under that Treaty, whether or not the microorganisms were
originally deposited for the purposes of patent procedure. 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" BCCM/acron/BP/4.

(iv) Making a New Deposit

When making a new deposit, the depositor must complete form BCCM/acron/BP/2 and furnish copies of the documents referred to in Rule 6.2. The attestation of receipt and the viability statements with respect to a new deposit are issued on the compulsory “international forms” BCCM/acron/BP/5 and BCCM/acron/BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

BCCMTM will inform third parties of the procedure to be followed in order to make a proper request. For those requests requiring proof of the right to receive samples, BCCMTM will supply the requesting parties copies of the standard request form BCCM/acron/BP/12 or of the request forms used by a given industrial property office (insofar as such office has transmitted the relevant forms to BCCMTM).

Notwithstanding any entitlement by a third party to receive samples under patent regulations, BCCMTM will conserve the samples of potentially hazardous microorganisms until the requesting party has proven that it holds an authorization to handle such organisms. Likewise, they will only furnish samples of a microorganism to recognized microbiological laboratories and not to private addresses. In the case of requests from abroad, the requesting party has to satisfy its own country’s requirements with regard to importation.

All samples of microorganisms furnished by BCCMTM will be taken from the batches they have prepared themselves or from the batches furnished by the depositor.

(b) Notification of the Depositor

When BCCMTM furnish a sample of a deposited microorganism to a third party, they will notify the depositor on the standard form BCCM/acron/BP/14, unless the depositor has waived his right to receive such notification.

(c) Cataloguing of Budapest Treaty Deposits

BCCMTM will not list, in the catalogs it publishes, the deposits made under the Budapest Treaty.
3. Schedule of Fees

1. For cultures of bacteria, yeasts, filamentous fungi, including actinomycetes
   (a) Storage 665 EUR
   (b) Preparation of the first batch of 20 freeze-dried samples for long term storage (only in case these are not provided by the depositor) 300 EUR
   (c) Issuance of a viability statement:
       - when a viability test is carried out 60 EUR
       - based on the last viability test 25 EUR
   (d) Furnishing of a sample
       - Fungi and yeasts 120 EUR
       - Bacteria 90 EUR
   (e) Communication of information 25 EUR
   (f) Issuance of an attestation 25 EUR

2. For arbuscular mycorrhizal fungi
   (a) Storage 1,300 EUR
   (b) Preparation of a batch of cryopreserved samples for long term storage (20 samples)(if applicable, depending on the species of AMF deposited) 600 EUR
   (c) Issuance of a viability statement:
       - when a viability test is carried out 500 EUR
       - based on the last viability test 25 EUR
   (d) Furnishing of a sample 120 EUR
   (e) Communication of information 25 EUR
   (f) Issuance of an attestation 25 EUR

3. For plasmids
   (a) Storage 665 EUR
   (b) Issuance of a viability statement:
       - when a viability test is carried out 60 EUR
       - based on the last viability test 25 EUR
   (c) Furnishing of a sample 105 EUR
   (d) Communication of information 25 EUR
   (e) Issuance of an attestation 25 EUR

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5 In case the recommended host strain is not available at BCCM/LMBP, the depositor is encouraged to deposit a plasmid-carrying culture. If this is not possible and the host has to be furnished by the depositor, a one-off fee of 160.00 euros for this host strain will be charged for quality control tests at the time of deposit (purity, viability), batch preparation, cryopreservation, safekeeping at -80°C for min. 30 years, administration.
4. For human cells, animal cells and hybridomas

(a) Storage 1,300

(b) Issuance of viability statement:
   - when a viability test is carried out 90
   - based on the last viability test 25

(c) Furnishing of a sample 110

(d) Communication of information 25

(e) Issuance of an attestation 25

5. For other genetic material

<table>
<thead>
<tr>
<th></th>
<th>Price offer on request at BCCM/LMBP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fees do not include VAT, transport costs or bank fees.

4. Guidance for Depositors

Depositors are reminded that all requests or deposits should be dealt directly with the BCCM™ collection concerned. They may also obtain the necessary forms from that collection, or from the BCCM website http://bccm.belspo.be/services/deposit.

The staff of the collections is of course available to potential depositors to provide any detailed information. The contact details of each of the collections are mentioned above.
NATIONAL BANK FOR INDUSTRIAL MICROORGANISMS AND CELL CULTURES (NBIMCC)

bul. Sv. Kliment Ohridski No. 49, bldg. 3
1756 Sofia

Telephone: (359-2) 872 08 65
Facsimile: (359-2) 872 08 65
E-mail: info@nbimcc.org
Internet: http://www.nbimcc.org

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, actinomycetes, filamentous fungi, yeasts, animal cell lines, animal and plant viruses, microorganisms containing plasmids.

The NBIMCC accepts for deposit only those microorganisms which, pursuant to the Regulation No. 4 on the protection of workers from risks related to exposure to biological agents at work (SJ No. 105 dated 08.11.2002) or Directive 2000/54/EC, belong to hazard groups 1 and 2.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The NBIMCC has the following requirements for the form and the quantity of the culture in which the microorganisms should be submitted for deposit:

Bacteria and fungi (including those containing plasmid) should be deposited in the form of three active cultures. Lyophilized cultures are also accepted but at least 10 samples.

Animal cell lines and hybridomas should be deposited in 12 frozen in liquid nitrogen cryotubes, each containing minimum 5 x 10⁶ cells.

Animal viruses are accepted as 20 frozen or freeze-dried samples.

In the case of plant viruses, at least 5 g fresh infected leaves should be deposited.
(ii) **Time Required for Viability Testing**

The minimum and maximum lengths of time required for testing the viability of the various kinds of microorganisms accepted by the NBIMCC are as follows:

- **Bacteria** from 3 to 14 days
- **Yeasts** from 3 to 14 days
- **Microorganisms containing plasmid** from 3 to 14 days
- **Fungi** from 5 to 21 days
- **Animal cell lines and hybridomas** from 7 to 14 days
- **Animal viruses** 30 or more days
- **Plant viruses** 30 or more days

(iii) **Depositor Checks and Renewal of Stocks**

The NBIMCC prepares its own lyophilized and/or frozen batches of bacteria, actinomycetes, yeasts, fungi and microorganisms containing plasmids by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. Nevertheless, the NBIMCC always keeps original material supplied by the depositor.

The NBIMCC does not prepare its own batches of animal cell lines as well as animal and plant viruses. New batches are prepared from the depositor’s original material for the renewal of stocks.

The depositor is required to test for authenticity samples from all batches after the preservation in NBIMCC.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of the NBIMCC is Bulgarian. Communications are also accepted in English.

*Contract.* The NBIMCC does not enter into a written contract with the depositor defining the liabilities of either party.

*Import and/or Quarantine Regulations.* The kinds of microorganisms accepted by the NBIMCC are not subject to quarantine regulations. However, import regulations must be observed in respect of certain kinds of microorganisms accepted by the NBIMCC.
(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the NBIMCC accession form equivalent of model form BP/1. The NBIMCC uses separate forms for the deposit of microorganisms (including those containing plasmid), animal cell lines, animal viruses and plant viruses.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, both in Bulgarian and English. The NBIMCC uses its own standard letters for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NBIMCC will telephone or e-mail the date of deposit and accession number before the official receipt is issued, but only after the viability test has been done and has given a positive result. Similarly, the NBIMCC will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NBIMCC does not ask the depositor for the name and address of his patent agent. However, if requested, the NBIMCC will supply copies of the receipt and the viability statement to either the depositor or his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted to deposits under the Budapest Treaty. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(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. The receipt and viability statement are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The NBIMCC advises third parties of the correct procedures to follow to make a valid request.

The NBIMCC furnishes a sample of a potentially hazardous microorganism under patent regulations to requesting parties after receiving a written statement proving that they are allowed to work with such organisms.

When responding to requests from overseas, the NBIMCC assumes the requesting party has met the import requirements of his own country.
(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

The NBIMCC does not list Budapest Treaty deposits in its published catalogue. If the depositor or a competent patent office instructs the NBIMCC to make samples of a microorganism available to anyone, that organism is listed in the next published NBIMCC catalogue.

3. Schedule of Fees

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>BGL</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>Storage</td>
<td>1,200</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a viability statement</td>
<td>120</td>
</tr>
<tr>
<td>(c)</td>
<td>Furnishing of a sample</td>
<td>120</td>
</tr>
</tbody>
</table>

4. Guidance for Depositors

The NBIMCC does not have specific written notes for the guidance of depositors, but is always ready to offer advice by telephone or correspondence.
1. Requirements for Deposit

(a) **Kinds of Microorganisms that May Be Deposited**

The IDAC will accept for deposit: animal viruses of Risk Group Levels 1, 2 and 3, which can be propagated in cell culture, Risk Group Levels 1, 2 and 3 bacteria, all bacteriophages, all mammalian cell lines, and all cloned genes. Fungi, hybridomas, yeasts, plasmid and phage vectors, libraries and other rDNA material will also be accepted.

The IDAC will only accept deposits which can be preserved without significant change to their properties by freezing or lyophilization. Deposits which cannot be so preserved or can only be maintained in active culture, may be accepted on an individual basis, with prior negotiation and determination of associated fees.

(b) **Technical Requirements and Procedures**

(i) **Form and Quantity**

The IDAC will only accept deposits which can be preserved without significant change to their properties by freezing or lyophilization. Deposits which cannot be preserved in this manner or can only be maintained in active culture may be accepted on an individual basis, with prior negotiation and determination of associated fees.

Depositors are encouraged to supply frozen or freeze-dried material. However, when possible, the IDAC will accept actively growing material, and preserve it by freezing or freeze-drying at an additional cost. In these cases a sample of the preserved material will be returned to the depositor for verification of properties. However, if the preserved material is viable but not acceptable (e.g., properties altered), a new deposit must be made, and the original deposit date will be void. Depositors are therefore urged to supply frozen or freeze-dried material prepared in their laboratory in order to avoid the possibility of this occurring.
The quantity of material required for the various types of deposits is as follows:

<table>
<thead>
<tr>
<th>Type</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microorganisms (including bacteria (either containing a plasmid or not containing a plasmid), bacteriophages, fungi and yeast)</td>
<td>10 frozen (0.5 ml each) or freeze-dried samples</td>
</tr>
<tr>
<td>Plasmids and Vectors not in host (e.g., purified DNA, libraries and associated rDNA material)</td>
<td>25 vials (min. 100 ng each)</td>
</tr>
<tr>
<td>Animal Viruses</td>
<td>25 frozen (1 ml each) or freeze-dried samples</td>
</tr>
<tr>
<td>Cell Lines and Hybridomas</td>
<td>25 frozen samples (2 – 6 million cells each)</td>
</tr>
</tbody>
</table>

(ii) **Time Required for Viability Testing**

The time required for testing the viability of the different types of deposits is indicated below. However, depositors should be aware that in certain cases viability testing may take longer.

<table>
<thead>
<tr>
<th>Type</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td>3 – 7 days</td>
</tr>
<tr>
<td>Fungi and yeasts</td>
<td>7 – 10 days</td>
</tr>
<tr>
<td>Cell lines, hybridomas and bacteriophages</td>
<td>7 – 10 days</td>
</tr>
<tr>
<td>Plasmid, phages and other rDNA¹</td>
<td>7 – 10 days</td>
</tr>
<tr>
<td>Animal viruses</td>
<td>30 or more days</td>
</tr>
</tbody>
</table>

(iii) **Depositor Checks and Renewal of Stocks**

It is the responsibility of the depositor to furnish a sufficient quantity of the material for the specified period of time. If a culture or other biological material should become non-viable or be destroyed during the effective term of the deposit, it is the responsibility of the depositor to replace it with viable material. The IDAC may consider, for a fee, to replenish the material on behalf of the depositor, however, it is the responsibility of the depositor to authenticate the material prepared and to inform the IDAC of the results. Whichever method is used for renewal of stocks the IDAC will maintain a portion of the material originally submitted for deposit.

¹ If applicable “viability” of the deposit is determined by the ability of the material to successfully transform, infect or otherwise alter a host cell.
(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of Canada and the IDAC are English and French. Communications in any other language are not accepted.

Contract. The IDAC 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, by completing the IDAC BP/1 deposit form, the depositor foregoes any right to withdraw his deposit during the required storage period and accepts that the material will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The IDAC is subject to Canadian and international regulations governing the importation, exportation and transportation of infectious substances. Information relating to the importation and safe handling of infectious substances affecting humans can be obtained through the Health Canada web site (http://www.hc-sc.gc.ca/hpb/lcdc/biosafety/index.html), or by contacting the Director, Office of Biosafety, Laboratory Centre for Disease Control, Ottawa, Ontario, K1A 0L2, tel: (613) 957-1779. Information regarding veterinary pathogens and permits may be obtained from Agriculture and Agri-Food Canada, 59 Camelot Drive, Nepean, Ontario K1A 0Y9, tel.: (613) 952-8000. Inquiries regarding the transportation of regulated material should be directed to the Director General of the Transport of Dangerous Goods Directorate of Transport Canada, Canada Building, 344 Slater Street, 14th Floor, Ottawa, Ontario K1A 0N5, tel.: (613) 998-0517. These agencies may also be able to assist with information relating to the relevant regulations in countries other than Canada however it is advised that the appropriate agencies for the country in question be contacted.

It is essential that the depositor contact the IDAC in advance of submitting a deposit which may be subject to these regulations to ensure that the appropriate documentation is obtained. This is particularly important for deposits made from outside of Canada. Failure to do so could result in the deposit being refused entry into the country.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The IDAC requires that depositors complete the Statement In The Case Of An Original Deposit (form BP/1) in order to meet the requirements of the Budapest Treaty. In the event of later amendments to the scientific description and/or proposed taxonomic designation the depositor must complete the IDAC form BP/7. In the case of a new deposit made under Article 4 of the Budapest Treaty the depositor must complete form BP/2.

Official Notifications to the Depositor. Notifications of receipt and viability are issued on the mandatory international forms (BP/4 and BP/9, respectively). Attestation of receipt of an amendment of the scientific description and/or proposed taxonomic designation is issues on form BP/8. If requested, notification of furnishing of a sample to a third party is issued on form BP/14.
Unofficial Notifications to the Depositor. If requested, the IDAC will convey the date of deposit and accession number after the submission has been received but before the official receipt is issued. Notification of the result of the viability testing is only communicated through official correspondence.

Supply of Information to a Patent Agent. If requested, the IDAC will supply copies of the receipt and viability statement to the depositor’s patent agent.

(iii) Converting a Previous Deposit

The IDAC does not permit the conversion of deposits not originally made for patent purposes for Budapest Treaty deposits. The procedures outlined above for making a deposit must be followed in all cases.

(iv) Making a New Deposit

In the advent that a new deposit is submitted the IDAC requires that the Statement In The Case Of A New Deposit (form BP/2) be completed. The deposit will retain its initial deposit number and date as long as the replacement deposit is viable, the deposit is made within three months of receiving notification from the IDAC and the IDAC receives a statement signed by the depositor alleging that the newly deposited material is the same as that originally deposited. Charges are for viability testing are required for new deposits.

2. Furnishing of Samples

(a) Requests for Samples

The IDAC makes available samples of deposited material only to parties who are so entitled under the terms of the Budapest Treaty and its Regulations. The IDAC will provide requesting parties with request forms (as appropriate) or assist with obtaining the necessary forms required for their request.

The IDAC accepts deposits of organisms which are potentially hazardous and may be subject to health and safety regulations. When such organisms are requested the IDAC will withhold issuing samples until it has confirmed that the requesting party can comply with such regulations. In certain cases, the IDAC may also require that the requesting party sign an assurance of acceptance of responsibility before agreeing to release a sample. In order to expedite the release of such samples it is therefore advisable that all requests be accompanied by documentation attesting to the fact that the requesting party has the facilities required for, and agrees to the regulations governing the handling of the requested material.

The IDAC attempts to ensure that the correct documentation is obtained prior to the shipping of the material requested. However, it is the responsibility of the requesting party to obtain all of the necessary permits which may be required.
(b) **Notification of the Depositor**

Unless the right to be so notified has been waived, the IDAC will notify the depositor on form BP/14 each time a sample of the deposit is furnished to a third party.

(c) **Cataloguing of Budapest Treaty Deposits**

At this time the IDAC does not publish a catalog of its culture collection.

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>(a)</th>
<th>Issuance of a viability statement</th>
<th>CAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>Storage (30 years)</td>
<td>800</td>
</tr>
<tr>
<td>(c)</td>
<td>30 years of notification of requesting parties</td>
<td>500</td>
</tr>
<tr>
<td>(d)</td>
<td>Furnishing of a sample (plus expedition cost)</td>
<td>50</td>
</tr>
<tr>
<td>(e)</td>
<td>Attestation of receipt of revised scientific description</td>
<td>50</td>
</tr>
<tr>
<td>(f)</td>
<td>Communication of scientific description to 3rd party</td>
<td>50</td>
</tr>
<tr>
<td>(g)</td>
<td>Amount for additional five years of storage beyond 30 years</td>
<td>125</td>
</tr>
</tbody>
</table>

This list is of base prices. Deposits requiring special conditions or care are subject to surcharges. All charges are subject to the Canadian Goods and Services Tax at the current rate.

4. **Guidance for Depositors**

The IDAC is in the process of preparing a detailed information package for depositors. Until this is available all inquiries should be directed to the main office.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

CChRGM may receive for long-term deposit microorganisms for agricultural and forestry, environmental and industrial-process use and impact. More specifically, CChRGM will accept for deposit fungi (molds, filamentous fungi, yeasts, higher fungi), bacteria (including actinomycetes), microorganisms which contain plasmids; those which can be preserved, without any alteration to their properties, by means of sub-culture and storage in cryopreservation and lyophylization.

CChRGM will accept pathogenic microorganisms from plants, antagonists of phytopathogens, nematophagae, entomopathogens, mycorrhizal, plant endophytes, bioremediators and microorganisms from industrial processes.

Those animal and human pathogenic microorganisms and/or of unknown nature are excluded from being deposited as such. In the same way, mixtures of cultures, contaminated cultures, those without an adequate scientific description or cultures whose identity cannot be verified are excluded.

For the time being, algae, protozoa, human cell lines, animal viruses and hybridomas cannot be received.

As a general rule, within CChRGM only strains that may be cultivated and preserved under technically feasible conditions, within the sphere of the collections conserved, without inducing significant changes in their characteristics, can be accepted.

Preparations of nucleic acids and phages are not for the time being accepted, pending development of techniques and procedures inside the laboratory.

Through its curator, CChRGM reserves the right to accept or reject microorganisms which, by their nature, require special treatment or present a risk in their handling and preparation for storage. Exceptionally, microorganisms may be accepted for deposit, which require special treatment, although the costs and conditions of the deposit shall be established and negotiated case by case, as appropriate.
(b) Technical Requirements and Procedures

(i) Form and Quantity

Organisms must be submitted for deposit as liquid cultures or in agar. Should samples be sent lyophilized, they will be accepted only after rehydratation and positive culturing. The minimum number of replicas that must be supplied for deposit is, in the case of fungi, of a pure culture in a known culture medium, free of contamination and other organisms (contaminated cultures will be rejected without being processed).

(ii) Time Required for Viability Testing

The average time required to carry out the viability analysis by CChRGM is 15 days, but depositors must take into account the fact that in some cases analysis may take up to 30 days. Any change will be notified to the depositor in advance.

(iii) Depositor Checks and Renewal of Stocks

CChRGM will prepare its own sub-cultures of organisms at the time of deposit. Cultures will be renewed in accordance with requests or the opinion of the laboratory already established for the different groups of microorganisms. Where the original material has been cryopreserved, the samples will be renewed through a subculture thereof or by requesting a new deposit from the depositor. Analysis of authenticity of the samples will be required from the first group of samples for deposit (not from the subsequent ones).

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of CChRGM are Spanish and English.

Contract. CChRGM will request the depositor to complete the application form, which serves as a contract whereby the depositor undertakes to:

- supply all the information requested by CChRGM;
- pay all the required fees;
- compensate CChRGM for any claim that may arise as a result of the dispatch of samples with information that has been altered, is misleading, amended or belongs to third parties;
- decline to withdraw his deposit during the period requested for its due storage;
- authorize CChRGM to supply the samples in accordance with Rule 11 of the Regulations under the Budapest Treaty.

Where an organism has been accepted for deposit, CChRGM shall notify the depositor and shall remind him that he is subject to the terms and conditions of the contract.

Import and/or Quarantine Regulations. The type of organisms accepted by CChRGM is subject to import and/or quarantine regulations as well as internationally recognized protocols on biosafety. For import and quarantine purposes, depositors must follow requirements and regulations
of the Livestock and Agriculture Service (Servicio Agricola Ganadero) and national customs services.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors must complete the application and deposit forms used by CChRGM for deposits according to the Budapest Treaty, equivalent to BP/1.

Official Notifications to the Depositor. The receipt and declaration of viability shall be issued on the compulsory international forms BP/4 and BP/9 respectively. The certificate for receipt of a subsequent indication or amendment of the scientific description and/or proposal of taxonomic designation shall be issued on form BP/8, the notification of supply of samples to third parties on form BP/14. For other official notifications, standard forms shall not be used.

Unofficial Notifications to the Depositor. If requested, CChRGM shall communicate by telephone, facsimile or email the date of deposit and the entry number after the organism has been received, but before the official receipt is issued. However, the depositor shall be informed that this information is provisional and that it depends on the result of the viability tests. CChRGM will also communicate the result of the viability analysis before the relevant certificate is issued.

Supply of Information to a Patent Agent. As a matter of course, CChRGM will ask the depositor to provide the name and address of his patent agent. If required, CChRGM will supply copies of the receipt and viability statement and any other information to the depositor and his patent agent.

(iii) Converting a Previous Deposit

CChRGM does not hold deposits made for patent purposes beyond what is stipulated by the Budapest Treaty.

(iv) Making a new Deposit

When the depositor makes a new deposit, he shall be asked to complete the model form BP/2 and to attach the documents required under Rule 6.2.

The receipt and viability certificate for a new deposit shall, as a matter of course, be issued using international forms BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

CChRGM will inform third parties of the procedures for the correct formulation of requests. In cases where requests require proof of authorization, CChRGM will supply the requesting parties with the request forms used by industrial property offices or copies of form BP/12.
Where requests from abroad are received, CChRGM assumes that the depositor knows the import requirements of his country.

All the samples sent by CChRGM come from groups of samples of specific preparations.

(b) Notification of the Depositor

The depositor will be informed, by letter and email, where samples of his organisms have been sent to third parties.

(c) Cataloguing of Budapest Treaty Deposits

CChRGM will publish the lists of deposits under the Budapest Treaty in its catalogues only with written authorization of the depositor.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Service</th>
<th>USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent deposit (30 years)</td>
<td>690</td>
</tr>
<tr>
<td>Furnishing of sample</td>
<td>96</td>
</tr>
<tr>
<td>Issue of viability statement</td>
<td>73</td>
</tr>
<tr>
<td>Communication of information</td>
<td>25</td>
</tr>
</tbody>
</table>

Note: The amounts do not take into account the dispatch costs and additional costs within Chile, as well as shipping charges. The amounts in Chilean pesos (CLP) are calculated based on the price of the dollar published by the Central Bank for the day on which the application for deposit is filed (sending of the application form).

4. Guidance for Depositors

The CChRGM does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone, letter or email.
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:

<table>
<thead>
<tr>
<th>Category</th>
<th>Minimum Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae, bacteria, molds, plant viruses, yeasts</td>
<td>6 lyophilized or on culture media</td>
</tr>
<tr>
<td>Bacteriophages (at least $10^8$ pfu/ml)</td>
<td>5 X 0.5 ml (free-cell lysate)</td>
</tr>
<tr>
<td>Animal cell lines, animal viruses, hybridomas, plasmids (DNA at least 20 meg/tube)</td>
<td>11</td>
</tr>
<tr>
<td>Seeds</td>
<td>2,500</td>
</tr>
</tbody>
</table>

(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:

<table>
<thead>
<tr>
<th>Category</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td>3 days (or up to 14 days)</td>
</tr>
<tr>
<td>Algae, molds, yeasts</td>
<td>5 days (or up to 20 days)</td>
</tr>
<tr>
<td>Animal cell lines, hybridomas, bacteriophages, plasmids</td>
<td>7 days (or up to 14 days)</td>
</tr>
<tr>
<td>Animal viruses, plant cell cultures, seeds</td>
<td>21 days (or up to 30 days)</td>
</tr>
<tr>
<td>Plant viruses</td>
<td>no period of time as yet</td>
</tr>
</tbody>
</table>

(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

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>RMB</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>Storage</td>
<td>3.000</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a viability statement</td>
<td>500</td>
</tr>
<tr>
<td>(c)</td>
<td>Furnishing of a sample</td>
<td>500</td>
</tr>
<tr>
<td>(d)</td>
<td>Communication of information</td>
<td>200</td>
</tr>
<tr>
<td>(e)</td>
<td>Application for the import or export license</td>
<td></td>
</tr>
</tbody>
</table>

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.
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:

- Bacteria, yeasts, filamentous fungi, phages, mycoplasma, single cell algae: 5
- Viruses, 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:

- Bacteria, yeasts: 3 days (or up to 20 days)
- 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

(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

\(^1\) For plasmids, “viability” testing consists in inserting the plasmid into a host. If the host is transformed, the “viability test” is regarded as positive.
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. A fee of $10 is charged for this service. The CGMCC similarly will telephone or email the result of the viability test before the official viability statement is issued.

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

(CN)
CJMCC/2016
Patent Office of the People’s Republic of China are listed in the CGMCC catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>RMB</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>Storage</td>
<td>3.000</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a viability statement</td>
<td>500</td>
</tr>
<tr>
<td>(c)</td>
<td>Furnishing of a sample</td>
<td>500</td>
</tr>
<tr>
<td>(d)</td>
<td>Communication of information</td>
<td>200</td>
</tr>
</tbody>
</table>

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.
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) Technical Requirements and Procedures

(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 x 5 ml having a minimum titre of 1 x 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 x 10^6 cells per ampoule (cells growing in suspension) or 2 x 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.

<table>
<thead>
<tr>
<th>Material</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Archea, Bacteria</td>
<td>3 days (or up to 14 days)</td>
</tr>
<tr>
<td>Fungi, Yeasts</td>
<td>5 days (or up to 20 days)</td>
</tr>
<tr>
<td>Algae</td>
<td>10 days (or up to 30 days)</td>
</tr>
<tr>
<td>Plasmids</td>
<td>7 days (or up to 14 days)</td>
</tr>
<tr>
<td>Bacteriophages</td>
<td>7 days (or up to 14 days)</td>
</tr>
<tr>
<td>Plant Cell Cultures</td>
<td>7 days (or up to 30 days)</td>
</tr>
<tr>
<td>Human and Animal Cell Lines</td>
<td>7 days (or up to 20 days)</td>
</tr>
</tbody>
</table>

(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) Notification to the Depositor

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

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Fee (RMB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>Storage</td>
<td>3,000</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a viability statement</td>
<td>500</td>
</tr>
<tr>
<td>(c)</td>
<td>Furnishing of a sample</td>
<td>500</td>
</tr>
<tr>
<td>(d)</td>
<td>Communication of information</td>
<td>200</td>
</tr>
<tr>
<td>(e)</td>
<td>Application for the import or export license</td>
<td>Depends on individual situation</td>
</tr>
</tbody>
</table>

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.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes), filamentous fungi, yeast-like microorganisms, yeasts accepted are those capable of long-term preservation without any substantial change of their initial properties, plasmids in a host.

The CCM accepts for deposit only those bacteria, filamentous fungi, yeast-like microorganisms and yeasts which, pursuant to *Laboratory Biosafety Manual* (World Health Organization, Geneva 1983), belong to hazard group I or II.

Microorganisms having special requirements for cultivation which the CCM is not technically capable of carrying out shall not be accepted.

Cultures without scientific description as well as cultures which cannot be identified shall not be accepted.

When depositing strains containing a plasmid, the CCM shall require information on the plasmid and its host strain in respect of their properties and classification (i.e., group P1, P2, P3 or P4). The CCM shall accept only plasmids belonging to group P1.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria and fungi, including those containing plasmids, are accepted by the CCM as lyophilized or actively growing cultures, except agar plate cultures (these are prone to become damaged in transport).

The depositor is required to provide two lyophilized or agar cultures when making his deposit.
(ii) **Time Required for Viability Testing**

The average time required for testing the viability of various microorganisms accepted by the CCM is five days, but the depositor should realize that in some cases, especially with slow growing microorganisms, viability testing may take as long as 14 days.

(iii) **Depositor Checks and Renewal of Stocks**

The CCM prepares its own lyophilized and/or frozen batches of bacteria and fungi at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganisms prepared by the CCM.

Whichever method is used for preparing batches of samples for distribution, the CCM always keeps original material supplied by the depositor.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of the CCM is Czech. Communications are also accepted in English.

*Contract.* The CCM does not enter into any written contract with the depositor defining the liabilities of either party but, by signing the CCM deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganisms will be distributed according to the relevant patent requirements.

*Import and/or Quarantine Regulations.* At present, there are no kinds of microorganisms in the CCM accepted under the Budapest Treaty which may be subject to import or quarantine regulations. But this may be changed in the future.

(ii) **Making the Original Deposit**

*Requirements to Be Met by the Depositor.* Depositors are required to complete form CCM-BP/1 (the equivalent of model form BP/1) which is the accession form used for Budapest Treaty deposits.

*Official Notifications to the Depositor.* The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, both in Czech and English. Notification of furnishing of a sample to a third party is issued on model form BP/14. The CCM uses its own standard letters for other official notifications.

*Unofficial Notifications to the Depositor.* If requested, the CCM will telephone or telefax the date of deposit and the accession number before the official receipt is issued, but only after a positive viability test has been obtained.
Supply of Information to a Patent Agent. The CCM does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the CCM will send 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 deposits under the Budapest Treaty only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty.

All conversions are subject to the storage fee normally levied for Budapest Treaty deposits.

(iv) Making a New Deposit

The depositor is required to complete the equivalent of 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 viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9.

2. Furnishing of Samples

(a) Request for Samples

The CCM 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 CCM 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).

When responding to requests from overseas, the CCM will ask the requesting party to provide an import permit if it knows that one is required for that particular country.

All samples furnished by the CCM are from batches of its own preparations.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

The CCM does not list Budapest Treaty deposits in its published catalog.
3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Patent Deposit of Cultures</th>
<th>CZK</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Deposit and storage for 30 years</td>
<td>26,500</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>1’650</td>
</tr>
<tr>
<td>(c) Furnishing of a sample</td>
<td>1,000</td>
</tr>
</tbody>
</table>

Value added tax (21%) will be charged in addition, if applicable. Extra charge is payable for handling, postage and banking. A prepayment may be requested for orders coming from abroad.

4. **Guidance for Depositors**

At present the CCM does not have specific written notes for the guidance of depositors, but is always ready to offer advice by telephone or correspondence.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and fungi (including yeasts) which can be preserved at -150 °C or in freeze-dried state without significant damage to or loss of their properties or viability.

VTTCC accepts only organisms belonging to risk groups 1 or 2 according to Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, and genetically modified microorganisms belonging to class 1 according to Council Directive 98/81/EC on the contained use of genetically modified microorganisms.

Biological material cannot be accepted, if it is contaminated by foreign organisms. Mixtures or microbial cultures of more than two microorganisms will not be accepted. Mixtures of two microorganisms will be accepted in case these a) cannot be cultivated separately as pure cultures and b) can easily be distinguished macroscopically or microscopically.

VTTCC reserves the right to refuse to accept for deposit any material which in its view represents an unacceptable hazard or which it cannot process.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, yeasts and filamentous fungi submitted for deposit in VTTCC should be supplied as three active or freeze-dried cultures of the same batch. Cultures submitted for deposit should be
free of foreign organisms. International regulations for packaging and shipping of microorganisms should be followed in the consignment.

(ii) Time Required for Viability Testing

The minimum time required for viability testing of the kinds of microorganisms accepted by VTTCC is 7 days. Depositors should consider that viability testing of slow growing organisms and organisms with special growth requirements may take longer.

(iii) Depositor Checks and Renewal of Stocks

VTTCC prepares frozen and/or freeze-dried batches of the deposited organism by subculturing the material supplied by the depositor. The depositor is requested to check the authenticity of a sample from each batch prepared from the material supplied. A portion of the original material is retained and stored by freezing or freeze-drying. New batches are prepared for renewal of stocks when necessary.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of VTT Culture Collection is English. Written statements and completed forms have to be in English, but communications are also accepted in Finnish and Swedish.

Contract. The form BP/1 for patent deposit in VTTCC is a contract between the depositor and VTTCC and it must be signed by the depositor. By signing the contract the depositor undertakes

- to supply VTTCC the sample and all the related necessary information requested by VTTCC;
- not to withdraw its deposit during the required storage period;
- to pay VTTCC all necessary fees related to the deposition under this contract;
- to authorize VTTCC to supply samples in accordance with the requirements and purposes of the patent procedure applicable;
- not to hold VTTCC liable for any damages related to deterioration of samples during storage when all precautions indicated by the depositor in respect of storage have been taken by VTTCC;
- to compensate VTTCC for any damage it may sustain as a consequence of dealing with the samples when all precautions indicated by the depositor in respect of dealing with the samples have been taken by VTTCC.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by VTTCC are not subject to import or quarantine regulations.

(ii) Making the Original Deposit
Requirements to Be Met by the Depositor. The depositor is required to complete the form BP/1 for patent deposit in VTT Culture Collection, available at the internet site of the collection. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/8. Notification of the furnishing of samples to third parties is issued on form BP/14.

Unofficial Notifications to the Depositor. If requested, VTTCC communicates the date of deposit and the accession number before the official receipt is issued, but only after a positive viability test. Likewise VTTCC communicates the finding of the viability test before the official viability statement is issued.

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

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty, whether or not they were originally made for patent purposes. Any earlier deposit is subject, on conversion, to the storage fee normally charged for deposits made under the Budapest Treaty. The administrative requirements for conversion are the same as those to be met for an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is requested to complete the equivalent of 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 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

VTTCC advises third parties of the correct procedures to be followed to make a valid request. In case of requests requiring proof of entitlement, VTTCC will provide requesting parties with copies of model request form BP/12. Samples will only be furnished to recognized microbiological laboratories and not to private addresses. When requests are received from abroad, VTTCC assumes that the requesting party has met the import requirements of his/her country.

All samples of deposited microorganisms furnished by VTTCC are from batches prepared by VTTCC.

(b) Notification of the Depositor
Depositors are notified on form BP/14 when samples of his/her microorganisms have been furnished to third parties.

(c) **Cataloguing of Budapest Treaty Deposits**

VTTCC does not list Budapest Treaty deposits in its published catalogue.

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th></th>
<th>EUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. (a) Accession and deposit (including initial viability check, preservation and storage for 30 years)</td>
<td>900</td>
</tr>
<tr>
<td>(b) Conversion of a deposit made outside of the Budapest Treaty into a deposit according to Budapest Treaty</td>
<td>900</td>
</tr>
<tr>
<td>(c) Prolongation of the duration of storage, per year</td>
<td>50</td>
</tr>
<tr>
<td>2. Issuance of viability statement</td>
<td></td>
</tr>
<tr>
<td>(a) Where a viability test is requested</td>
<td>120</td>
</tr>
<tr>
<td>(b) On the basis of last viability test</td>
<td>50</td>
</tr>
<tr>
<td>3. Furnishing of a sample</td>
<td>170</td>
</tr>
<tr>
<td>4. Communication of information</td>
<td>50</td>
</tr>
<tr>
<td>5. Issuance of an attestation</td>
<td>120</td>
</tr>
</tbody>
</table>

Fees do not include VAT, transport costs or bank fees.

4. **Guidance for Depositors**

VTTCC does not publish specific information for the guidance of depositors under the Budapest Treaty. Depositors are encouraged to contact VTTCC prior to making the deposit for further information on the procedure.
1. Requirements for Deposit

(a) Kinds of Microorganism that May Be Deposited

Animal cell cultures, including human cell lines, genetically modified cell lines and hybridomas, bacteria (including actinomycetes), bacteria containing plasmids, filamentous fungi and yeasts, and viruses, EXCEPT:

- plant cells;
- microorganisms whose manipulation calls for physical insulation standards of P3 or P4 according to the information provided by the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules and Laboratory Safety Monograph;
- microorganisms liable to require viability testing that the CNCM is technically not able to carry out;
- mixtures of undefined and/or unidentifiable microorganisms.

The CNCM reserves the possibility of refusing any cell culture which, according to the curator, involves an unacceptable risk or is not suitable, for technical reasons, for handling and any microorganism for security reasons; specific risks to human beings, animals, plants and the environment.

In the eventuality of the deposit of cultures that are not or cannot be lyophilized, the CNCM must be consulted, prior to the transmittal of the microorganism, regarding the possibilities and conditions for acceptance of the samples; however, it is advisable to make this prior consultation in all cases.
(b) Technical Requirements and Procedures

(i) Form and Quantity

The depositor must provide 12 replicates, either frozen or lyophilized, resulting from a single preparation and containing at least $10^6$ viable units per ml. Lower concentrations may be allowed in exceptional cases.

The depositor should in addition supply any live material that is not available in an open collection at the CNCM but is necessary for checks on and/or the preservation of the microorganism to be deposited, and also any substance necessary for those purposes that is inaccessible or not readily accessible.

(ii) Time Required for Viability Testing

The average time required by the CNCM for testing the viability of the various kinds of microorganism is given below (but depositors should realize that the times given may be exceeded in the case of certain slow-developing microorganisms, or others whose viability checks call for particularly long preparatory phases):

- **Bacteria, bacteriophages**: 14 days
- **Filamentous fungi, yeasts**: 25 days
- **Animal or human cell cultures**: 40 days
- **Viruses (except bacteriophages)**: 60 days

(iii) Depositor Checks and Renewal of Stocks

The CNCM prepares its own batches, frozen in liquid nitrogen, at the time of deposit and whenever necessary thereafter by subculturing material supplied by the depositor. These stocks are intended to fulfill requests for samples. The depositor is required to test all batches of his microorganism prepared by the CNCM for continued presence of all its known specific properties.

In all cases the CNCM stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

*Language.* The official language of the CNCM is French. Communications in English are also accepted. All forms to be completed are available in English as well as French. Letters and notifications are written in either French or English.
Contract. The CNCM enters into a contract with the depositor. By signing the contract the depositor acknowledges that he has noted the conditions governing the deposit of a microorganism under the Budapest Treaty, the procedural requirements to be observed in the relevant dealings with the CNCM and also the relative liability in the event of an incident.

Import and/or Quarantine Regulations. For infectious material from abroad the CNCM provides the depositor with a label to be attached to his package. It ensures the free entry of the microorganism into French territory, subject to the package conforming to international regulations of the transport of hazardous substances, and to compliance with all the necessary formalities for the export of the microorganism.

Very few microorganisms require special authorization to be handled and stored on the territory of France. Should it be necessary, the applicant would have to supply all the particulars required by the competent authorities, to which the CNCM would then immediately submit the necessary request for authorization.

There are no quarantine regulations applicable to microorganisms at present.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor has to complete and sign the deposit and contract forms (see under 1(c)(i) above). CNCM uses different deposit forms, depending on whether bacteria, bacteria cultivated on cell systems, bacteriophages, filamentous fungi and yeasts, viruses or cell cultures are being deposited. Every deposit form is completed with a statement by the depositor that he has made all the notifications required by national regulations in force in the country of origin with respect to the use and dissemination of the microorganism being deposited, and that he has received the necessary authorizations to that end.

The CNCM strongly advises the depositor to fax the deposit form back to it before the microorganism is sent, and to inform it without delay of the intended deposit date and the shipping method. The originals of the deposit documents should be sent before or with the microorganism itself.

In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor is required to complete a BP/7 form which may be requested from the CNCM by mail or fax.

Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9 respectively. Individual letters are used for all other official notifications.

Unofficial Notifications to the Depositor. On receiving the microorganism in a condition that does not preclude its acceptance for obvious reasons, the CNCM will fax the date and number of the deposit to the depositor. If the deposit is accepted later, the accession number will be the same as the registration number.
Supply of Information to a Patent Agent. The CNCM does not ask the depositor to give the name and address of a patent agent; it will however, at his request, provide his patent agent with copies or the originals, as specified in the request, of the receipt and viability statement.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor into deposits under the Budapest Treaty if they were originally made for the purposes of a patent procedure or for security purposes of confidential character. Any request for conversion of a deposit made outside the Treaty must bear the signature of the original depositor and give the date on which the original deposit was received, the accession number assigned to it by the CNCM, the name and address of the depositor, the mention that the conversion is requested under the Budapest Treaty and an undertaking not to withdraw the deposit during the period specified in Rule 9.1. The CNCM enters into a contract with the depositor (see under 1(c)(i) above). All conversions are subject to payment of the storage fee normally levied for Budapest Treaty deposits.

(iv) Making a New Deposit

When making a new deposit the depositor has to complete model form BP/2, which is already partly completed and is supplied to him by the CNCM, and to send copies of the documents mentioned in Rule 6.2. The CNCM enters into a contract with the depositor (see under 1(c)(i) above). For the sending of the microorganism the depositor has to conform to the same requirements as at the time of the original deposit (see under 1(b)(i) and 1(c)(i) above). The receipt and the viability statement of a new deposit are issued on mandatory “international forms” BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The CNCM 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 CNCM supplies requesting parties with copies of model request form BP/12, but does not supply the request forms used by individual industrial property offices.

Notwithstanding any entitlement to receive samples under patent regulations, the CNCM stores samples of potentially hazardous microorganisms until such time as the requesting party signs a declaration stating that he has made all the notifications in his country that are required by the regulations in force concerning it, and that he has received all the necessary authorizations to that end. When responding to requests from overseas, the CNCM will also request the requesting party to provide it with adequate import authorization or a declaration stating that no such authorization is necessary for the proper shipping of the microorganism.

(FR)
CNCM/2020
(b) Notification of the Depositor

When the CNCM receives a request for a sample or sends samples of deposited microorganisms to third parties, it shall immediately inform the depositors concerned of the fact.

(c) Cataloguing of Budapest Treaty Deposits

The CNCM does not list deposits made under the Budapest Treaty in any catalogue.

3. Schedule of Fees

(a) Storage:
- bacteria, filamentous fungi, yeasts, phages
  - freeze-dried
  - frozen at –80°C
  - frozen in liquid nitrogen
- cell cultures
- animal viruses
  - propagated on embryonated eggs
  - propagated on cultured cells

(b) Issuance of a viability statement:
- requiring a new viability test
- in other cases

(c) Furnishing of a sample (plus shipping costs)

(d) Communication of information or issuance of an attestation

<table>
<thead>
<tr>
<th>Description</th>
<th>EUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage</td>
<td></td>
</tr>
<tr>
<td>- bacteria, filamentous fungi, yeasts, phages</td>
<td></td>
</tr>
<tr>
<td>- freeze-dried</td>
<td>609.80</td>
</tr>
<tr>
<td>- frozen at –80°C</td>
<td>701.27</td>
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<tr>
<td>- frozen in liquid nitrogen</td>
<td>1,448.27</td>
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<tr>
<td>- cell cultures</td>
<td></td>
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<tr>
<td>- animal viruses</td>
<td></td>
</tr>
<tr>
<td>- propagated on embryonated eggs</td>
<td>788.92</td>
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<tr>
<td>- propagated on cultured cells</td>
<td>1,086.96</td>
</tr>
<tr>
<td>Issuance of a viability statement</td>
<td></td>
</tr>
<tr>
<td>- requiring a new viability test</td>
<td>106.71</td>
</tr>
<tr>
<td>- in other cases</td>
<td>18.29</td>
</tr>
<tr>
<td>Furnishing of a sample (plus shipping costs)</td>
<td>106.71</td>
</tr>
<tr>
<td>Communication of information or issuance of an attestation</td>
<td>38.11</td>
</tr>
</tbody>
</table>

Fees are subject to Value-Added Tax (VAT) according to current French regulations.

4. Guidance for Depositors

Details of the deposit procedure may be requested by mail or fax from the CNCM, which moreover is always available to provide additional information and guidance by telephone within the limits of its competence.
1. Requirements for Deposit

(a) **Kinds of Microorganisms that May Be Deposited**

Bacteria (including mycoplasma) and archaea (both including those containing plasmids), fungi (including yeasts), bacteriophages, plasmid DNAs, plant viruses, plant cell cultures (undifferentiated plant cell cultures, embryogenic plant cell cultures and tissues, *in-vitro* shoot cultures), human and animal cell cultures (including hybridomas).

The DSMZ accepts for deposit only those microorganisms which, pursuant to the Directive 2000/54/EC on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work (OJ No. L262, pp. 21-45 of September 18, 2000) or the respective German Law (*Biostoffverordnung* (BGI. 1pp. 2514 as of July 15, 2014)) belong to risk group 1 or 2.

Genetically manipulated organisms and isolated DNA must be processable in accordance with Class 1 or 2 of Directive 98/81/EC on the contained use of genetically modified microorganisms (OJ No. L330, pp. 13-31 of December 5, 1998) or safety level S1 or S2 of the German Law Regulating Genetic Engineering (BGI. 1, pp. 2066-2083 of December 21, 1993, last changed by Art. 2 abs. 27 and Art. 4 Abs 14 G of August 7, 2013, I 3154).

The biological material indicated above cannot be accepted if it is contaminated by foreign organisms.

Mixtures of microbial cultures of more than two components will not be accepted. Mixtures of two components will only be accepted if these a) cannot be cultivated separately as pure cultures and b) can easily be distinguished macroscopically and/or microscopically.

Plant viruses which cannot be multiplied through mechanical infection of plants cannot be accepted for deposit.

The DSMZ reserves the right to refuse to accept for deposit material which in its view represents an unacceptable hazard or which it is not in a position to process.
In all instances, it must be possible to preserve the deposited material by lyophilization or storage in liquid nitrogen or by some other method of long-term preservation without significant change.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The DSMZ has the following special requirements for the form in which the microorganisms should be submitted for deposit.

- Bacteria, archaea and fungi should, where possible, be deposited in the form of two actively growing cultures. Lyophilized cultures are also accepted.

- Bacteriophages should be deposited in minimum quantities of $2 \times 5$ ml having a minimum titre of $1 \times 10^9$ pfu pro ml.

- Plasmids as isolated DNA preparations should be in a minimum quantity of $2 \times 20$ [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 DSMZ.

- Plant viruses should be deposited in the form of dried or frozen material along with the host’s seeds, unless the host is generally available. 100 [micro] l of serum suitable for immunoelectron microscopy should also be deposited for the purity and identity test.

- Plant material 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. If the cryopreservation procedure should be carried out at the DSMZ (on the depositor’s expenses), actively growing plant material in the form of undifferentiated cell cultures or tissues (five Petri dishes) or suspension cultures (three culture vessels) or actively growing in-vitro plantlets (shoots or shooty structures, at least 10) have to be provided.

- Animal and human cell cultures should be deposited as frozen cultures in 12 ampoules (all prepared at the same time), each containing at least $5 \times 10^6$ cells per ampoule (cells growing in suspension) or $2 \times 10^6$ cells per ampoule (adherent cells).

The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the DSMZ, animal and human cell cultures must be examined to ensure they are free from viruses. Cultures should be sent in appropriate containers.
(ii) **Time Required for Viability Testing**

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

- **Bacteria, archaea, yeasts, bacteriophages and plasmids**: 2 days (or up to 3 weeks)
- **Fungi**: 3 days (or up to 3 weeks)
- **Plant viruses**: 2 weeks
- **Plant cell cultures**: 3 to 4 weeks (or up to 6 months)
- **Human and animal cell cultures (including test for contamination with mycoplasma)**: 2 weeks

(iii) **Depositor Checks and Renewal of Stocks**

The DSMZ prepares its own lyophilized and/or frozen batches of bacteria, archaea, fungi and yeasts at the time of deposit by subculturing material supplied by the depositor (but not from plasmids, bacteriophages, plant cell cultures, plant viruses or animal and human cell cultures). New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the DSMZ.

Despite the methods used for preparing batches of samples for distribution, the DSMZ nevertheless stores a portion of the original material supplied by the depositor, if the culture supplied allows this.

(c) **Administrative Requirements and Procedures**

(i) **General**

**Language.** The official language of the DSMZ is German. Communications are also accepted in English. Correspondence in French is accepted, except in the case of forms.

**Contract.** The DSMZ does not enter into a written contract with the depositor defining the liabilities of either party but, by signing the DSMZ deposit form, the depositor accepts the General Terms and Conditions of the DSMZ and surrenders any right to withdraw his microorganism during the required storage period.
Import and/or Quarantine Regulations. In very few cases import regulations apply to the kinds of microorganisms accepted by the DSMZ. In such cases, the depositor must supply the species name of the microorganism, whereupon the DSMZ will apply to obtain the necessary permit. The kinds of microorganisms accepted by the DSMZ are not subject to quarantine regulations. Further information about import requirements may be obtained from: Bundesminister für Ernährung, Landwirtschaft und Verbraucherschutz, Wilhelmstr. 64, 10117 Berlin, Germany.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete form DSMZ-BP/1 (the equivalent of model form BP/1) which is the deposition form used for Budapest Treaty deposits. The DSMZ uses separate forms for the deposit of bacteria, archaea or fungi, bacteriophages, plasmids, plant viruses, plant cell cultures and animal and human cell cultures. 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 DSMZ 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, both in German and English. 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. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The DSMZ will communicate by e-mail 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. The DSMZ does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the DSMZ will send 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 made for patent purposes. However, in the case of deposits previously made for scientific purposes and which are already generally available from the DSMZ, the depositor is requested to authorize the DSMZ to continue to make them so available and to waive his right to be notified of the release of samples. If the depositor is unwilling to accede to this request, he must make another deposit of the same organism under the Budapest Treaty. These constraints do not apply to deposits previously made for patent purposes or to deposits made confidentially for safekeeping. Any deposit previously made free of charge is subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. With the exceptions noted above, the administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.
(iv) Making a New Deposit

The depositor is requested to complete the equivalent of 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 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

The DSMZ 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 DSMZ 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).

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 DSMZ will withhold samples of potentially hazardous microorganisms until the requesting party has provided evidence that he is allowed to work with such organism. When responding to requests from overseas, the DSMZ will ask the requesting party to provide an import permit if it knows that one is required for that particular country.

All samples of bacteria, archaea and fungi furnished by the DSMZ are from batches of its own preparations of the microorganism.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

In accordance with Rule 9.2 of the Treaty, the DSMZ does not list Budapest Treaty deposits in its published catalogue.
### 3. Schedule of Fees

#### I.1

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage according to Rule 12.1 (a)(i) of the Regulations under the Budapest Treaty (comprising the initial viability check, the preservation and the storage of the biological material)</td>
<td></td>
</tr>
<tr>
<td>- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses</td>
<td>800</td>
</tr>
<tr>
<td>- plant cell cultures, human and animal cell cultures</td>
<td>1,400</td>
</tr>
<tr>
<td>(b) Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty</td>
<td></td>
</tr>
<tr>
<td>- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses</td>
<td>800</td>
</tr>
<tr>
<td>- plant cell cultures, human and animal cell cultures</td>
<td>1,400</td>
</tr>
<tr>
<td>(c) Prolongation of the duration of the storage over the one provided by Rule 9 of the Regulations under the Budapest Treaty, per year</td>
<td></td>
</tr>
<tr>
<td>- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses</td>
<td>30</td>
</tr>
<tr>
<td>- plant cell cultures, human and animal cell cultures</td>
<td>50</td>
</tr>
</tbody>
</table>

#### I.2

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) 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</td>
<td>120</td>
</tr>
<tr>
<td>(b) on the basis of the most recent viability test</td>
<td>50</td>
</tr>
</tbody>
</table>

#### I.3

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furnishing of a sample according to Rule 12.1(a)(iv) of the Regulations under the Budapest Treaty (plus current freight costs)</td>
<td>120</td>
</tr>
</tbody>
</table>

#### I.4

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication of information under Rule 7.6 of the Regulations under the Budapest Treaty</td>
<td>50</td>
</tr>
</tbody>
</table>

#### I.5

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attestation referred to in Rule 8.2 of the Regulations under the Budapest Treaty</td>
<td>50</td>
</tr>
</tbody>
</table>

For the customers within Germany the fees are subject to VAT, currently at the rate of 7 %. Turnover tax, again currently at the rate of 7 %, must be charged on EU orders not quoting a VAT registration number.

A processing fee of 5-30 Euros to cover handling and bank charges is payable on all invoices.

#### 4. Guidance for Depositors

The DSMZ provides specific written notes for the guidance of prospective depositors on its home page (www.dsmz.de). In addition, it is always ready to give advice by telephone or by e-mail.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including *Streptomyces*) except obligate human pathogenic species (e.g., *Corynebacterium diphtheriae*, *Mycobacterium leprae*, *Yersinia pestis*, etc.).

Fungi, including yeasts and molds, except some pathogens (*Blastomyces*, *Coccidioides*, *Histoplasma*, etc.), as well as certain basidiomycetous and plant pathogenic fungi which cannot be preserved reliably.

The following may not, at present, be accepted for deposit:
- viruses, phages, rickettsiae,
- algae, protozoa,
- cell lines, hybridomas.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The NCAIM accepts microorganisms for deposit as either lyophilized preparations or active cultures. The minimum number of replicates that the depositor must supply when making his deposit is 25 for lyophilized preparations or three for active cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of microorganisms accepted by the NCAIM is seven days, but depositors should realize that in some cases viability testing may take as long as 14 days.
(iii) **Depositor Checks and Renewal of Stocks**

Where the microorganism is deposited in active culture, the NCAIM prepares its own batches by subculturing the material supplied by the depositor. The depositor is required to check for authenticity samples of all such batches. The NCAIM does not prepare its own batches of microorganisms that have been supplied as lyophilized preparations by the depositor.

In all cases, the NCAIM renews diminishing stocks of deposited microorganisms by asking the depositor to make a new deposit.

Whichever method is used for preparing batches of samples for distribution, the NCAIM nevertheless stores a portion of the original material supplied by the depositor.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of the NCAIM is Hungarian. Communications are also accepted in English, French, German and Russian.

*Contract.* The NCAIM does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the NCAIM deposit form the depositor surrenders any right to withdraw his deposit during the required storage period.

*Import and/or Quarantine Regulations.* The kinds of microorganisms accepted by the NCAIM are not subject to import or quarantine regulations.

(ii) **Making the Original Deposit**

*Requirements to Be Met by the Depositor.* The depositor is required to complete model form BP/1, which is used by the NCAIM as its accession form for Budapest Treaty deposits. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the NCAIM has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third party is issued on form BP/14. The NCAIM uses its own standard letters for other official notifications.

*Unofficial Notifications to the Depositor.* If requested, the NCAIM will telephone or e-mail the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The NCAIM will similarly communicate the result of the viability test before the viability statement is issued.
Supply of Information to a Patent Agent. The NCAIM does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the NCAIM will send 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. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fee had previously been paid in respect of those deposits.

The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(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. The receipt and viability statement are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The NCAIM 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 NCAIM 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 to receive samples under patent regulations, a requesting party must show, by a business letterhead or requisition form or in some other way, that he is trained in microbiology and has access to a properly equipped laboratory. When responding to requests from overseas, the NCAIM assumes the requesting party has met the import requirements of his own country.

Samples furnished by the NCAIM may be from preparations supplied by the depositor, or from its own preparations, depending on the form in which the microorganism was deposited.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.
(c) Cataloguing of Budapest Treaty Deposits

The NCAIM does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Description</th>
<th>HUF</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage</td>
<td>150,000</td>
</tr>
<tr>
<td>(b) Issuance of an attestation pursuant to Rule 8.2 of the Regulations under</td>
<td>10,000</td>
</tr>
<tr>
<td>the Treaty and communication under Rule 7.6 of the Regulations under the Treaty</td>
<td></td>
</tr>
<tr>
<td>(c) Issuance of a viability statement with the exception provided for in</td>
<td>25,000</td>
</tr>
<tr>
<td>the first sentence of Rule 10.2(e) of the Regulations of the Treaty</td>
<td></td>
</tr>
<tr>
<td>(d) Furnishing of a sample with the exception provided for in the first</td>
<td>30,000</td>
</tr>
<tr>
<td>sentence of Rule 11.4(h) of the Regulations under the Treaty</td>
<td></td>
</tr>
</tbody>
</table>

4. Guidance for Depositors

The NCAIM does not at present produce a standard letter or guidance notes for prospective depositors.
1. Requirements for Deposit

(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) Technical Requirements and Procedures

(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) Time Required for Viability Testing

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:

<table>
<thead>
<tr>
<th>Type</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria, yeast and plasmids</td>
<td>4 days to 3 weeks</td>
</tr>
<tr>
<td>Actinomycetes, fungi</td>
<td>7 days to 4 weeks</td>
</tr>
</tbody>
</table>

(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) General

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.

(IN)
MCC/2013
(ii) Making the Original Deposit

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. Furnishing of Samples

(a) Requests for Samples

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) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

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

Bacteria, fungi, yeast and plasmids

(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.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The MTCC will accept bacteria, fungi, yeasts, bacteriophages, plasmids in a host and/or as isolated DNA preparations belonging to Hazard Groups 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 the S1 or S2 facility or conform to Group 1 or 2 organisms.

The MTCC reserves the right to refuse to accept a deposit if, in its view, the deposit may be an unacceptable hazard or the MTCC may not be in a position to process it. Deposit of bacteria and fungi from other countries pathogenic to plants and animals, which can be processed in the S1 or S2 facility, will be accepted only if cleared by the appropriate authority in India.

(b) Technical Requirements and Procedures

(i) Form and Quantity

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

- **Bacteria and fungi (including yeasts)**: 10 freeze-dried ampoules and 2 active cultures (on slants). If freeze-dried cultures cannot be submitted the MTCC may do the freeze-drying on payment by the depositor.

- **Bacteriophages**: 5 x 2 ml quantity with a minimum titre of $1 \times 10^9$ pfu per ml. Suitable host of the bacteriophage also needs to be deposited in active form (2 slants).

- **Plasmids**: 5 x 20 micrograms of isolated and purified DNA preparations. Suitable host of the plasmid also needs to be deposited in active form (2 slants).
The deposit should be accompanied by appropriate forms duly completed by the depositor. These forms can be obtained from the MTCC. Separate forms need to be used for bacteria, fungi (including yeasts), bacteriophages 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) Time Required for Viability Testing

The MTCC will test viability as quickly as possible. Since microorganisms may grow quite slowly, the time required for viability testing for different microorganisms varies. The average time that will be required for viability testing is indicated below:

<table>
<thead>
<tr>
<th></th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria, yeast, bacteriophages and plasmids</td>
<td>4 days to 3 weeks</td>
</tr>
<tr>
<td>Fungi</td>
<td>7 days to 4 weeks</td>
</tr>
</tbody>
</table>

(iii) Depositor Checks and Renewal of Stocks

The MTCC may prepare, as and when it finds necessary, new batch(es) of lyophilized and frozen (in liquid nitrogen) cultures by subculturing materials supplied by the depositor. The MTCC 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) General

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

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 MTCC regarding such deposits before dispatching cultures.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. A depositor will be required to send a completed BP/1 Form which is the accession form 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 Notification 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 of 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 Notification to the Depositor. If requested, the MTCC 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 requested by the depositor, the MTCC 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 MTCC 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 MTCC catalogue (printed or electronic) and had no restriction for distribution by the MTCC, the depositor will be requested to authorize the MTCC 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. Deposits previously made with the MTCC 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 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. Furnishing of Samples

(a) Request for Samples

The MTCC will follow procedures as provided under the 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 the proper facility 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 MTCC will furnish samples prepared by it from the deposited sample(s).

(b) Notification of the Depositor

A depositor will be notified on BP/14 Form when samples of their deposit have been furnished to third parties.
(c) Cataloguing of Budapest Treaty Deposits

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

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Description</th>
<th>INR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage</td>
<td>15,000</td>
</tr>
<tr>
<td>(b) Conversion of a deposit</td>
<td>15,000</td>
</tr>
<tr>
<td>(c) Extension of duration storage (per year)</td>
<td>2,000</td>
</tr>
<tr>
<td>(d) Issuance of a viability statement on the basis of test</td>
<td>3,000</td>
</tr>
<tr>
<td>(e) Issuance of a viability statement on the basis of last viability test</td>
<td>1,000</td>
</tr>
<tr>
<td>(f) Furnishing of a sample</td>
<td>3,000</td>
</tr>
<tr>
<td>(g) Communication of information</td>
<td>1,000</td>
</tr>
<tr>
<td>(h) Issuance of an attestation</td>
<td>1,000</td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

The MTCC will be happy to provide written notes or advice to prospective depositors.
IN - INDIA

NATIONAL AGRICULTURALLY IMPORTANT MICROBIAL CULTURE COLLECTION (NAIMCC)

ICAR-National Bureau of Agriculturally Important Microorganisms
Kushmaur
Maunath Bhanjan PIN 275 103
Uttar Pradesh
India

Telephone: (91-547) 253 00 80
Facsimile: (91-547) 253 03 81
E-mail: director.nbaim@icar.gov.in
Internet: http://www.nbaim.org.in

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposed


Apart from microorganisms, Microbial Genomic Resources Repository (MGRR) accepts genetic materials like plasmids, vectors, etc. of microbial origin.

The NAIMCC reserves the rights to refuse a deposit of microbial material whose conservation involves hazards or received in bad conditions or too difficult to handle or restricted from import by Indian Law.

(b) Technical Requirements and Procedures

(i) Form and Quantity

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

- Bacteria and fungi including yeasts: 10 freeze-dried ampoules and 2 active cultures (on slants). If freeze-dried cultures cannot be submitted the NAIMCC may do the freeze-drying on payment by the depositor
- Blue green algae (cyanobacteria): 5 slants of active cultures and 5 tubes containing culture in liquid medium
Plasmids, vectors, clones etc. of microbial origin: 5 x 20 micrograms of isolated and purified DNA preparations. Suitable host of the plasmid also needs to be deposited in active form (5 slants).

(ii) Time Required for Viability Testing

The NAIMCC will generally take one to eight weeks for viability test depending upon the type of cultures and growth pattern.

- Bacteria: 2-4 weeks
- Fungi: 4-6 weeks
- Cyanobacteria: 4-8 weeks

(iii) Depositor Checks and Renewal of Stocks

The NAIMCC will prepare, as and when it finds necessary, new batch(es) of lyophilized cultures by subculturing materials supplied by the depositor. The NAIMCC 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) General

Language. The official languages are English, Hindi or Bilingual.

Contract. The NAIMCC does not enter into any written contract with the depositor defining the liabilities of either party, but by signing the NAIMCC 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 depositors from abroad should communicate with NAIMCC/ICAR-NBAIM regarding such deposits before dispatch of cultures.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor: A depositor will be required to send a completed BP/1 Form which is the accession form 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 of 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: Upon written request, the NAIMCC 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. Upon written request by the depositor, the NAIMCC 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 NAIMCC 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 NAIMCC catalogue (printed or electronic) and had no restriction for distribution by the NAIMCC, the depositor will be requested to authorize the NAIMCC 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. Deposits previously made with the NAIMCC 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 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. Furnishing of Samples

(a) Requests for Samples

NAIMCC will furnish the samples under the conditions as per procedure provided in Rule 11 of the Regulations under the Budapest Treaty. 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 the proper facility 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 NAIMCC will furnish samples prepared by it from the deposited sample(s).

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

Materials deposited under the Budapest Treaty will not be published in the NAIMCC catalogue (printed or electronic) or displayed on the Internet.
3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Microbial and genetic materials</th>
<th>Indian Rupees</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage under Rule 12.1(a)(i)</td>
<td>20,000</td>
</tr>
<tr>
<td>(b) Conversion of a deposit from non-Budapest Treaty to a deposit in Budapest Treaty</td>
<td>20,000</td>
</tr>
<tr>
<td>(c) Prolongation of the duration of the storage over the one provided by Rule 9 of the Regulations under Budapest Treaty, per year</td>
<td>2,000</td>
</tr>
<tr>
<td>(d) Issue of viability statement on the basis of test</td>
<td>3,000</td>
</tr>
<tr>
<td>(e) Issue of viability statement on the basis of last viability test</td>
<td>1,000</td>
</tr>
<tr>
<td>(f) Furnishing of samples</td>
<td>3,000</td>
</tr>
<tr>
<td>(g) Communication of information under Rule 7.6</td>
<td>1,000</td>
</tr>
<tr>
<td>(h) Attestation referred to in Rule 8.2</td>
<td>1,000</td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

The NAIMCC will be happy to provide written notes or advice to prospective depositors.
1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

Human and animal cell lines and hybridomas, provided that they can be stored in liquid nitrogen vapors, without any significant loss of viability. The genetically modified cell lines are also accepted if they belong to category 1 of genetically modified microorganisms, and if they have been registered by the depositor. No deposits are accepted of cell lines and hybridomas beyond category of containment 2.

The ICLC reserves the right to refuse any material whose manipulation represents an unacceptable risk or technical difficulty. The ICLC requests that a form on the cell line/hybridoma characteristics be filled in on deposit.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cell lines and hybridomas. At least 12 frozen ampoules must be provided for each cell line deposited, containing not less than 2 x 10^6 cells per ampoule. The ampoules must be sent with a quantity of dry ice sufficient to remain frozen during the transport. If the package is found inadequate, the culture will not be accepted.

(ii) Time Required for Viability Testing

The average delay needed for the control of viability of the cell lines and hybridomas is of 10-14 days (the depositors should be aware that in some cases the control may take longer).
(iii) **Depositor Checks and Renewal of Stocks**

In general, the Ospedale Policlinico San Martino IRCCS does not prepare its stocks of cell lines/hybridomas, and when the stocks are exhausted because of the delivery of samples, it requests the depositor to make a new deposit. In some special cases, by an agreement with the depositor, the Ospedale Policlinico San Martino IRCCS can prepare its stocks of the material, asking the depositor to verify the authenticity and quality of the material.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of the Ospedale Policlinico San Martino IRCCS is Italian. Deposits are also accepted in English and French.

*Contract.* The depositor must fill in a form in which he declares his agreement on the following:

- to deposit the material only in the required form and quantity;

- to indicate the characteristics of the cell line/hybridoma relating to danger and pathogenicity;

- to pay all required fees, including the postal expenses for the shipment(s) of the cell line/hybridoma to the Ospedale Policlinico San Martino IRCCS;

- to comply with the requirements of the Budapest Treaty;

- to comply with the requirements of the Ospedale Policlinico San Martino IRCCS concerning the deposit of microorganisms.

*Import and/or Quarantine Regulations.* The kind of material accepted for deposit by Ospedale Policlinico San Martino IRCCS is not required to follow any particular rule.

(ii) **Making the Original Deposit**

*Requirements to be Met by the Depositor.* The depositor is required to fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma.

Forty eight hours before shipping the material, the depositor must inform the Ospedale Policlinico San Martino IRCCS about the number of samples sent for deposit, the means of transport chosen and the expected time of arrival. If the material is sent by air, the Ospedale Policlinico San Martino IRCCS must be informed of the flight number, destination, number of bill and carrier.

*Official Notifications to the Depositor.* The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9.
Unofficial Notifications to the Depositor. If requested, the Ospedale Policlinico San Martino IRCCS will communicate by telephone the date of deposit and the accession number of the cell line/hybridoma, before the official receipt is issued.

Supply of Information to a Patent Agent. If requested, the Ospedale Policlinico San Martino IRCCS will send a copy of the viability statement to the patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the Budapest Treaty can be converted by the original depositor to deposits under the Budapest Treaty. In this case, the fees normally payable under the Budapest Treaty are due. The other requirements are the same as for an original deposit.

(iv) Making a New Deposit

When making a new deposit, the depositor must fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma, and the depositor must send a copy of the documents and of the declaration indicated in Rule 6.2. As to the shipment, the depositor must follow the technical requirements and procedures described in point 1(b) above.

2. Furnishing of Samples

(a) Requests for Samples

The Ospedale Policlinico San Martino IRCCS does not inform the requesting parties about the procedure to be followed for the request, and does not provide the forms of request which can be obtained from the relevant Patent Offices.

The Ospedale Policlinico San Martino IRCCS assumes that the requesting parties have satisfied all the national requirements concerning importation.

(b) Notification to the Depositor

When Ospedale Policlinico San Martino IRCCS delivers samples of the deposited microorganisms to third parties, it notifies the depositor by letter.

(c) Cataloguing of Budapest Treaty Deposits

The Ospedale Policlinico San Martino IRCCS does not include the deposits made under the Budapest Treaty in its catalogs.
3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Service</th>
<th>EUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell lines and hybridomas</td>
<td></td>
</tr>
<tr>
<td>(a) Storage</td>
<td>1,350</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>100</td>
</tr>
<tr>
<td>(c) Furnishing of a sample</td>
<td>150</td>
</tr>
<tr>
<td>(d) Communication and request of authorizations to the competent</td>
<td>130</td>
</tr>
<tr>
<td>authorities</td>
<td></td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

The forms of the Ospedale Policlinico San Martino IRCCS for the deposit contain the recommendations for the depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that may be Deposited

Yeast and yeast-like fungi, with the exception of those having properties that may be dangerous to human health.

(b) Technical Requirements and Procedures

(i) Form and quantity

Samples must be sent in test tubes in liquid or gel form or in freeze-dried ampoules in rigid-sided containers. Frozen or deep frozen cultures must be shipped in containers of expanded polystyrene containing a quantity of dry ice sufficient to guarantee 48 hours autonomy at room temperature. The cells of the strain dispatched must be in pure culture and provide a high level of viability. In the presence of contamination by bacteria, molds, other yeasts and acarina, the dispatched culture is immediately sterilized.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of deposited cultures is 20 days.

(iii) Deppositor Checks and Renewal of Stocks

The DBVPG prepares its own batches of the microorganism at the time of deposit by subculturing the material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The DBVPG always stores a portion of the original material supplied by the depositor.
(c) Administrative Requirement and Procedures

(i) General

Language. The official language of the DBVPG is Italian. Deposits are also accepted in English and French.

Contract. The depositor must fill in a form in which he/she declares his agreement on the following:

- to deposit the material only in the required form and quantity;
- to indicate the characteristics of the yeast culture related to danger or pathogenicity;
- to pay all the required fees;
- to comply with the requirements of the Budapest Treaty;
- to comply with the requirements of the DBVPG concerning the deposit of yeasts.

Import and/or Quarantine Regulations. The material accepted for deposit by DBVPG is not required to follow any particular rule.

(ii) Making the Original Deposit

Requirements to be Met by the Deppositor. The depositor is required to fill in a deposit form which includes a declaration on the pathogenicity of the yeast culture. Forty-eight hours before shipping the material, the depositor must inform the DBVPG about the number of samples sent for deposit, the means of transportation and the expected time of arrival; in case of air shipment, the DBVPG must be informed of the flight number, destination, number of bill and carrier.

Official Notification to the Deppositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9.

Unofficial Notification to the Deppositor. If requested, the DBVPG will communicate by telephone the date of deposit and the accession number of the yeast culture, before the official receipt is issued.

Supply of Information to a Patent Agent. If requested, the DBVPG will send a copy of the viability statement to the patent agent.
(iii) Converting a Previous Deposit

Deposits made outside the Budapest Treaty can be converted by the original depositor to deposits under the Budapest Treaty. In this case, the fees normally payable under the Budapest Treaty are due. The requirements are the same as for an original deposit.

(iv) Making a New Deposit

When making a new deposit, the depositor must fill in a deposit form which includes a declaration on the pathogenicity of the yeast culture, and the depositor must send a copy of the documents of the declaration indicated in Rule 6.2. As to the shipment, the depositor must follow the technical requirements and procedures described in point 1(b).

2. Furnishing of Samples

(a) Requests for Samples

The DBVPG does not inform the requesting parties about the procedure to be followed for the request, and does not provide the forms of request which can be obtained from the relevant Patent Office.

The DBVPG assumes that the requesting parties have satisfied all the national requirements concerning importation.

(b) Notification to the Depositor

When the DBVPG delivers samples of the deposited microorganism to third parties, it notifies the depositor by letter.

(c) Cataloguing of Budapest Treaty Deposits

The DBVPG does not include the deposits made under the Budapest Treaty in its catalogs.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>(a) Storage for 30 years</th>
<th>EUR 650</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>EUR 50</td>
</tr>
<tr>
<td>(c) Furnishing of a sample:</td>
<td></td>
</tr>
<tr>
<td>- agar slants</td>
<td>EUR 40</td>
</tr>
<tr>
<td>- freeze-dried samples</td>
<td>EUR 15</td>
</tr>
<tr>
<td>(d) Communication of information</td>
<td>EUR 25</td>
</tr>
</tbody>
</table>
4. **Guidance for the Depositors**

The forms of the DBVPG for the deposit contain the recommendations for the depositor.
1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

- Animal bacteria isolated from tissues and organs and from food;
- Human and Animal viruses;
- Bacteriophages and plasmids.

Except: microorganisms and plasmids having properties which are or may be dangerous to human/animal health or to the environment.

IZSLER accepts for deposit microorganisms according to Directive 2000/54/EC, on the Protection of Workers from Risks related to Exposure to Biological Agents at work of 18 September 2000 (OJ L262 page 21-45). At IZSLER, animal pathogens of level risk 1 and 2 will be accepted. Those listed in article 265 and 265 bis of “Testo Unico delle Leggi Sanitarie”, respectively will not be accepted for deposit.

Viruses of humans of level risk 1 and 2 will be accepted at IZSLER.

No mixed microbiological cultures will be accepted. They will be accepted if sent separately. Microorganisms and plasmids having properties which are or may be dangerous to human/animal health or to the environment will not be accepted.
IZSLER reserves the right to refuse any biological resources that represent a high hazard or that, for technical reasons, cannot be processed.

Biological resources can be sent frozen or freeze-dried and their storage will be made at -20°C, and -80°C according to the method that allows a long-term preservation of vitality and maintenance of the characteristic of the material.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IZSLER BVR has the following requirements for the form of the microorganisms and plasmids that are submitted for deposit:

- Bacteria and viruses should be sent frozen or freeze-dried cultures. Twelve vials must be provided from a single preparation and at a concentration of no less than $10^5$ viable units /vial.

- The material for deposit must be tested and free from contamination by foreign microorganisms by the Depositor

- Bacteriophages 12 frozen vials (1 ml each with a titre of at least $10^8$ pfu/ml)

- Plasmids (in hosts) 12 lyophilized vials plus 3 agar cultures

- Plasmids (purified DNA) 12 frozen vials (25 micrograms each of isolated and purified DNA preparations).

Suitable host of the plasmid also need to be deposited in an active form (2 slants).

(ii) Time Required for Viability Testing

The time requested for testing the viability of the different kinds of microorganisms is below indicated. It must outlined that for slow growing microorganisms, tests for viability must be longer and they are indicated in the bracket

- Bacteria average time 14 days (up to 3 weeks)
- Human and Animal Viruses average time 20 days
- Bacteriophages average time 14 days
- Plasmids in hosts or purified DNA* average time 8 or up to 10 days (longer in slow growing hosts)

* A “viability test” for plasmids consists of transforming a suitable host with the plasmid. If the host is transformed, the "viability test" is regarded as positive.
(iii) **Depositor Checks and Renewal of Stocks**

In general, IZSLER does not prepare batches of bacteria and viruses and when the batches are exhausted it requests the depositor to make a new deposit. Only in particular case and following previous written consent of the depositor, IZSLER can prepare a new batch of the material. However, the depositor has to control the quality characteristics of the material.

A portion of each original material supplied by the depositor is stored as *master* deposit.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of IZSLER is Italian. Communications and correspondence are accepted in Italian and in English.

*Contract.* A contract between IZSLER and the depositor must be prepared. It has to be signed by both parties and the depositor acknowledges the conditions of the deposit under the Budapest Treaty, the rules and requirements to be observed and the relative liability in the event of an incident.

In particular, the depositor has to declare the following:

- quantity and form of the material to be deposited;
- characteristics and biological risk of the material;
- payment of the fees charged;
- to comply with the requirements of the Budapest Treaty and with those of IZSLER notified to WIPO.

*Import and/or Quarantine Regulations.* IZSLER requests an import authorization from Italian Ministry of Health.

No quarantine regulation must be followed for microorganisms that are accepted by IZSLER.

Transport of infectious material in Italy is subjected to the package conforming to international regulations of the transport of hazardous materials.

(ii) **Making the Original Deposit**

*Requirements to be Met by the Depositor.* Depositors have to complete and sign the contract and deposit forms for the Budapest Treaty deposits. Each form is specific for each type of Biological Resource.

In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor is required to complete a BP/7 form which may be requested from IZSLER by e-mail.
Sending of Biological Resource to be deposited must be previously agreed between two parties.

Original deposit documents have to be sent together with the biological resource; however, it is advised to send them before sending by e-mail.

**Official Notifications to the Depositor.** The receipt and the viability statement are communicated by transmission of “international forms” BP/4 and BP9, respectively. Other notifications are sent by individual letters.

Any attestation concerning a change of the technical description and/or the proposed taxonomic designation will be delivered on form BP/8.

Furthermore, any notification on the furnishing of samples to third parties will be sent to the Depositor on form BP/14.

Official forms will be sent to the depositor only after the results of viability testing and when deposit is accepted. Accession number will be the same of the registration number.

**Unofficial Notifications to the Depositor.** IZSLER will communicate by e-mail the date of deposit and number of deposit before the official statement of receipt and viability testing are made.

**Supply of Information to a Patent Agent.** IZSLER will provide, if requested, information to the patent agent.

(iii) **Converting a Previous Deposit**

Deposit of other types (open deposit, safe deposit) can be converted by the depositor into deposit under the Budapest Treaty. In this event the depositor has to indicate the date on which the original deposit was received, the accession number of the biological resource, the name and address of the depositor and the request of conversion of the deposit and to maintain deposit and distribution of the microorganism for research purposes during the period specified in rule 9.1. In this event the batch has to be moved from the previous to the new deposit. In alternative, the depositor prepares a new batch to be deposited under the Budapest Treaty. The new deposit is subjected to the rules and administrative requirements of the Budapest Treaty.

(iv) **Making a New Deposit**

The depositor has to complete the BP/2 model form in order to make a new deposit and to send copies of the documents mentioned in Rule 6.2. Statements of the receipt and viability testing are sent on mandatory international forms BP/5 and BP/9.
2. Furnishing of Samples

(a) Requests for Samples

IZSLER notifies third parties of the correct procedures to order patent microorganisms. In the case of requests of proof of entitlement, IZSLER will send to requesting party copies of the model request form BP/12.

Third parties will receive a microorganism under patent regulations following providing evidence that they are allowed to work with such a microorganism.

Moreover, all documents, including permit importations, are requested by IZSLER to respond to requests from overseas, or a declaration stating that no authorization is necessary for the proper shipping of the microorganism.

(b) Notification to the Depositor

Depositors are informed by form BP/14 on the distribution of a patent microorganism to third parties.

(c) Cataloguing of Budapest Treaty Deposits

IZSLER does not publish list of deposits under the Budapest Treaty in any published catalogue.

3. Schedule of Fees

Human and animal bacteria
- Freeze dried € 608.80
- Frozen at -80°C € 701.27
- Frozen liquid nitrogen € 1448.27

Human and animal viruses
- From embryonated chicken embryos € 788.92
- From cell cultures € 1086.96

Bacteriophages
- Frozen at -80°C € 701.27
- Frozen liquid nitrogen € 1448.27

Plasmids (in hosts or as an isolated DNA)
- Freeze dried € 608.80
- Frozen at -80°C € 701.27

Viability
- Issuance of viability statement based on last test € 60.00
- Viability test (bacteria) € 100.00
- Viability test (virus) € 150.00
- Viability test (bacteriophage) € 100.00
- Viability test (plasmid in hosts or as an isolated DNA) € 110.00

Distribution
- Furnishing of a sample (bacteriophage) (plus shipping costs) € 400.00
Furnishing of a sample (virus) (plus shipping costs) € 400.00  
Furnishing of a sample (bacteriophage) (plus shipping costs) € 400.00  
Furnishing of a sample (plasmid) (plus shipping costs) € 105.00  
Communication of information or issuance of an attestation € 50.00

Value Added TAX (VAT) is added according to Italian regulations

4. Guidance for Depositors

IZSLER provides a written note for the request of deposit under the Budapest Treaty. It is at the home page of IZSLER (www.ibvr.org). Further information can be requested by e-mail.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Protozoa, plant cell cultures, seeds and algae, EXCEPT:

- microorganisms classified as biological safety level (BSL) 3 or 4 according to the Guidelines for the Handling of the Experiment of Microorganisms in NITE;
- microorganisms that require the containment measure levels P3 or P3P for experiments, as described in the Ministerial Ordinance stipulating Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (2004), which is based on the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (2003);
- mixtures of undefined and/or unidentifiable microorganisms.

IPOD reserves the right to refuse to accept deposit that is technically or legally too difficult to manage.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms should be submitted for deposit as frozen samples or as agar stab or slant cultures. The minimum number of replicates that must be supplied by the depositor when making his deposit, and the form in which they must be submitted, are as follows:

- Plant cell cultures: 5 slant cultures
- Protozoa and algae: 10 tubes or 5 agar stabs or 5 slant cultures
- Seed: 100 packs / 25 seeds per 1 pack

(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 IPOD is 20 days, but depositors should realize that in some cases viability testing may take as long as 60 days.
(iii) Depositor Checks and Renewal of Stocks

The IPOD prepares its own batches of the microorganism at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. For seeds and samples supplied by depositor as frozen samples, the IPOD stores samples originally supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the IPOD is Japanese. However, the power of attorney and other attached documents can be in another language, but must be accompanied by a Japanese translation. Requests for samples may be in Japanese or English.

Contract. The IPOD does not enter into a written contract with the depositor defining the liabilities of either party but, by signing the IPOD deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. Certain plant and animal pathogens are subject to import and/or quarantine regulations. The IPOD advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits. On average, obtaining a permit takes about three weeks. Further information can be obtained from the Yokohama Plant Protection Station, Ministry of Agriculture, Forestry and Fisheries, 5-57 Kitanankadori, Naka-ku, Yokohama, Japan, and from the Animal Quarantine Service, Ministry of Agriculture, Forestry and Fisheries, 11-1 Hara-machi, Isogo-ku, Yokohama, Japan.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the IPOD as its accession form for Budapest Treaty deposits. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the IPOD 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. 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 release of a sample to a third party is issued on form BP/14. The IPOD has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. The IPOD will inform the date of deposit and “provisional” accession number before the official receipt is issued, but the depositor must recognize that this information becomes official only on completion of the viability test and the payment.
Supply of Information to a Patent Agent. The IPOD does not routinely ask the depositor for the name and address of his patent agent. The IPOD will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt of the previous deposit. Conversions are subject to the normal storage fee levied for Budapest Treaty deposits in cases where any fee was previously charged in respect of their deposit for patent purposes outside the provisions of the Treaty.

(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. The receipt and viability statement are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The IPOD 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 IPOD 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).

Requesting parties are required to complete the IPOD form BP/14 (Acknowledgement and Agreement for Furnishing and Use of Samples) to comply with health and safety requirements. When responding to requests from overseas, the IPOD assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the IPOD are from batches of its own preparations of the microorganism, with the exception of seeds and samples supplied by depositor as lyophilized or frozen samples.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

The IPOD does not list Budapest Treaty deposits in its published catalog.
3. **Schedule of Fees**

(a) **Storage**

(i) Refrigerated or frozen
   - Original deposit (for 30 years) 98,000
   - New deposit 38,600
   - Extension of storage duration (per year) 8,000

(ii) Subculturing of active culture
   - Original deposit (for 30 years) 1,232,000
   - New deposit 38,600
   - Extension of storage duration (per year) 45,800

(b) Issuance of an attestation under Rule 8.2 2,800

(c) Issuance of a viability statement

   (i) When a viability test is carried out 32,100

   (ii) Based on the last viability test 2,800

(d) Furnishing of a sample (shipping fee excluded) 39,100

(e) Issuance of a communication under Rule 7.6 2,800

Fees do not include tax.

For each of the above items, a transaction fee of 2,500 JPY will be applied to all orders placed outside Japan.

In case more than two invoices should be issued in a single case, a handling fee of 2,600 JPY will be charged per each additional invoice.

4. **Guidance for Depositors**

The IPOD produces notes for the guidance of prospective depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May be Deposited

Actinomycetes, animal cell cultures (including hybridomas and human cell cultures), archa, bacteria, bacteriophages, embryos, fungi, plasmids (in hosts or not in hosts) and yeasts, EXCEPT:

- microorganisms which belong to biosafety level 3 or level 4 according to the NITE (National Institute of Technology and Evaluation) Classification.

- microorganisms which call for containment measures level P3, P3A or P3P as described in the Ministerial Ordinance stipulating Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (2004), which is based on the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (2003).

- Mixtures of undefined and/or unidentifiable microorganisms.

NPMD reserves the right to refuse to accept deposit that is technically or legally too difficult to manage.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The NPMD accepts microorganisms for deposit any lyophilized or frozen samples. In case the microorganisms are difficult to be stored as lyophilized or frozen samples, agar stabs or slant cultures are also acceptable. The depositor should send the following to NPMD:

Actinomycetes, archea, bacteria, bacteriophages, fungi, plasmids (in hosts or not in hosts) and yeasts 10 ampoules, 10 tubes, 5 agar stabs or 5 slant cultures
Animal cell cultures (including hybridomas and human cell cultures) and embryos

(ii) **Time Required for Viability Testing**

The average length of time required for testing the viability of the microorganisms is as follows, but in some cases viability testing may take longer than the figures indicated below.

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasmids</td>
<td>1 day</td>
</tr>
<tr>
<td>Bacteria</td>
<td>3 days</td>
</tr>
<tr>
<td>Yeasts</td>
<td>5 days</td>
</tr>
<tr>
<td>Actinomycetes, fungi and bacteriophages</td>
<td>7 days</td>
</tr>
<tr>
<td>Embryos</td>
<td>7 days</td>
</tr>
<tr>
<td>Animal cell cultures (including hybridomas and human cell cultures)</td>
<td>3 to 4 weeks</td>
</tr>
</tbody>
</table>

(iii) **Depositor Checks and Renewal of Stocks**

The NPMD stores samples originally supplied by the depositor, and does not subculture material supplied by the depositor. The NPMD requires the depositor to supply the samples to replenish diminishing stocks. If requested, the NPMD makes its own preparations by subculture from material supplied by the depositor at an additional fee. In this case, the NPMD requires the depositor to test for authenticity of samples prepared by the NPMD and to inform the NPMD of the result.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of the NPMD is Japanese. Requests for the furnishing of samples may be in Japanese or English.

*Contract.* The NPMD enters into a written contact with the depositor by which the latter is bound.

- to provide the necessary information requested by the NPMD;
- to replenish the microorganism at his own expense if the NPMD is no longer able to furnish samples of it;
- not to withdraw the deposit during the required storage period.
Import and/or Quarantine Regulations. Certain plant and animal pathogens are subject to import and/or quarantine regulations. Further information can be obtained from Yokohama Plant Protection Station or Animal Quarantine Station administrated by the Ministry of Agriculture, Forestry and Fisheries of Japan. http://www.maff.go.jp/eindex

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, in addition to the NPMD form 2 (Acknowledgement and Agreement for Original Deposit under the Budapest Treaty). In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the NPMD has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8.

Unofficial Notifications to the Depositor. The NPMD will inform the date of deposit and “provisional” accession number before the official receipt is issued, but the depositor must recognize that this information becomes official only on completion of the viability test and the payment.

Supply of Information to a Patent Agent. The NPMD does not ask the depositor for the name and address of his patent agent, if requested, the NPMD will supply the receipt and the viability statement through 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 provided they were originally made for patent purposes. 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 the depositor is also required to supply a copy of the receipt of the previous deposit. The storage fee will be charged to the original depositor for conversion.

(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 specified in Rule 6.2. The receipt and the viability statement 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 NPMD advises third parties of the correct procedures to follow in order to make a valid request and supplies the request forms used by Japan Patent Office. Request forms used by other individual industrial properties office must be obtained from the appropriate industrial property offices. Requesting parties are required to complete the NPMD form 14 (Acknowledgement and Agreement for Furnishing and Use of Samples) to comply with health and safety requirements. When responding to requests from overseas, the NPMD assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the NPMD may be from preparations supplied by the depositor, with the exception of those not supplied by the depositor as lyophilized or frozen samples.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

The NPMD does not publish any catalogue.

3. Schedule of Fees

(a) Storage

(i) Refrigerated or frozen
   – Original deposit (for 30 years) 98,000
   – New deposit 38,600
   – Extension of storage duration (per year) 8,000

(ii) Subculturing of active culture
   – Original deposit (for 30 years) 1,232,000
   – New deposit 38,600
   – Extension of storage duration (per year) 45,800

(b) Issuance of an attestation under Rule 8.2 2,800

(c) Issuance of a viability statement

(i) When a viability test is carried out 32,100
(ii) Based on the last viability test 2,800

(d) Furnishing of a sample (shipping fee excluded) 39,100

(e) Issuance of a communication under Rule 7.6 2,800

Fees do not include tax.

For each of the above items, a transaction fee of 2,500 JPY will be applied to all orders placed outside Japan.

In case more than two invoices should be issued in a single case, a handling fee of
2,600 JPY will be charged per each additional invoice.

4. Guidance for Depositors

The NPMD provides pamphlets for the guidance of prospective depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, fungi (including yeasts), plasmids in a host with the exception of pathogenic microorganisms of hazard group 3 or 4. Microorganisms having special requirements for cultivation, which the MSCL is not technically capable of carrying out, shall not be accepted.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to MSCL for deposit must be in the form of agar stabs (slants) or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs (slants) or 25 lyophilized ampoules.

(ii) Time Required for Viability Testing

The average time required for testing the viability of various microorganisms accepted by MSCL is 7 days, but in some cases viability testing may take 20 days.

(iii) Depositor Checks and Renewal of Stocks

The MSCL prepares its own batches by subculturing material originally supplied by the depositor. New batches are prepared for renewal of diminishing stocks. MSCL routinely asks the depositor to check the authenticity of the preparations made by the MSCL at the time of deposit from material supplied by the depositor. The MSCL routinely checks newly received deposits for contamination and, if they are found contaminated, returns them to the depositor. The MSCL stores original material supplied by the depositor.
1. Requirements for Deposit

(a) **Kinds of Microorganisms that May be Deposited**

Actinomycetes, animal cell cultures (including hybridomas and human cell cultures), archea, bacteria, bacteriophages, embryos, fungi, plasmids (in hosts or not in hosts) and yeasts, EXCEPT:

- microorganisms which belong to biosafety level 3 or level 4 according to the NITE (National Institute of Technology and Evaluation) Classification.

- microorganisms which call for containment measures level P3, P3A or P3P as described in the Ministerial Ordinance stipulating Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (2004), which is based on the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (2003).

- Mixtures of undefined and/or unidentifiable microorganisms.

NPMD reserves the right to refuse to accept deposit that is technically or legally too difficult to manage.

(b) **Technical Requirements and Procedures**

(i) **Form and Quantity**

The NPMD accepts microorganisms for deposit any lyophilized or frozen samples. In case the microorganisms are difficult to be stored as lyophilized or frozen samples, agar stabs or slant cultures are also acceptable. The depositor should send the following to NPMD:

| Actinomycetes, archea, bacteria, bacteriophages, fungi, plasmids (in hosts or not in hosts) and yeasts | 10 ampoules, 10 tubes, 5 agar stabs or 5 slant cultures |
Animal cell cultures (including hybridomas and human cell cultures) and embryos

(ii)  **Time Required for Viability Testing**

The average length of time required for testing the viability of the microorganisms is as follows, but in some cases viability testing may take longer than the figures indicated below.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasmids</td>
<td>1 day</td>
</tr>
<tr>
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(iii) **Depositor Checks and Renewal of Stocks**

The NPMD stores samples originally supplied by the depositor, and does not subculture material supplied by the depositor. The NPMD requires the depositor to supply the samples to replenish diminishing stocks. If requested, the NPMD makes its own preparations by subculture from material supplied by the depositor at an additional fee. In this case, the NPMD requires the depositor to test for authenticity of samples prepared by the NPMD and to inform the NPMD of the result.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of the NPMD is Japanese. Requests for the furnishing of samples may be in Japanese or English.

*Contract.* The NPMD enters into a written contact with the depositor by which the latter is bound.

- to provide the necessary information requested by the NPMD;
- to replenish the microorganism at his own expense if the NPMD is no longer able to furnish samples of it;
- not to withdraw the deposit during the required storage period.
Import and/or Quarantine Regulations. Certain plant and animal pathogens are subject to import and/or quarantine regulations. Further information can be obtained from Yokohama Plant Protection Station or Animal Quarantine Station administrated by the Ministry of Agriculture, Forestry and Fisheries of Japan. http://www.maff.go.jp/e/index

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, in addition to the NPMD form 2 (Acknowledgement and Agreement for Original Deposit under the Budapest Treaty). In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the NPMD has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8.

Unofficial Notifications to the Depositor. The NPMD will inform the date of deposit and “provisional” accession number before the official receipt is issued, but the depositor must recognize that this information becomes official only on completion of the viability test and the payment.

Supply of Information to a Patent Agent. The NPMD does not ask the depositor for the name and address of his patent agent, if requested, the NPMD will supply the receipt and the viability statement through 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 provided they were originally made for patent purposes. 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 the depositor is also required to supply a copy of the receipt of the previous deposit. The storage fee will be charged to the original depositor for conversion.

(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 specified in Rule 6.2. The receipt and the viability statement 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 NPMD advises third parties of the correct procedures to follow in order to make a valid request and supplies the request forms used by Japan Patent Office. Request forms used by other individual industrial properties office must be obtained from the appropriate industrial property offices. Requesting parties are required to complete the NPMD form 14 (Acknowledgement and Agreement for Furnishing and Use of Samples) to comply with health and safety requirements. When responding to requests from overseas, the NPMD assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the NPMD may be from preparations supplied by the depositor, with the exception of those not supplied by the depositor as lyophilized or frozen samples.

(b) Notification of the Deposter

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

(c) Cataloguing of Budapest Treaty Deposits

The NPMD does not publish any catalogue.

3. Schedule of Fees

(a) Storage

(i) Refrigerated or frozen

– Original deposit (for 30 years) 98,000
– New deposit 38,600
– Extension of storage duration (per year) 8,000

(ii) Subculturing of active culture

– Original deposit (for 30 years) 1,232,000
– New deposit 38,600
– Extension of storage duration (per year) 45,800

(b) Issuance of an attestation under Rule 8.2 2,800

(c) Issuance of a viability statement

(i) When a viability test is carried out 32,100
(ii) Based on the last viability test 2,800

(d) Furnishing of a sample (shipping fee excluded) 39,100

(e) Issuance of a communication under Rule 7.6 2,800

Fees do not include tax.

For each of the above items, a transaction fee of 2,500 JPY will be applied to all orders placed outside Japan.

In case more than two invoices should be issued in a single case, a handling fee of
2,600 JPY will be charged per each additional invoice.

4. **Guidance for Depositors**

The NPMD provides pamphlets for the guidance of prospective depositors.
(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the MSCL is Latvian. Communications are accepted in English, German and Russian.

Contract. The MSCL does not enter into any written contract with the depositor defining the liabilities of either party but, by signing the MSCL deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganisms will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by the MSCL are not subject to import or quarantine regulations. The MSCL does not advise the depositor of the procedures he must follow to obtain an import permit.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. Depositors are required to complete form MSCL–BP/1 (the equivalent of model form BP/1) which is the accession form used for Budapest Treaty deposits. They must complete the equivalent of model form BP/2 when making a new deposit and the equivalent of model form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Except the mandatory “international forms,” official notifications are not issued on standard forms.

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

Supply of Information to a Patent Agent. The MSCL does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the MSCL will send 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 deposits under the Budapest Treaty only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty.

All conversions are subject to the storage fee normally levied for Budapest Treaty deposits.
(iv) Making a New Deposit

The depositor is required to complete the equivalent of 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 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

The MSCL 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 MSCL 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). All samples furnished by the MSCL are from batches of its own preparations.

(b) Notification of Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

The MSCL does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Description</th>
<th>Euros</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage</td>
<td>426.86</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>42.69</td>
</tr>
<tr>
<td>(c) Furnishing of a sample (plus expedition cost)</td>
<td>42.69</td>
</tr>
</tbody>
</table>

The fees are subject to the Value Added Tax (VAT) at the rate of 21 %.

4. Guidance for Depositors

At present, the MSCL does not have specific written notes for the guidance of depositors, but is always ready to offer advice by telephone, telefax or e-mail.
COLECCIÓN DE MICROORGANISMOS DEL CNRG (CM-CNRG)

Boulevard de la Biodiversidad No. 400
Col. Rancho las Cruces,
Tepatitlán de Morelos, Jalisco, C.P. 47600
Mexico

Telephone: +52378-1065020 ext. 5107 5207, 5202.
Email: cm-cnrg@inifap.gob.mx;
delatorre.fernando@inifap.gob.mx - José Fernando de la Torre Sanchez, Principal Manager – CNRG-INIFAP
arteaga.ramon@inifap.gob.mx - Ramón Ignacio Arteaga Garibay, Manager – CM-CNRG
Internet: under construction, to be hosted on the webpage of CIRPAC-INIFAP:
www.inifapcirpac.gob.mx

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The CM-CNRG accepts the following deposits of microorganisms and materials: microalgae, animal viruses, plant viruses, bacteria (non-pathogenic), bacteria (pathogenic), bacteriophages, mammalian embryos and gametes, eukaryotic DNA, hybridomas, fungi (pathogenic), fungi (non-pathogenic), human cell cultures, yeasts (non-pathogenic), nematodes, viroids, animal cell cultures, plant cell cultures, mycoplasmas, plasmids (in host), plasmids (without host), protozoa (non-parasitic), DNA of microorganisms, RNA of microorganisms, genomic libraries, microbial consortia.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The CM-CNRG will accept deposits which can be preserved by freezing, cryogenic preservation in liquid nitrogen or freeze-drying without significant change to their properties. Deposits which cannot be preserved in this manner or can only be maintained in active culture may be accepted on an individual basis, with prior negotiation and determination of associated fees.

Depositors are encouraged to supply frozen or freeze-dried material. Nevertheless, the CM-CNRG will accept actively growing material, and preserve it by freezing or freeze-drying upon request for an additional charge. In these cases, a sample of the preserved material will be returned to the depositor who shall check and confirm authenticity of the preserved materials and verify of properties. However, if the preserved material is viable but not acceptable (e.g. properties altered), a new deposit must be made, and the original deposit date will be void. Depositors are therefore urged to supply frozen or freeze-dried material prepared in their
laboratory in order to avoid the possibility of this occurring.

Materials for deposit should be pure (uncontaminated) and should be sent the quantity of material required according the type of deposits as follows:

<table>
<thead>
<tr>
<th>Types of deposits</th>
<th>Quantity of material required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microorganisms (including bacteria (either containing a plasmid/vector or not containing a plasmid/vector), mycoplasmas, bacteriophages, fungi and yeast).</td>
<td>25 frozen (1 ml each) or freeze-dried samples</td>
</tr>
<tr>
<td>DNA and RNA (eukaryotic and prokaryotic), Plasmids and vectors not in host (e.g., purified DNA, libraries and associated rDNA material)</td>
<td>25 vials (min. 100 ng each)</td>
</tr>
<tr>
<td>Animal and plant viruses and viroids</td>
<td>25 frozen (1 ml each) or freeze-dried samples</td>
</tr>
<tr>
<td>Cell lines (human, animal and plant) and hybridomas</td>
<td>25 frozen samples (2-6 million cells each)</td>
</tr>
<tr>
<td>Mammalian embryos and gametes</td>
<td>10 frozen embryos 10 frozen straws (0.5 ml/20 million sperm) 10 frozen straws (10 ovules each)</td>
</tr>
<tr>
<td>Microalgae</td>
<td>25 frozen samples (1 ml each)</td>
</tr>
<tr>
<td>Protozoa</td>
<td>25 frozen samples (1 ml each)</td>
</tr>
<tr>
<td>Nematodes</td>
<td>25 frozen samples (1 ml each)</td>
</tr>
<tr>
<td>Microbial consortia</td>
<td>25 vials (10 g or 10 ml each)</td>
</tr>
</tbody>
</table>

1 The CM-CNRG may prepare, as deemed necessary or upon request, lots of samples for preservation by freezing, liquid nitrogen or lyophilization from available materials.

The deposit should be accompanied by appropriate forms duly completed by the depositor. These forms can be obtained from the CM-CNRG. Separate forms need to be used for each deposit.

A fee for storage (Rule 12.1(a) (i) of the Regulations under the Budapest Treaty) must be paid for each deposit.

The CM-CNRG reserves the right to refuse to accept a deposit if, in its view, the deposit may be an unacceptable hazard or the CM-CNRG 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 Mexico.

(ii) Time Required for Viability Testing

The CM-CNRG 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. Time required for testing the viability of the different types of deposits is indicated below. However, depositors should be aware that in certain cases viability testing may take longer.
<table>
<thead>
<tr>
<th>Types of deposits</th>
<th>Time required for testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td>3-7 days</td>
</tr>
<tr>
<td>Fungi and yeast</td>
<td>7-15 days</td>
</tr>
<tr>
<td>Protozoa</td>
<td>7-15 days</td>
</tr>
<tr>
<td>Animal and plant viruses and viroids</td>
<td>30 or more days</td>
</tr>
<tr>
<td>Cell lines (human, animal and plant, hybridomas and bacteriophages)</td>
<td>30 or more days</td>
</tr>
<tr>
<td>Mammalian embryos and gametes</td>
<td>30 or more days</td>
</tr>
<tr>
<td>Microalgae</td>
<td>30 or more days</td>
</tr>
<tr>
<td>Nematodes</td>
<td>30 or more days</td>
</tr>
<tr>
<td>Plasmid, phages and other rDNA</td>
<td>7-10 days</td>
</tr>
<tr>
<td>Microbial consortia</td>
<td>Does not apply</td>
</tr>
</tbody>
</table>

2It is the responsibility of the depositor to characterize the microbial consortium and verify their viability prior to deposit. The CM-CNRG is not responsible for changes in the characteristics of the properties of the consortium once they have been deposited.

(iii) Depositor Checks and Renewal of Stocks

It is the responsibility of the depositor to furnish a sufficient quantity of the material for the specified period of time. If a culture or other biological material should become non-viable or be destroyed during the effective term of the deposit, it is the responsibility of the depositor to replace it with viable material. The CM-CNRG may consider, for a fee, to replenish the material on behalf of the depositor, however, it is the responsibility of the depositor to authenticate the material prepared and to inform the CM-CNRG of the results. Whichever method is used for renewal of stocks the CM-CNRG will maintain a portion of the material originally submitted for deposit.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of the CM-CNRG are Spanish and English. Communications in any other language are not accepted.

Contract. The CM-CNRG 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, by completing the CM-CNRG BP/1 deposit form (Statement in the case of an original deposit pursuant to Rule 6.1), the depositor foregoes any right to withdraw his deposit during the required storage period. The depositor also accepts that the material will be distributed according to the relevant patent requirements and agrees to provide all information required by the CM-CNRG.

When an organism has been accepted as a deposit, the CM-CNRG will notify the depositor, recalling the obligations set out in the terms and conditions of the Treaty.

Import and/or Quarantine Regulations. The CM-CNRG does not administer the import/export procedures nor the quarantine process required for the deposit of material.
Biological materials from outside Mexico may require import clearance and/or be subjected to quarantine regulations of Mexico.

The depositor from outside Mexico should communicate with the Mexican authorities regarding such deposits before dispatching biological materials. It is essential that the depositor contact the CN-CNRG in advance of submitting a deposit which may be subject to these regulations to ensure that the appropriate documentation is obtained. Failure to do so could result in the deposit being refused entry into the country.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors must meet the formal request and access requirements employed by the CM-CNRG for deposits under the Budapest Treaty, analogous to Form BP/1 (Statement in the case of an original deposit pursuant to Rule 6.1).

Official Notifications to the Depositor. Receipts and viability statements are published using the compulsory international Forms BP/4 (Receipt in the case of an original deposit issued pursuant to rule 7.1) and BP/9 (Viability statement issued pursuant to rule 10.2) respectively. Attestations concerning later indications or amendments of the scientific description and/or proposed taxonomic designation are published using Form BP/8 (attestation concerning the later indication or an amendment of the scientific description and/or proposed taxonomic designation pursuant to rule 8.2). Notifications of the furnishing of samples of deposited microorganisms are published using Form BP/14 (notification of the furnishing of samples of deposited microorganisms issued pursuant to rule 11.4(g)). Other notifications will not be carried out using standard forms.

Unofficial Notifications to the Depositor. The CM-CNRG will honor requests for unofficial notifications by telephone, fax or email, providing the date of the deposit and the entry number, during the period between receipt of the organism and the issuance of the official receipt. Nevertheless, the depositor will also be informed that any such information is provisional and dependent on the outcome of viability/identity tests. The CM-CNRG will also communicate the results of the viability analysis before they are published by means of the corresponding certificate.

Supply of Information to a Patent Agent. The CM-CNRG may request the depositor to inform it of the names and addresses of legal representatives or patent attorneys. Upon request, the CM-CNRG will supply copies of sample receipts, viability states and any other information to the depositor, legal representative and/or patent attorney.
(iii) Converting a Previous Deposit

The CM-CNRG does not permit the conversion of deposits not originally made for patent purposes for Budapest Treaty deposits. The procedures outlined above for making a deposit must be followed in all cases.

(iv) Making a New Deposit

In the case that a new deposit is submitted the CM-CNRG requires that the Form BP/2 (Statement in the Case of a New Deposit with the Same International Depositary Authority (Rule 6.2)) be completed. The deposit will retain its initial deposit number and date as long as the replacement deposit is viable, the deposit is made within three months of receiving notification from the CM-CNRG.

The depositor must send to the CM-CNRG a statement signed by the depositor alleging that the newly deposited material is the same as that originally deposited. Charges for viability testing are required for new deposits.

2. Furnishing of Samples

(a) Requests for Samples

The CM-CNRG makes available samples of deposited material only to parties who are so entitled under the terms of the Budapest Treaty and its Regulations. The CM-CNRG will inform third parties of the correct procedure for requests. Where requests require proof of authorization, the CM-CNRG will supply the requesting party with the request forms used by intellectual property offices.

The CM-CNRG accepts deposits of organisms which are potentially hazardous and may be subject to health and safety regulations (only for storage, not for handling nor viability test). When such organisms are requested the CM-CNRG will withhold issuing samples until it has confirmed that the requesting party can comply with such regulations. In certain cases, the CM-CNRG may also require that the requesting party sign an assurance of acceptance of responsibility before agreeing to release a sample. In order to expedite the release of such samples it is therefore advisable that all requests be accompanied by documentation attesting to the fact that the requesting party has the facilities required for, and agrees to the regulations governing, the handling of the requested material.

For requests coming from abroad, the CM-CNRG will assume that the requesting party is familiar with the requirements for importation to its country. All samples sent by the CM-CNRG will be prepared as individual lots.

(b) Notification of the Deppositor

The depositor will be informed officially, in writing on form BP/14 (notification of the furnishing of samples of deposited microorganisms issued pursuant to rule 11.4(g)) and by email, when a sample of a deposited organism has been sent to a third party.
(c) Cataloguing of Budapest Treaty Deposits

The CM-CNRG will publish lists of Budapest Treaty deposits in its catalogues only with prior written authorization from the depositor under terms established by the CM-CNRG (Webpage under construction).

3. Schedule of Fees

The CM-CNRG sets its tariffs (see the following table), for preservation services, sending certificates, declaring viability, delivering samples, etc.

Fees established by CM-CNRG

<table>
<thead>
<tr>
<th>Type of service</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deposit of cell cultures (Rule 6.1)</td>
<td>$12,650</td>
</tr>
<tr>
<td>Deposit of other types of microorganism (Rule 6.1)</td>
<td>$10,450/strain</td>
</tr>
<tr>
<td>New deposit</td>
<td>$1,430/strain</td>
</tr>
<tr>
<td>Storage extension beyond the period provided for by the Budapest Treaty (Rule 9)</td>
<td>$440/year and strain</td>
</tr>
<tr>
<td>Issuance of viability certificates (upon request)</td>
<td>$2,145/certificate and strain</td>
</tr>
<tr>
<td>Reissuance of viability certificates</td>
<td>$1,870</td>
</tr>
<tr>
<td>Furnishing of samples (Rule 11)</td>
<td>$2,145</td>
</tr>
<tr>
<td>Providing information (Rule 7.6)</td>
<td>$2,145/communication and strain</td>
</tr>
</tbody>
</table>

All fees are in Mexican pesos.

Prices do not include value added tax (IVA), which will be added to the final amount.

4. Guidance for Depositors

1. The depositor must contact the CM-CNRG by e-mail/telephone about the acceptability of the material(s) before sending. Please e-mail the CM-CNRG at cm.cnrg@inifap.gob.mx; arteaga.ramon@inifap.gob.mx or contact at 01 800 088 2222 ext. 84818, 84805, 84824 and (+52) 378 1065 020 ext. 5107, 5202, 5207.

2. Once the CM-CNRG agrees to accept the microorganism(s) or any other material(s) it sends Form BP/1 (Statement in the case of an original deposit pursuant to Rule 6.1) by email or personal delivery to the depositor.

3. The depositor sends the microorganism(s) or any other material(s) along with the properly completed Form BP/1 (Statement in the case of an original deposit pursuant to Rule 6.1) and the copy of required fee.

(MX)
CM-CNRG/2016
4. The depositor must take proper care in packing the microorganism(s) or any other material(s) samples (tube, plate, box, flask, etc.) so that they are not damaged during transit. This is necessary to ensure safety of persons who may come in contact of the material. Samples received in damaged condition are not processed by CM-CNRG.

5. The microorganism(s) or any other material(s) are processed for checking viability, purity and identity. Time required for viability testing (refer to page 2: (b) Technical Requirements and Procedures, (ii) Time Required for Viability Testing):

6. Pure and viable microorganism(s) or material(s) are assigned an accession number by the CM-CNRG and preserved at -80 °C, in liquid nitrogen and/or by freeze-drying. In case of microorganism(s) or material(s) are not pure or non-viable, the depositor is informed immediately by e-mail. If the depositor does not contact the CM-CNRG prior to shipping your biological materials there could be delays in processing your patent deposit.

7. The CM-CNRG will send to the depositor an unofficial notification about CM-CNRG accession number.

8. Two samples of preserved microorganism(s) or material(s) are sent to the depositor. The depositor opens one sample and most check if the preserved material represents the original deposit. He/She sends depositor’s confirmation form.

9. CM-CNRG accession number, the receipt and viability statement will be officially issued in Spanish (or English upon request) on the mandatory international Forms BP/4 (Receipt in the case of an original deposit issued pursuant to rule 7.1) and BP/9 (Viability statement issued pursuant to rule 10.2), respectively.
1. Conditions Relating to Deposit

(a) Kinds of Microorganisms Accepted for Deposit

The CCMM accept all types of bacterial strains, including actinomycetes, fungi and yeasts. The CCMM do not accept microorganisms belonging to a higher hazard group than Group 2 of the UK Advisory Committee on Dangerous Pathogens.

(b) Requirements and Technical Procedures

(i) Form and Quantity

As a general rule, the CCMM will only accept strains that can be cultivated in technically feasible conditions.

Exceptionally, the CMM may accept deposits of mixtures of microorganisms, but undefined or non-identifiable mixtures are automatically excluded. However, the acceptance of mixtures of microorganisms is subject to decision and the fees related thereto must be fixed on a case-by-case basis after prior negotiation with the potential depositor.

The CCMM also reserve the right to refuse a deposit of microbiological material if the preservation thereof poses excess risks.

The CCMM require that the depositor provide the following: 3 active or freeze-dried cultures, whereby one of the said cultures must undergo a viability test and is subsequently used to prepare a minimum stock of 20 samples of cryopreserved and/or 20 vials of freeze-dried cells.
(ii) **Required Deadline for Viability Test**

The required deadline for viability tests of deposited strains is generally 3-10 working days according to the type of microorganisms (bacteria, yeast or fungus) and the culture medium used.

(iii) **Depositor Checks and Renewal of Stocks**

Stocks will be renewed using one of the two remaining vials originally provided by the depositor. The vial will undergo a viability test and will be used to prepare a minimum stock of 20 samples or cryopreserved and/or 20 vials of freeze-dried cells.

The CCMM guarantee the authenticity, viability and purity of their preparations. No depositor checks are required.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official languages of the CCMM are Arabic, French and English.

*Contract.* The CCMM have pre-formatted forms for each type of deposit (original, new or conversion of a previous deposit). These forms must be completed by the depositor as appropriate.

*Import and/or Quarantine Regulations.* The CCMM will not accept microorganisms which must be placed in quarantine.

(ii) **Making the Original Deposit**

In accordance with Rule 6.3(a) of the Regulations under the Budapest Treaty, before the deposit of a microorganism can be accepted, the CCMM require the following:

- The microorganism must be deposited in the form and quantity necessary for the CCMM to meet their obligations under the Regulations of the Budapest Treaty;

- The form established by the CCMM must be duly completed and furnished by the depositor for the purpose of the administrative procedures;

- The written statement referred to in Rule 6.1(a) or 6.2(a) must be drafted correctly in French or in English;

- The fee for storage referred to in Rule 12.1(a) must be paid;

- The depositor must obtain all of the required authorizations for transportation of the deposit;
(iii)  Conversion of a Previous Deposit

Rule 6.4(d) allows for a deposit originally made outside the provisions of the Treaty and before the CCMM became an IDA to be converted to a deposit made under the Treaty.

The requirements for converting an existing deposit into a “Budapest Deposit” are the same as those which must be met when making an original deposit under the Treaty except that the microorganism itself, of course, will already have been sent and received. However, it must be realized that when a deposit is converted under Rule 6.4(d), for the purposes of the Treaty, the date of deposit is held to be the date on which the CCMM acquired IDA status, not the earlier date on which the collection physically received the microorganism.

The form established by the CCMM must be duly completed and furnished by the depositor for the purposes of the administrative procedures.

(iv)  Making a New Deposit

Where the CCMM cannot furnish samples of the deposited microorganism, for any reason, in particular:

a. where such microorganism is no longer viable, or

b. where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions, the CCMM shall, promptly after having noted its inability to furnish such samples, notify the depositor of such inability, indicating the cause thereof, and the depositor shall have the right to make a new deposit of the microorganism which was originally deposited (Article 4 of the Treaty).

The new deposit shall be made with the CCMM where the original deposit was made, however

2. Furnishing of Samples

(a) Requests for Samples

The CCMM inform third parties of the procedure that is to be followed in order to establish a formal request for furnishing samples. They provide the requesting parties with the appropriate forma required for such requests. The samples furnished by the CCMM may come from preparations that they have prepared themselves.

(b) Notification of the Depositor

The depositor is notified by official mail when samples have been furnished.

(c) Cataloguing of Budapest Treaty Deposits

CCMM do not list Budapest Treaty deposits of microorganisms that they have accepted in their published catalogue.
3. Schedule of Fees

a) Preservation: 3’325 DH

b) Issuance of a viability statement:
   - when a viability test is carried out 300 DH
   - based on the last viability test 150 DH

c) Furnishing of a sample 500 DH

d) Communication of information 150 DH

e) Issuance of an attestation of an amendment to the scientific description and/or taxonomic designation of the microorganism 200 DH

f) Preparation of a batch of freeze-dried microorganisms for long term storage (this fee does not apply if the freeze-dried is not furnished by the depositor) 2’000 DH

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

All information relating to the deposit of microorganisms for the purposes of patent procedure can be found on the following websites: www.cnrst.ma and www.ccmm.ma
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Fungi, yeasts, bacteria, plasmids in pure form or in a host of the kinds accepted by CBS and phages that can be maintained with routine laboratory techniques without significant modification during appropriate storage at low temperature, in liquid nitrogen or during storage in the lyophilized state. Strains requiring special cultural conditions can be accepted under special conditions and are subject to additional fees (on request).

The following bacteria of pathogenic group I (PG I: World Health Organization (WHO)) are accepted only when they can be maintained by the Rijks Instituut voor Volksgezondheid en Milieuhygiène (RIVM), Centraal Diergeneeskundig Instituut (CDI) or the Royal Institute for Tropical Research: Bordetella (all species), Brucella (all species), Erysipelothrix (all species), Leptospira (all species), Listeria (all species), Mycobacterium paratuberculosis, Pasteurella (all species), Treponema (all species).

The following bacteria of pathogenic group II (PG II (WHO)) are accepted only when they can be maintained by RIVM or CDI: Bartonella (all species), Francisella (all species), Mycobacterium bovis, Mycobacterium tuberculosis, Pseudomonas mallei, Pseudomonas pseudomallei.

The following bacteria are not accepted: Bacillus anthracis and Yersinia pestis.
(b) Technical Requirements and Procedures

(i) Form and Quantity

The CBS prefers to receive microorganisms submitted for deposit as lyophilized preparations. Where it is undesirable or impossible to supply lyophilized preparations, active cultures growing in or on a suitable nutrient medium are acceptable. The minimum number of replicates that must be supplied by the depositor when making his deposit is as follows:

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Form and Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fungi</td>
<td>12 lyophilized cultures; or 2 agar cultures;</td>
</tr>
<tr>
<td>Yeasts</td>
<td>12 lyophilized plus 1 agar culture; or 2 agar cultures;</td>
</tr>
<tr>
<td>Bacteria</td>
<td>12 lyophilized plus 1 agar culture; or 3 agar cultures;</td>
</tr>
<tr>
<td>Plasmids (in hosts)</td>
<td>12 lyophilized plus 1 agar culture; or 3 agar cultures;</td>
</tr>
<tr>
<td>Plasmids (purified DNA)</td>
<td>minimum quantity of 50 g;</td>
</tr>
<tr>
<td>Phages</td>
<td>10 ml with a titre of at least 10^9 pfu/ml.</td>
</tr>
</tbody>
</table>

In cases where the depositor is unable to supply lyophilized preparations, the CBS prepares lyophilized cultures at the time of deposit from the material supplied by the depositor at a fee of Euro 125 for a batch of 10 ampoules freeze-dried material. When the material cannot be freeze-dried, CBS prepares a batch of 10 frozen straws at a fee of Euro 175. The preparation of a phage lysate with a sufficiently high titre can be done at a fee of Euro 500. Plasmid stocks are not prepared by the CBS.

The depositor is required to check the authenticity of a sample of the batch prepared by the CBS, and to inform the CBS of the result.

(ii) Time Required for Viability Testing

The average length of time required for testing viability of the various kinds of microorganisms accepted by the CBS is given below, but depositors should realize that occasionally viability testing may take longer. This is especially likely if unusual antibiotics or other additives are necessary in the medium.

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fungi, bacteria, plasmids in hosts</td>
<td>2 weeks</td>
</tr>
<tr>
<td>or purified DNA, (^1) phages</td>
<td></td>
</tr>
<tr>
<td>Yeasts</td>
<td>1 week</td>
</tr>
</tbody>
</table>

\(^1\) A “viability test” for plasmids consists of transforming a suitable host with the plasmid. If the host is transformed, the “viability test” is regarded as positive.
(iii) Depositor Checks and Renewal of Stocks

The CBS routinely asks the depositor to check the authenticity of the deposited preparations after transfers. New batches of cultures are prepared whenever it is necessary to renew diminishing stocks.

Whichever method is used for preparing batches of samples for distribution, the CBS always keeps a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CBS is English. Communications are also accepted in Dutch, German and French. The preferred language for correspondence is English.

Contract. The CBS does not enter into any written contract with the depositor defining the liabilities of either party but, by signing the CBS deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganism will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. Certain microorganisms are subject to import and/or quarantine regulations. The CBS will advise depositors about these and will make the necessary arrangements for transportation and, if necessary, licenses (fees on request). The CBS should be contacted for precise instructions in this regard, and, in cases of plant pathogens, further information may be obtained from: Plantenziektenkundige Dienst (PD), Geertjesweg 15, Postbus 9102, 6700 NC Wageningen, Netherlands.

The CBS should be contacted in advance if deposit of any of the following plant pathogenic bacteria is intended:


(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the CBS accession form for patent deposits and model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/8. Standard forms are not used for other official notifications.
Unofficial Notifications to the Depositor. If requested, the CBS will telephone or e-mail the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CBS similarly will telephone or telex the result of the viability test before the official viability statement is issued.

Supply of Information to a Patent Agent. The CBS does not ask the depositor to give the name and address of his patent agent. Depending on the wishes of the depositor, the CBS will supply copies of the receipt and viability statement either to the depositor or to his patent agent, but not to both.

(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. All converted deposits are subject to the storage fee normally levied for Budapest Treaty deposits, with the exception of deposits previously made under the European Patent Convention. 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

When making a new deposit, the depositor is required to complete model form BP/2 and to send copies of the relevant documents (Rule 6.2); otherwise the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

The CBS 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 CBS 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, in the case of potentially hazardous microorganisms, the CBS will first confirm that the requesting party is competent to handle them. Samples are not released to private persons not engaged in a relevant profession. When responding to requests from overseas, the CBS assumes that the requesting party has met the import requirements of his own country.

Samples of yeasts and of bacteria furnished by the CBS are usually from batches of its own preparations, but samples of other microorganisms are usually from preparations supplied by the depositor.
(b) **Notification of the Depositor**

Unless he has waived his right to be so notified, the CBS notifies the depositor by letter when samples of his microorganisms have been furnished to third parties. The CBS offers a reduced fee for storage to depositors who waive their right to be notified of the release of samples.

(c) **Cataloguing of Budapest Treaty Deposits**

The CBS does not list Budapest Treaty deposits in its published catalog.

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Description</th>
<th>EUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage (30 years)</td>
<td>650</td>
</tr>
<tr>
<td>(b) Conversion of a deposit</td>
<td>650</td>
</tr>
<tr>
<td>(c) Preservation of stock material for the deposition of 30 years:</td>
<td></td>
</tr>
<tr>
<td>- set of 10 ampoules of freeze-dried material</td>
<td>125</td>
</tr>
<tr>
<td>- set of 10 frozen straws</td>
<td>175</td>
</tr>
<tr>
<td>(d) Issuance of a viability statement, except where Rule 10.2(e) of the</td>
<td></td>
</tr>
<tr>
<td>Regulations of the Budapest Treaty applies:</td>
<td></td>
</tr>
<tr>
<td>- if the viability test is to be carried out</td>
<td>80</td>
</tr>
<tr>
<td>- based on the last viability test</td>
<td>25</td>
</tr>
<tr>
<td>(e) Communication of information</td>
<td>25</td>
</tr>
<tr>
<td>(f) Issuance of an attestation</td>
<td>25</td>
</tr>
<tr>
<td>(g) Furnishing of a sample:</td>
<td></td>
</tr>
<tr>
<td>- in accordance with Rule 11.2(ii), 11.3(a) and 11.3(b) of the Regulations of the Budapest Treaty</td>
<td>100</td>
</tr>
<tr>
<td>- in accordance with Rule 11.2(i) of the Regulations of the Budapest Treaty:</td>
<td></td>
</tr>
<tr>
<td>- agar slant</td>
<td>40</td>
</tr>
<tr>
<td>- freeze-dried ampoule</td>
<td>15</td>
</tr>
<tr>
<td>(h) Surcharge to cover bank and administrative costs</td>
<td>10</td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

The CBS does not produce a standard letter or guidance notes for prospective depositors, but from time to time guidance is provided in the CBS Newsletter.
1. Requirements for Deposit

(a) Kinds of Microorganism that May Be Deposited

Bacteria, yeasts and filamentous fungi are accepted which are capable of long-term preservation without any substantial change in their initial properties.

Note:
- dangerous pathogens and species that can be hazardous to man and animals will not be accepted;
- microorganisms with special requirements for cultivation that the IAFB Collection of Industrial Microorganisms is not capable of carrying out technically will not be accepted;
- mixtures and cultures without scientific description and cultures that cannot be identified will not be accepted;
- when strains containing a plasmid are deposited, the IAFB Collection of Industrial Microorganisms will require information on the properties and classification of the plasmid and its host strain (i.e., group P1, P2, P3 or P4). The Collection will accept only plasmids and host strains belonging to group P1.
(b) Technical Requirements and Procedures

(i) Form and Quantity

The Collection of Industrial Microorganisms prefers to receive microorganisms submitted for deposit as lyophilized preparations. When it is undesirable or impossible to supply lyophilized preparations, active cultures growing in or on a suitable nutrient medium are acceptable.

The minimum number of replicates that the depositor must supply when making his deposit is 20 for lyophilized preparations or three active cultures (agar slants).

(ii) Time Required for Viability Testing

The average length of time for testing viability is 7 to 14 days, but occasionally viability testing may take longer, particularly if unusual antibiotics or other additives are necessary in the medium.

(iii) Depositor Checks and Renewal of Stocks

Where the microorganism is deposited as an active culture, the Collection of Industrial Microorganisms prepares its own batches by subculturing the material supplied by the depositor. The Collection of Industrial Microorganisms routinely asks the depositor to check the authenticity of the deposited preparations after subculturing.

New batches of cultures are prepared whenever it is necessary to renew diminishing stocks. Whatever method is used for preparing batches of samples of distribution, the Collection of Industrial Microorganisms always keeps a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the IAFB Collection is Polish. Communications in English or Russian are also accepted.

Contract. The IAFB Collection does not enter into a written contract with the depositor defining the liabilities of the two parties. However, by signing the IAFB Collection deposit form, the depositor surrenders any right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. The kinds of microorganism accepted by the Collection of Industrial Microorganisms are not subject to import or quarantine regulations.
(ii) Making the Original Deposit

**Requirements to Be Met by the Depositor.** The depositor is required to complete model form BP/1. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third party is issued on model form BP/14. The IAFB Collection uses its own standard letters for other official notifications.

**Unofficial Notifications to the Depositor.** If requested, the IAFB Collection will give the date of deposit and accession number by telephone, fax or e-mail when a microorganism has been received and before the official receipt is issued. The IAFB Collection will also give the result of the viability test by telephone, fax or e-mail before the official viability statement is issued.

**Supply of Information to a Patent Agent.** The IAFB Collection does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the Collection of Industrial Microorganisms will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The administrative requirements for conversion are the same as those to be met for an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to send copies of the relevant documents (Rule 6.2); otherwise the procedure is similar to that for making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

The IAFB Collection 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 Collection of Industrial Microorganisms will provide the requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices.
(b) **Notification of the Depositor**

Unless the right to be so notified has been waived, the IAFB Collection notifies the depositor by letter when samples of its microorganisms have been furnished to third parties.

(c) **Cataloguing of Budapest Treaty Deposits**

The IAFB Collection does not list Budapest Treaty deposits in its List of Cultures.

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th></th>
<th>PLN</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage</td>
<td>3,400</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>350</td>
</tr>
<tr>
<td>(c) Furnishing of a sample</td>
<td>400</td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

The IAFB Collection does not produce a standard letter or guidelines for prospective depositors, but can of course be contacted for specific information. All inquiries should be addressed to the Collection of Industrial Microorganisms.
1. Requirements for Deposit

(a) Kinds of Microorganism that May Be Deposited

Bacteria (including actinomycetes) and bacteriophages that are capable of long-term preservation without any substantial change in their initial properties are accepted.

Note:

- dangerous pathogens and species that may be hazardous to man and animals will be conditionally accepted;

- microorganisms with special requirements for cultivation that the PCM is not capable of carrying out technically will not be accepted;

- mixtures and cultures with no scientific description and cultures which cannot be identified will not be accepted;

- when strains containing a plasmid are deposited, the PCM will require information on the properties and classification of the plasmid and its host strain (i.e., group P1, P2, or P4). The PCM will accept only plasmids and host strains belonging to group P1.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria (including those containing plasmids) must be submitted for deposit as lyophilized preparations or on culture transport media, except agar plate cultures (these are too easily damaged in transport). Bacteriophages have to be sent together with a suitable host. The material for deposit must be free of contamination by foreign organisms. All replicates of the microorganism to be deposited should be from the same batch. The deposit must be accompanied by the appropriate form, duly completed. Forms are obtainable from the PCM.
The minimum number of replicates that must be provided by the depositor when making his deposit and the form in which they must be submitted are as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td>10 lyophilized or on media or frozen (0,5ml each)</td>
</tr>
<tr>
<td>Bacteriophages</td>
<td>sufficient quantity and titre for preservation (at least $10^8$ pfu/ml, 10 x 10ml or 2 x 5ml cell-free lysate)</td>
</tr>
</tbody>
</table>

The depositor is required to check the authenticity of a sample from the batch prepared by the PCM, and to inform the PCM of the result.

(ii) **Time Required for Viability Testing**

The average time required for testing the viability of microorganisms accepted by the PCM is given below, but depositors should understand that in some cases viability testing may take longer, as indicated by the bracketed figures:

<table>
<thead>
<tr>
<th>Category</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td>3 days (or up to 14 days)</td>
</tr>
<tr>
<td>Actinomycetes and other slow-growing organisms</td>
<td>5 days (or up to 20 days)</td>
</tr>
<tr>
<td>Bacteriophages</td>
<td>7 days (or up to 14 days)</td>
</tr>
</tbody>
</table>

(iii) **Depositor Checks and Renewal of Stocks**

The PCM has prepared its own batch of microorganisms by subculturing material supplied by depositors. The depositor is asked to check the authenticity of batches prepared by the PCM from material supplied by him at the time of deposit. The PCM stores the original material supplied by the depositor.

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.* The official language of the PCM is Polish. Communications in English are accepted.

*Contract.* The PCM does not enter into a written contract with the depositor defining the liabilities of the two parties but, by signing the deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period and accepts that the material will be distributed according to the relevant patent requirements.

*Import and/or Quarantine Regulations.* At present, the kinds of microorganism accepted by the PCM for deposit under the Budapest Treaty are not subject to import or quarantine regulations.
(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the application and accession form for deposit under the Budapest Treaty, which is equivalent to model form BP/1. The PCM uses separate forms for bacteria and for bacteriophages. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. 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 PCM will give the date of deposit and accession number by telephone, e-mail or fax after the microorganism has been received and before the official receipt is issued. However, the depositor is informed that the information is provisional and subject to the outcome of the viability test. Similarly, the PCM will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The PCM does not routinely ask the depositor for the name and address of his patent agent. It will send copies of the receipt and viability statement to the patent agent if requested to do so.

(iii) Converting a Previous Deposit

Deposits not made under the Budapest Treaty may be converted into deposits under the Budapest Treaty, regardless of whether or not they were originally deposited for patent purposes. The administrative requirements for conversion are the same as those to be met for an original deposit under the Budapest Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to supply copies of the documents specified in Rule 6.2. 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 PCM advises third parties of the procedure to be followed in order to make a proper request. For requests that require proof of the right to receive samples, PCM will supply the requesting parties with copies of the standard request form BP/12 and/or forms used by individual industrial property offices (where it has been supplied with such forms).
Notwithstanding any entitlement of a third party to receive samples under patent regulations, the PCM will withhold samples of potentially dangerous microorganisms until it has satisfied itself that the requesting party is competent to handle such organisms. When responding to requests from overseas, the PCM assumes that the requesting party has met the import requirements of his own country.

Samples of bacteria furnished by PCM are usually from batches prepared by itself; samples of bacteriophages may be from batches of its own or from material supplied by the depositor.

(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

The PCM does not list Budapest Treaty deposits in his published catalogue.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>(a) Storage</th>
<th>PLN 1,200</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>40</td>
</tr>
<tr>
<td>(c) Furnishing of a sample</td>
<td>100</td>
</tr>
</tbody>
</table>

4. Guidance for Depositors

At present, the PCM does not produce a standard letter or guidelines for prospective depositors, but offers advice by telephone, fax or e-mail.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The KACC will accept bacteria (non-pathogenic including actinomycetes), fungi (non-pathogenic), yeasts (non-pathogenic), mushroom, plasmids in hosts, plant viruses, bacteriophages and plant seeds.

KACC accepts only those organisms belonging to risk groups 1 or 2, in accordance with Directive 2000/54/EC on the protection of workers from job risks related to exposure to biological agents.

KACC reserves the right to refuse the deposit of any material which in its view represents an unacceptable hazard or which it cannot process.

KACC must be consulted in advance about the conditions for acceptance.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The KACC accepts microorganisms submitted for deposit as lyophilized or frozen. 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 is as follows:

- Bacteria, fungi, yeasts, mushroom, bacteria containing plasmid 10
- Bacteriophages (at least $10^9$ pfu/ml) 10 ml

Viruses should be deposited in the form of lyophilized or dried material along with the host. The minimum number of replicates that must be provided by the depositor is as follows:

- Plant viruses 10 g
In all cases, seeds should be fresh, healthy, undamaged, and free from soil or plant-derived debris. Less than 5% of the deposit should contain empty seeds. Normally, a germination rate of at least 85% is required, but deposits may be accepted in certain circumstances where such a regeneration rate is impossible to achieve.

- Plant seeds

(ii) Time Required for Viability Testing

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

- Bacteria, fungi, yeasts, mushroom, bacteria containing plasmid, plant viruses, bacteriophages 14 days (or up to 30 days)
- Plant seeds Depends entirely on the kind of seed

(iii) Depositor Checks and Renewal of Stocks

The KACC prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The KACC generally does not prepare its own batches of viruses, bacteriophages and seeds. In such cases, the depositor is responsible for replenishing the stock to ensure that there is sufficient stock to make the deposit available to the general public for the required period of deposit.

Whichever method is used for preparing batches of samples for distribution, the KACC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of the KACC are Korean and English. Communications in any other language are not accepted.

Contract. The KACC does not enter into any written contract with the depositor defining the liabilities of either party. Also, by completing the KACC BP/1 deposit form, the depositor foregoes any right to withdraw his deposit during the required storage period and accepts that the material will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. It is essential that the depositor contact the KACC in advance of submitting a deposit which may be subject to these regulations to ensure that the appropriate documentation is obtained. This is particularly important for deposits made from outside of Korea. Failure to do so could result in the deposit being refused entry into the country.
(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the KACC as its accession form for Budapest Treaty deposits. 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 KACC 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. 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 furnishing of a sample to a third party is issued on form BP/14. The KACC has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KACC will write an e-mail the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KACC will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KACC does not routinely ask the depositor for the name and address of his patent agent. The KACC will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(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. The receipt and viability statement 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 KACC advises third parties about the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the KACC 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). The KACC furnished samples on the basis that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KACC assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the KACC 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

The KACC does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Services</th>
<th>KRW</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Deposit (including initial viability check, preservation and storage for 30 years):</td>
<td></td>
</tr>
<tr>
<td>- original deposit</td>
<td>800,000</td>
</tr>
<tr>
<td>- new deposit</td>
<td>70,000</td>
</tr>
<tr>
<td>2) Furnishing of a sample</td>
<td>100,000</td>
</tr>
<tr>
<td>3) Issuance of a viability statement:</td>
<td></td>
</tr>
<tr>
<td>- where a viability test is requested</td>
<td>70,000</td>
</tr>
<tr>
<td>- on the basis of the most recent viability test</td>
<td>10,000</td>
</tr>
<tr>
<td>4) Issuance of an attestation under Rule 8.2</td>
<td>10,000</td>
</tr>
<tr>
<td>5) Communication of information under Rule 7.6</td>
<td>10,000</td>
</tr>
</tbody>
</table>

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

At Present, the KACC does not produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal embryos, bacteria (including actinomycetes), bacteria containing plasmids (either in hosts or not in hosts), bacteriophages, RNA, cell cultures (including hybridoma lines), eukaryotic DNA, fungi (including yeasts), human cell cultures, molds, murine embryos, plant cell cultures, plant seeds, protozoa (non-parasitic), and animal and plant viruses, EXCEPT:

- microorganisms having properties which are or may be dangerous to human health and/or the environment;

- microorganisms which require special containment for experimentation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cultures submitted to the KCTC for deposit should be lyophilized. Viruses that cannot be lyophilized and bacteriophages should be frozen. 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 submitted by the depositor is as follows:

Actinomycetes, bacteria, fungi, yeasts, bacteria containing plasmid 10

Plasmids, algae, protozoa, animal and plant cell lines, hybridomas, viruses, bacteriophages 25
(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the microorganisms accepted by the KCTC is given below, but depositors should realize that in some cases it may take longer:

- **Bacteria**: 7 days (or up to 14 days)
- **Fungi, yeasts, actinomycetes, algae, protozoa**: 10 days (or up to 20 days)
- **Plasmids, bacteria containing plasmids, viruses, bacteriophages, animal and plant cell lines, hybridomas**: 14 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

The KCTC prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples of all batches of his microorganisms prepared by the KCTC.

Whichever method is used for preparing batches of samples for distribution, the KCTC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

*Language.* Korean is the official language of the KCTC. However, correspondence may also be carried out in English.

*Contract.* The KCTC does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCTC deposit form the depositor surrenders any right to withdraw his deposit during the required storage period.

*Import and/or Quarantine Regulations.* Overseas depositors must contact the KCTC in advance for advice about the shipping of their microorganisms. Certain pathogens are subject to import and/or quarantine regulations. The KCTC advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

*Requirements to Be Met by the Depositor.* Depositors are required to complete the equivalent of model form BP/1, which is used by the KCTC as its accession form for Budapest Treaty deposits. 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 KCTC 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. 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 furnishing of a sample to a third party is issued on form BP/14. The KCTC has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KCTC will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KCTC will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KCTC does not routinely ask the depositor for the name and address of his patent agent. The KCTC will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(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. The receipt and viability statement 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 KCTC 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 KCTC 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).

The KCTC furnishes samples on the basis that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KCTC assumes that the requesting party has met the import requirements of his own country.
All samples of microorganisms furnished by the KCTC 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

The KCTC does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Services</th>
<th>KRW</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Deposit (including initial viability check, preservation and storage for 30 years)</td>
<td></td>
</tr>
<tr>
<td>- Original deposit (bacteria, fungi, yeasts, bacteriophages, molds, animal and plant viruses, eukaryotic DNA, RNA, plasmids, seeds)</td>
<td>800,000</td>
</tr>
<tr>
<td>- Original deposit (human, animal and plant cell cultures, embryos, murine embryos, hybridomas, algae, non-parasitic protozoa)</td>
<td>900,000</td>
</tr>
<tr>
<td>- New deposit</td>
<td>70,000</td>
</tr>
<tr>
<td>2. Furnishing of a sample</td>
<td></td>
</tr>
<tr>
<td>- Bacteria, fungi, yeasts, bacteriophages, molds, animal and plant viruses, eukaryotic DNA, RNA, plasmids, seeds</td>
<td>100,000</td>
</tr>
<tr>
<td>- Human, animal and plant cell cultures, embryos, murine embryos, hybridomas, algae, non-parasitic protozoa</td>
<td>150,000</td>
</tr>
<tr>
<td>3. Issuance of a viability statement</td>
<td></td>
</tr>
<tr>
<td>- Where a viability test is requested</td>
<td>70,000</td>
</tr>
<tr>
<td>- On the basis of the most recent viability test</td>
<td>10,000</td>
</tr>
<tr>
<td>4. Issuance of an attestation under Rule 8.2</td>
<td>10,000</td>
</tr>
<tr>
<td>5. Communication of information under Rule 7.6</td>
<td>10,000</td>
</tr>
</tbody>
</table>

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

The KCTC does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Cell lines (human, animal, plant and hybridomas), eukaryotic DNA, plasmids (either in hosts or not in hosts), EXCEPT:

- cell lines having properties which are or may be hazardous to human health and/or the environment;
- cell lines which have special requirements for experimentation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cell lines submitted to KCLRF for deposit should be in the form of frozen and viable culture. All cell lines submitted to KCLRF for deposit should be free of contaminants.

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

Cell lines in frozen form: 7

(ii) Time Required for Viability Testing

The average time required for testing the viability of cell lines accepted by KCLRF is as follows:

Cell lines (animal, plant and hybridomas) 14 days (or up to 28 days)

In some cases, the test may take longer.
(iii) Depositor Checks and Renewal of Stocks

KCLRF prepares its own batches in frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter. The depositor is required to check for authenticity samples of all batches prepared by KCLRF. Regardless of the methods for preparing the batches of samples for distribution, KCLRF stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. Korean is the official language of KCLRF, but correspondence may be carried out also in English.

Contract. KCLRF does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCLRF deposit form, the depositor surrenders the right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact KCLRF in advance for advice about the shipping of their cell lines. Certain pathogens are subject to import and/or quarantine regulations. KCLRF advises prospective depositors concerning the procedures which must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by KCLRF as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third party is issued on model form BP/14. KCLRF has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, KCLRF will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. KCLRF will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. KCLRF does not routinely ask the depositor for the name and address of his patent agent. KCLRF will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.
(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 only if they were originally made for patent purposes. The administrative requirements for the conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is required to supply also a copy of the receipt for the previous deposit. All conversions are subject to payment of the normal storage fee levied on Budapest Treaty deposits, regardless of whether any fee had been paid previously in respect of those deposits.

(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. The receipt and viability statement for a new deposit are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

KCLRF 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, KCLRF will provide the requesting parties with copies of a model request form BP/12 and/or request forms used by individual industrial property offices (where they have been supplied with such forms).

KCLRF furnishes samples on the basis that it is the responsibility of the requesting party to ensure that it complies with any relevant health and safety requirements. When responding to requests from overseas, KCLRF assumes that the requesting party has met the import requirements of its own country.

All samples of cell lines furnished by KCLRF are from batches of its own preparation.

(b) Notification of the Depositor

Depositors are notified in model form BP/14 when samples of their cell lines have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

KCLRF does not list Budapest Treaty deposits in the catalog of its publications.
3. Schedule of Fees

<table>
<thead>
<tr>
<th>Services</th>
<th>KRW</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Deposit (including initial viability check, preservation and storage for 30 years)</td>
<td></td>
</tr>
<tr>
<td>- Original deposit (eukaryotic DNA, plasmids)</td>
<td>800,000</td>
</tr>
<tr>
<td>- Original deposit (human, animal and plant cell cultures, hybridomas)</td>
<td>900,000</td>
</tr>
<tr>
<td>- New deposit</td>
<td>70,000</td>
</tr>
<tr>
<td>2. Furnishing of a sample</td>
<td></td>
</tr>
<tr>
<td>- Eukaryotic DNA, plasmids</td>
<td>100,000</td>
</tr>
<tr>
<td>- Human, animal and plant cell cultures, hybridomas</td>
<td>150,000</td>
</tr>
<tr>
<td>3. Issuance of a viability statement</td>
<td></td>
</tr>
<tr>
<td>- Where a viability test is requested</td>
<td>70,000</td>
</tr>
<tr>
<td>- On the basis of the most recent viability test</td>
<td>10,000</td>
</tr>
<tr>
<td>4. Issuance of an attestation under Rule 8.2</td>
<td>10,000</td>
</tr>
<tr>
<td>5. Communication of information under Rule 7.6</td>
<td>10,000</td>
</tr>
</tbody>
</table>

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

KCLRF does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.
1. Requirements for Deposit

(a) **Kinds of Microorganisms that May Be Deposited**

   Bacteria, actinomycetes, fungi, yeasts, plasmids, bacteria containing plasmids, viruses, bacteriophages, EXCEPT:

   - hybridomas, plant tissue cultures, rickettsiae;
   - microorganisms liable to require viability testing that the KCCM is technically not able to carry out;
   - mixtures of undefined and/or unidentifiable microorganisms.

   The KCCM reserves the right to refuse any microorganism for security reasons: specific risks to human beings, animals, plants and the environment. In cases where a microorganism cannot be lyophilized, the KCCM must be consulted in advance about the conditions for acceptance.

(b) **Technical Requirements and Procedures**

   (i) **Form and Quantity**

   Whenever possible, cultures submitted to the KCCM for deposit should be lyophilized. Viruses that cannot be lyophilized and bacteriophages should be frozen. All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

   Bacteriophage suspensions must contain at least $10^7$ plaque forming units per ml.
The minimum number of replicates that must be submitted by the depositor is as follows:

- Bacteria, fungi, yeasts, actinomycetes: 8
- Plasmids, bacteria containing plasmids, viruses, bacteriophages: 25

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the microorganisms accepted by the KCCM is given below, but depositors should realize that in some cases it may take longer.

- Bacteria: 7 days (or up to 14 days)
- Fungi, yeasts, actinomycetes: 10 days (or up to 20 days)
- Plasmids, bacteria containing plasmids, viruses, bacteriophages: 14 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

The KCCM prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples of all batches of his microorganisms prepared by the KCCM.

Whichever method is used for preparing batches of samples for distribution, the KCCM nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the KCCM is Korean. However, communications in English are also accepted.

Contract. The KCCM does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCCM deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact the KCCM in advance for advice about the shipping of their microorganisms. Certain pathogens are subject to import and/or quarantine regulations. The KCCM advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits.
(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the KCCM as its accession form for Budapest Treaty deposits. 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 KCCM 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. 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 furnishing of a sample to a third party is issued on form BP/14. The KCCM has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KCCM will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KCCM will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KCCM does not routinely ask the depositor for the name and address of his patent agent. The KCCM will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(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. The receipt and viability statement 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 KCCM 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 KCCM 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).

The KCCM furnishes samples in the belief that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KCCM assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the KCCM 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

The KCCM does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Services</th>
<th>KRW</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Deposit (including initial viability check, preservation and storage for 30 years)</td>
<td></td>
</tr>
<tr>
<td>- Original deposit</td>
<td>800,000</td>
</tr>
<tr>
<td>- New deposit</td>
<td>70,000</td>
</tr>
<tr>
<td>2. Furnishing of a sample</td>
<td>100,000</td>
</tr>
<tr>
<td>3. Issuance of a viability statement</td>
<td></td>
</tr>
<tr>
<td>- Where a viability test is requested</td>
<td>70,000</td>
</tr>
<tr>
<td>- On the basis of the most recent viability test</td>
<td>10,000</td>
</tr>
<tr>
<td>4. Issuance of an attestation under Rule 8.2</td>
<td>10,000</td>
</tr>
<tr>
<td>5. Communication of information under Rule 7.6</td>
<td>10,000</td>
</tr>
</tbody>
</table>

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

The KCCM does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts), also if they are carriers of recombinant DNA, are accepted for deposit, to the exclusion of microorganisms that are covered by hazard categories in relation to man, animal or plant health and appear on the lists published by national regulatory authorities.

VKM does not accept for deposit:

- microorganisms whose manipulation needs physical containment levels P2, P3 or P4, as described in “Laboratory Safety Monographs”;

- microorganisms liable to require viability testing that VKM is technically not able to carry out and mixtures of undefined and/or unidentifiable microorganisms.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to VKM for deposit must be in the form of agar stabs or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs or 50 ampoules.
(ii) **Time Required for Viability Testing**

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

- **Bacteria** 7 days (or up to 30 days)
- **Fungi** 7 days (or up to 25 days)
- **Yeasts** 7 days (or up to 14 days)

(iii) **Depositor Checks and Renewal of Stocks**

VKM prepares its own batches by subculturing material originally supplied by the depositor. As a rule, new batches are prepared from these and by subculturing VKM’s own preparations as necessary thereafter for the renewal of diminishing stocks. VKM routinely asks the depositor to check the authenticity of the preparations made by VKM at the time of deposit from material supplied by the depositor. VKM routinely checks newly received deposits for contamination and, if they are found contaminated, it returns them to the depositor.

VKM stores original material supplied by the depositor.

(c) **Administrative Requirements and Procedures**

(i) **General**

**Language.** The official language of VKM is Russian. Communications may also be exchanged in English.

**Contract.** VKM does not enter into a contract with the depositor. Completion by the depositor of form BP/1 is considered sufficient.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by VKM are not subject to import or quarantine regulations. VKM does not advise the depositor on the procedures he must follow to obtain an import permit. To this effect, the depositor must check the applicable national regulations.

(ii) **Making the Original Deposit**

Requirements to Be Met by the Depositor. The depositor must complete form BP/1 when making the original deposit and when converting a deposit made outside the Budapest Treaty. He must complete form BP/2 when making a new deposit and form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Other than the mandatory “international forms”, official notifications are not issued on standard forms.
Unofficial Notifications to the Depositor. VKM does not notify unofficially to the depositor the date of deposit and the accession number nor the result of the viability test before the relevant receipt and viability statement are issued.

Supply of Information to a Patent Agent. VKM does not ask the depositor to supply the name and address of his patent attorney. However, if requested, it will supply copies of the official receipt and viability statement to both the depositor or his attorney.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty, 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 fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion of a deposit not previously made for patent purposes are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is not required to meet any requirement additional to those provided for in connection with the original deposit.

2. Furnishing of Samples

(a) Requests for Samples

VKM advises third parties of the correct procedure to follow in order to make a valid request and will supply such parties with copies of model request form BP/12 or request forms used by individual industrial property offices.

When responding to requests for samples from overseas, VKM assumes that the requesting party has met the import requirements of his own country.

(b) Notification of the Depositor

VKM does not notify depositors when samples of their microorganism are furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

VKM does not list deposits made under the Budapest Treaty in its published catalog.
3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Description</th>
<th>USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage</td>
<td>650</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>100</td>
</tr>
<tr>
<td>(c) Furnishing of a sample</td>
<td>130</td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

VKM does not at present produce a standard letter or guidance notes for prospective depositors, but would be willing to answer inquiries or questions, preferably by e-mail.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA), plant cell cultures, animal and human cell cultures (including hybridoma lines), EXCEPT:

- microorganisms having properties which are or may be dangerous to health or the environment;
- microorganisms which need the special containment required for experiments.

Deposits containing recombinant DNA molecules must not require physical containment higher than level P2 as described in the National Institute of Health “Guidelines for Research Involving Recombinant DNA Molecules” (USA).

(b) Technical Requirements and Procedures

(i) Form and Quantity

The VKPM prefers to receive microorganisms submitted for deposit as lyophilized preparations. Where it is undesirable or impossible to supply lyophilized preparations, active culture growing in or on a suitable nutrient medium are acceptable. The minimum number of replicates that must be supplied by the depositor is as follows:

- Fungi, yeasts, bacteria, plasmids (in host): 20 lyophilized cultures or 5 agar cultures
- Plasmids (purified DNA): 25 vials (100ng each)
- Cell lines and hybridomas: 25 frozen samples
- Bacteriophages: 5x0.5ml (free cell lysate) (at least 10^8 pfu/ml)
Bacteriophages and plasmids need to be sent with a suitable host, if such a host is not available in the public collection of the VKPM.

(ii) Time Required for Viability Testing

The average length of time requested for testing the viability of the kinds of microorganisms accepted by the VKPM is given below:

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria, plasmids in hosts</td>
<td>10</td>
</tr>
<tr>
<td>Fungi, yeasts, bacteriophages, cell lines, hybridomas</td>
<td>20</td>
</tr>
</tbody>
</table>

(iii) Depositor Checks and Renewal of Stocks

In case of necessity, the VKPM prepares the additional samples of bacteria, fungi, yeast by subculturing material supplied by the depositor. The depositor is entitled to test for authenticity samples from all batches prepared by the VKPM.

Despite the method used for preparing batches of samples for distribution, the VKPM nevertheless stores a portion of the original material supplied by the depositor, if the culture supplied allows this.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the VKPM is Russian. Communications may also be exchanged in English.

Contract. The VKPM does not enter into any written contract with the depositor defining the liabilities of either party, except the VKPM-BP/1 application form, which depositor is required to complete.

Import and/or Quarantine Regulations. Certain microorganisms accepted for deposit by the VKPM are subject to import regulations. The VKPM may obtain on behalf of the depositor the necessary import permits; however, the depositor must supply information on the non-pathogenicity of the microorganisms.

Microorganisms accepted for deposit by the VKPM must not be subject to quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the VKPM-BP/1 accession form for patent deposits (the equivalent of model form BP/1). In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.
Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Notification of the furnishing of samples to third parties is issued on model form BP/14. The VKPM uses the standard form in preference for the other official notifications.

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

Supply of Information to a Patent Agent. If requested, the VKPM supplies copies of the receipt and viability statement to the depositor’s patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provision of the Budapest Treaty may be converted to Budapest Treaty deposits, provided that they were originally made for patent purposes, or they were confidential for safe-keeping. All converted deposits are subject to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion of a deposit are the same as those to be met by an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to send copies of the relevant documents specified in Rule 6.2; otherwise the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

The VKPM advises third parties of the correct procedure to follow in order to make a valid request and will supply such parties with copies of model request form BP/12.

(b) Notification of the Depositor

The VKPM notifies the depositor on form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

At the request of the depositor, the VKPM lists Budapest Treaty deposits in its published catalog. All microorganisms that are the subject of granted and published patents of the Russian Federation are listed in the catalog.
3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Description</th>
<th>EUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage (30 years):</td>
<td></td>
</tr>
<tr>
<td>- bacteria (including actinomicetes), fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA)</td>
<td>500</td>
</tr>
<tr>
<td>- cell lines, hybridomas</td>
<td>800</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement:</td>
<td></td>
</tr>
<tr>
<td>- bacteria (including actinomicetes), fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA)</td>
<td>100</td>
</tr>
<tr>
<td>- cell lines, hybridomas</td>
<td>150</td>
</tr>
<tr>
<td>(c) Furnishing of a sample:</td>
<td></td>
</tr>
<tr>
<td>- bacteria (including actinomicetes), fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA)</td>
<td>100</td>
</tr>
<tr>
<td>- cell lines, hybridomas</td>
<td>150</td>
</tr>
<tr>
<td>(d) Communication of information under Rule 7.6 or issuance of an attestation under Rule 8.2</td>
<td>30</td>
</tr>
<tr>
<td>(e) Other fees (communication, carriage)</td>
<td></td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

The VKPM produces notes for the guidance of potential depositors.
SK – SLOVAKIA

CULTURE COLLECTION OF YEASTS (CCY)

Institute of Chemistry
Slovak Academy of Sciences
Dúbravská cesta, 9
845 38 Bratislava

Telephone: (421-2) 59 41 02 62
Facsimile: (421-2) 59 41 02 22
E-mail: yeasts@ccy.sk
Internet: http://www.ccy.sk/

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Yeasts which can be stored in liquid nitrogen or as active cultures without any substantial change in their properties.

Yeasts whose storage can be accomplished by standard laboratory techniques without appreciable adapting during storage in liquid nitrogen or during storage on agar slant.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The CCY accepts microorganisms for deposit as either lyophilized preparations or active cultures. The minimum number of replicates that must be provided by the depositor when making his deposit is four for lyophilized preparations and two for agar slope cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of yeasts cultures by the CCY is six days, but in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The CCY prepares its own batches of yeasts by subculturing the material supplied by the depositor. New batches are prepared from the depositor’s original material for the renewal of stocks. The CCY routinely asks the depositor to check the authenticity of the preparations made by the CCY at the time of deposit from material supplied by the depositor.

The CCY stores original material supplied by the depositor.

(SK)
CCY/2013
(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCY is Slovak. Communications are also accepted in English.

Contract. The CCY does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the CCY deposit form, the depositor surrenders any right to withdraw his microorganisms during the required storage period.

Import and/or Quarantine Regulations. Import and/or quarantine regulations do not apply to the kinds of microorganisms accepted by the CCY for deposit.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the equivalent of model form BP/1, which is used by the CCY as its accession form for Budapest Treaty deposits. 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 CCY 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. 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. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The CCY does not telephone or email the date of deposit, accession number or results of the viability test in advance of the relevant official notifications.

Supply of Information to a Patent Agent. The CCY does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the CCY will send 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. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fee had previously been paid in respect of those deposits.

The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.
(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. The receipt and viability statement are issued on mandatory “international forms” BP/5 and BP/9, respectively.

2. **Furnishing of Samples**

(a) **Requests for Samples**

The CCY 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 CCY 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).

When responding to requests from overseas, the CCY assumes that the requesting party has met the import requirements of his own country.

All samples furnished by the CCY are from batches of its own preparations.

(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**

The CCY does not list Budapest Treaty deposits in its published catalog.

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Description</th>
<th>EUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage</td>
<td>664</td>
</tr>
<tr>
<td>(b) Issuance of a viability statement</td>
<td>33</td>
</tr>
<tr>
<td>(c) Furnishing of a sample</td>
<td>40</td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

The CCY does not produce a standard letter or guidance notes for prospective depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Freshwater, marine, hypersaline and soil microalgae and cyanobacteria and marine macroalgae which can be preserved by means of subcultures without change of their properties.

BEA will shortly accept microalgae, cyanobacteria and macroalgae (tissue or spores) which can be preserved by means of cryopreservation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Organisms must be submitted for deposit as liquid cultures or in agar. The minimum number of identical copies that must be supplied for deposit is five. The cultures of microalgae and cyanobacteria shall contain a minimum of $10^2$ to $10^4$ cells per millilitre, depending on the species and three plants in the case of macroalgae.

(ii) Time Required for Viability Testing

The average time required for analyzing viability of microalgae, cyanobacteria and macroalgae accepted by the BEA is seven days, but depositors must take into account that in some cases analysis can take up to 35 days.

(iii) Depositor Checks and Renewal of Stocks

The BEA will prepare its own lots of organisms at the time of deposit, and will make a subculture of the material supplied by the depositor. The new lots are prepared according to the needs for renewal of lots which have been exhausted. Where the original material has been cryopreserved, the lots will be renewed by means of a subculture thereof or by requesting a new deposit from the depositor. The depositor will be required to analyze the authenticity of the samples of the first lot (not of subsequent lots) of the organisms prepared by the BEA. Except for the cryopreserved material, the BEA shall not store the material supplied by the depositor.
(c) Administrative Requirements and Procedure

(i) General

Language. The official languages of the BEA are Spanish and English.

Contract. The depositor will be required to complete the BEA application form, which constitutes a contract by means of which the depositor agrees to:

- supply all the information requested by the BEA;
- pay all the requisite fees;
- compensate the BEA for any claim that may arise as a result of the dispatch of samples, unless such claims are due to negligence on the part of the BEA;
- not withdraw his deposit during the period required for its due storage;
- authorize the BEA to supply samples, in accordance with the patent procedure requirements in force at that time.

Where an organism has been accepted for deposit, the BEA will notify the depositor accordingly and will remind him that he is subject to the terms and conditions of the contract.

Import and/or Quarantine Regulations. The type of organisms accepted by the BEA is not subject to import and/or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors must complete the application and access forms used by the BEA for deposits, according to the Budapest Treaty, equivalent to model BP/1.

Official Notifications to the Depositor. Receipt and declaration of viability are published in the compulsory international models BP/4 and BP/9 respectively. The certificate of receipt of information or a subsequent amendment of the scientific description and/or proposal for taxonomic designation is published in model BP/8. Notification of submission of samples to third parties is published in model BP/14. For other official notifications standard models will not be used.

Unofficial Notifications to the Depositor. If requested, the BEA will communicate by telephone, fax or electronic mail the date of deposit and entry number after the organism has been received, but before the official receipt is published. However, the depositor will be informed that the information is provisional and that it depends on the result of the viability tests. The BEA will also communicate the result of the viability analysis before the certificate therefor is published.

Supply of Information to a Patent Agent. As a matter of course, the BEA will ask the depositor for the name and address of his patent agent. If required, the BEA will supply copies of the receipt of the samples, the state of viability and any other information to the depositor and to 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 deposits under the Budapest Treaty, whether or not they were originally made for patent purposes. Any deposit previously made free of charge is subject, on conversion, to the payment of the storage fee specified in this technical memorandum, and also to whatever fees may be payable for successive updating. With the above exceptions, the administrative requirements for conversion are the same as those to be met for an original deposit effected under the Treaty. The date of deposit for such samples will then be that of the conversion.

(iv) Making a New Deposit

When the depositor makes a new deposit, he will be asked to complete the model form BP/2 and to attach the most relevant documents required by Rule 6.2. The receipt and certificate of viability for a new deposit will be published as a matter of course in the international models BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The BEA will inform third parties of the procedures for the correct filing of applications. In the case of requests where supporting authorization is required, the BEA will provide the requesting parties with the application forms used by industrial property offices.

Where requests are received from abroad, the BEA assumes that the depositor is familiar with the requirements for import from his country.

All the samples sent by the BEA come from lots containing its own preparations.

(b) Notification of the Depositor

The depositor will be informed, by letter and electronic mail, when samples of his organisms have been sent to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The BEA will publish the lists of deposits under the Budapest Treaty in its catalogues only with the written authorization of the depositor.
3. Schedule of Fees

(a) Storage:
   - Cryopreserved strains (Rule 6.1) ... Euros 800
   - Other methods ... case-by-case
(b) Issuance of viability statement (Rule 10.2) ... 50
(c) Furnishing of samples (Rule 11) ... 60 (plus dispatch cost)
(d) Communication of information (Rule 7.6) ... 50

4. Guidance for Depositors

No provision.
1. Requirements for Deposit

(a) **Kinds of Microorganisms that May Be Deposited**

Bacteria, archaea, filamentous fungi, yeast and plasmids, which may be preserved, without any significant alteration of their properties, by freezing or freeze-drying, and which belong to a risk group up to 3(*) according to the Spanish legislation (*Guía Técnica para la Evaluación y Prevención de Riesgos relacionados con la Exposición a Agentes Biológicos del Instituto Nacional de Seguridad e Higiene en el Trabajo, RD 664/1997 de 12 Mayo*). Microorganisms belonging to risk group 3(*) (equivalent to risk group 3(**) in Directive 2000/54/EC), are those that may present a limited risk of infection for workers because they are not normally infectious by the airborne route.

The CECT does not accept the following biological material for deposit: algae and cyanobacteria, embryos, protozoa, animal cell lines, plant cell lines, mycoplasms, plant seeds, viruses and bacteriophages.

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

(b) **Technical Requirements and Procedures**

(i) **Form and Quantity**

Bacteria and fungi (including those containing plasmids) are accepted in freeze-dried form in ampoules or in the form of active cultures in agar solution. The depositor should send the CECT five ampoules or agar samples of each strain.

(ii) **Time Required for Viability Testing**

On average, the time required for testing the viability of bacterial samples is three days (or up to 14 days), and for fungus strains six days (or up to 30 days). The depositor has to take into account that, in certain cases, viability testing can take a great deal of time, as indicated by the bracketed figures.
(iii) Depositor Checks and Renewal of Stocks

The CECT prepares its frozen or freeze-dried batches by subculturing the materials supplied by the depositor. While the batches are being completed, further batches are prepared on the basis of frozen or freeze-dried samples from the first batch prepared. Whatever the method used for the preparation of batches or samples for distribution, the CECT freeze-dries, freezes and retains a portion of the original material supplied by the depositor. The delivery of the strains to the depositor for authenticity checking will be on request and the incidental administrative and delivery costs will be charged.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of the CECT are Spanish and English.

Contract. The application to the CECT that the depositor has to complete is a contract under which the depositor undertakes:

- to supply all the necessary information requested by the CECT;
- to pay all the necessary fees;
- to indemnify the CECT against any claim that may be made on it as a result of the sending of samples, except where the claims are due to negligence on the part of the CECT;
- not to withdraw the deposit during the time required for its period of storage;
- to authorize the CECT to supply samples in accordance with the requirements of the patent procedure applicable at the time.

Import and/or Quarantine Regulations. The packaging and dispatch of CECT cultures is done in accordance with the laws of the Convention of the Universal Postal Union. Depositors from abroad apply to the CECT in advance for information on the correct procedure for the dispatch of samples. Spain does not allow infectious substances to be sent by air mail, with the exception of samples originating in the United Kingdom and sent direct to the CECT. The samples may be sent direct to the CECT from other countries as freight in accordance with IATA rules.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors have to complete the application and accession forms used by the CECT for deposits under the Budapest Treaty, which are equivalent to model form BP/1.

Official Notifications to the Depositor. The receipt and viability statement 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 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 standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CECT communicates the date of deposit and the accession number by telephone after the microorganism has been received but before the official receipt is issued. In that case however the depositor is informed that the information is provisional and subject to the outcome of the viability tests. The CECT likewise communicates the finding of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The CECT routinely asks the depositor for the name and address of his patent agent and, if so requested, supplies 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 deposits under the Budapest Treaty, whether or not they were originally made for patent purposes. Any deposit previously made is subject, on conversion, to the payment of the storage fee specified in this technical memorandum, and also to whatever fees may be payable for successive updating. With the above exceptions, the administrative requirements for conversion are the same as those to be met for an original deposit effected under the Treaty. The date of deposit for such samples will then be that of the conversion.

(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

The CECT advises third parties of the correct procedures to be followed in making a valid request. In the case of requests requiring proof of entitlement, the CECT provides requesters with copies of model request form BP/12. When requests are received from abroad, the CECT presumes that the individual concerned is familiar with his country’s import requirements.

All samples of bacteria and fungi furnished by the CECT are taken from batches prepared by itself.

(b) Notification of the Depositor

The depositor is informed on model form BP/14 when samples of his microorganisms have been sent to third parties.
(c) **Cataloguing of Budapest Treaty Deposits**

The CECT issues lists of deposits under the Budapest Treaty in its catalogs only with the express written consent of the depositor.

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Storage of:</th>
<th>EUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Original deposits</td>
<td>640</td>
</tr>
<tr>
<td>(b) New deposits</td>
<td>80</td>
</tr>
<tr>
<td>(c) Extension of the duration of the storage beyond the period provided for in Rule 9 of the Regulations under the Budapest Treaty, per year</td>
<td>60</td>
</tr>
<tr>
<td>Issuance of a viability statement:</td>
<td></td>
</tr>
<tr>
<td>(a) Where a viability test is requested</td>
<td>111</td>
</tr>
<tr>
<td>(b) On the basis of the most recent viability test</td>
<td>45</td>
</tr>
<tr>
<td>Furnishing of samples</td>
<td>111</td>
</tr>
<tr>
<td>Communication of information</td>
<td>111</td>
</tr>
</tbody>
</table>

4. **Guidance for Depositors**

For the moment, the CECT does not publish specific information for the guidance of prospective depositors, but is always willing to provide information by telephone or correspondence.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

In accordance with Article 6(2)(v) of the Treaty and Rule (3)(b)(iii) of the Regulations, CCOS has set out the microorganisms in the table below accepted for the Patent Deposit.

In its public collection and its bank for confidential deposits, CCOS currently manages cell cultures and strains of bacteria, cyanobacteria, yeasts and filamentous fungi that all reach biosafety level 2.

CCOS can thus only accommodate species of microorganisms up to biosafety level 2, that are culturable with currently available methods and can be stored in the long term using the standard techniques, such as freeze-drying or storage in the gaseous phase of liquid nitrogen. Storage of cultures requiring constant re-proliferation will be provided only on payment of a surcharge.

CCOS also offers the establishment and preservation of biological material (BioService); in this case, the identity of materials produced by CCOS must be confirmed separately by the depositor. Apart from microorganisms, CCOS already preserves animal and human cell lines in secure and confidential conditions, as well as the primary cell lines of various customers.

The table below shows the organisms accepted for deposit and the quantity of samples to be provided by the depositor within the framework of “Patent Deposit”.

<table>
<thead>
<tr>
<th>Accepted organisms</th>
<th>Temperature and form of preservation</th>
<th>Quantity of samples to be deposited</th>
<th>Propagation and conservation suggested by CCOS</th>
</tr>
</thead>
</table>
| Bacteria (incl. cyanobacteria) | -196°C, cryoculture ²  
- 80°C, cryoculture  
4°C, lyophilisate | 21 or 2 | Yes |

1 If the propagation of the material can be carried out by CCOS, two samples are necessary.

2 Cryoculture: cryovials of 2 ml with 1 to 2 ml of microorganisms provided with the corresponding antifreeze medium.

Number of cells advised for cultures of animal and human cells >10⁶ ml, and >10⁷ ml for bacteria.
<table>
<thead>
<tr>
<th>Biological Material</th>
<th>Storage Conditions</th>
<th>Required Quantity</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cultures of animal cells (incl. Hybridomas)</td>
<td>-196°C, cryoculture</td>
<td>21 or 2</td>
<td>Yes (ZHAW)</td>
</tr>
<tr>
<td>Cultures of human cells</td>
<td>-196°C, cryoculture</td>
<td>21 or 2</td>
<td>Yes (ZHAW)</td>
</tr>
<tr>
<td>Nucleic acids (DNA, RNA, plasmids)</td>
<td>-80°C, vials</td>
<td>21</td>
<td>No</td>
</tr>
<tr>
<td>Fungi (incl. yeasts and molds)</td>
<td>-196°C, cryoculture, -80°C, cryoculture, 4°C, lyophilisate</td>
<td>21 or 2</td>
<td>Yes</td>
</tr>
<tr>
<td>Algae</td>
<td>-196°C, cryoculture</td>
<td>21</td>
<td>No</td>
</tr>
<tr>
<td>Bacteriophages</td>
<td>-196°C, cryoculture</td>
<td>21</td>
<td>No</td>
</tr>
<tr>
<td>Nematodes</td>
<td>-196°C, cryoculture</td>
<td>21</td>
<td>No</td>
</tr>
<tr>
<td>Protozoa</td>
<td>-196°C, cryoculture</td>
<td>21</td>
<td>No</td>
</tr>
</tbody>
</table>

(b) Technical Requirements and Procedures

(i) Form and Quantity

The depositor has to supply 21 samples of the biological material preferably in standard cryotubes (H 47.3 mm, D 13.1 mm, 2 ml, frozen) or as lyophilisates (room temperature) as stated in the table above. If the depositor choose CCOS BioService for the production of copies, depositor has to provide 2 samples in any kind of common scientific shape.

(ii) Time Required for Viability Testing

The required time for viability testing depends on the biological material and especially slow growing microorganisms need more time for testing (as indicated in brackets):

- **Bacteria:** 3 days (up to 21 days)
- **Cyanobacteria:** 14 days (up to 84 days)
- **Fungi, yeasts, molds:** 5 days (up to 28 days)
- **Cell cultures, hybridomas:** 14 days (up to 28 days)
- **Other biological material:** upon request

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3 The culture will be made in the laboratories of ZHAW from CCOS lab personal.
4 Suitable containers for samples; recommended concentration: 100 ng/container.
Depositor Checks and Renewal of Stocks

The depositor is responsible for replenishing the stock to ensure that there is sufficient stock to make the deposit available to the entitled public for the required period of the deposit.

CCOS offers the establishment and preservation of biological material by its BioServices; in this case, the identity of materials produced by CCOS must be confirmed separately by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. In accordance with Rule 3.1(b)(v) of the Regulations, the official languages of CCOS are: English, German, French and Italian.

Contract. CCOS and depositor close a general BioStorage contract prior to the deposit.

Import and/or Quarantine Regulations. If any import permit is required, CCOS will help for applying at the Federal Custom Administration (www.ezv.admin.ch).

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor has to duly complete the CCOS equivalent of model form BP/1 of 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, the depositor has to duly complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on the CCOS equivalent of model form 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.

Unofficial Notifications to the Depositor. The depositor may request any unofficial notifications by e-mail or telephone before the official receipt is issued.

Supply of Information to a Patent Agent. The depositor has to request CCOS to send copies of the receipt and viability statement to his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted to Patent Deposits. The old deposit contract will be terminated and the material will undergo the procedure as required for an original Patent Deposit without the need of supplying original material to CCOS.
(iv) **Making a New Deposit**

When making a new deposit, the depositor has to duly complete the CCOS equivalent of model form BP/2 and furnish copies of the documents referred to in Rule 6.2. The receipt and viability statement for a new deposit are issued on the CCOS equivalent of model form BP/5 and BP/9, respectively.

2. **Furnishing of Samples**

(a) **Requests for Samples**

CCOS will inform third parties of the procedure to be followed in order to make a valid request. In the case of requests requiring proof of entitlement, CCOS 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, CCOS will withhold samples of potentially hazardous microorganisms until the requesting party has provided evidence that he is allowed to work with such organism. In any case of requests, the requesting party has to comply with its own country’s requirements regarding import, handling of biological material and biosafety regulations.

All furnished samples of a Patent Deposit will be taken from batches of CCOS or depositor preparations, respectively.

(b) **Notification of the Depositor**

The depositor will be notified by CCOS when a sample of the deposited microorganism will be furnished to third parties on the CCOS equivalent of model form BP/14, unless the depositor has waived his right to receive such notification.

(c) **Cataloguing of Budapest Treaty Deposits**

In accordance with Rule 9.2 of the Treaty, CCOS does not list Patent Deposits in its public catalogue.

3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) for preservation:</td>
<td></td>
</tr>
<tr>
<td>a) storage for 30 years for microorganisms and cell cultures</td>
<td>2’500</td>
</tr>
<tr>
<td>b) storage for 30 years for DNA</td>
<td>1’500</td>
</tr>
</tbody>
</table>

(CH)

CCOS/2017
ii) issuance of the attestation referred to in Rule 8.2  50

iii) issuance of viability statements  50

iv) furnishing of samples of microorganisms or cell cultures  250

v) communication of information under Rule 7.6  50

Notes:

CCOS undertakes to furnish appropriately and in good time the samples of microorganisms deposited in accordance with Article 6(2)(viii) of the Treaty and Rule 2.3 of the Regulations.

The list above covers the basic services. A surcharge may be required for CCOS BioServices and deposits which require special conditions or care.

These charges are subject to value-added tax (VAT) according to the Swiss regulations in force and do not include shipment costs.

4. Guidance for Depositors

CCOS provides information about the procedure of making a deposit on its home page (www.ccos.ch) and can give advice by telephone or e-mail.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Nematodes, fungal isolates (including yeasts) and bacteria (including actinomycetes), other than known human and animal pathogens that can be preserved without significant change to their properties by methods of preservation in use. Organisms up to and including ACDP Category 2 deposits are accepted by the Collection.

Notwithstanding the foregoing, IMI reserves the right to refuse to accept any material for deposit which in the opinion of the Curator presents an unacceptable risk or is technically unsuitable to handle. IMI will accept organisms which do not significantly change after long-term nitrogen freezing or freeze-drying. A statement regarding potential pathogenicity and storage conditions is required when a deposit is made.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IMI prefers fungi to be submitted as healthy, clean, sporing cultures on agar slants suitable for preparing suspensions for freeze-drying and liquid nitrogen storage. The minimum number of replicates to be supplied by the depositor when making his deposit should be six.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of fungi accepted by the IMI is 14 days, but depositors should be aware that in some cases viability testing may take as long as 21 days.
Depositor Checks and Renewal of Stocks

Depending on the number and conditions of the cultures sent for deposit, the IMI either prepares frozen and lyophilized batches direct from the depositor’s material or from subcultures derived from it. New batches are prepared as necessary for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the IMI.

Whichever method is used for preparing batches of samples for distribution, the IMI nevertheless stores a portion of the original material supplied by the depositor.

Administrative Requirements and Procedures

(i) General

Language. The official language of the IMI is English. Communications in any other language are not accepted.

Contract. The IMI application form (CC PF1), which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the IMI;
- to replace the microorganism at his expense if the IMI is no longer able to furnish samples of it;
- to pay all necessary fees;
- to indemnify the IMI against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of the IMI;
- not to withdraw his deposit during the required storage period;
- to authorize the IMI to furnish samples according to the appropriate patent requirements.

After the deposit and acceptance procedure is complete, the depositor is sent a standard letter (form CC PF3) reminding him of his contractual obligations.

Import and/or Quarantine Regulations. Plant pathogenic fungi not indigenous to the United Kingdom are subject to import regulations. The IMI holds a permit for the import of such organisms and will advise the depositor of any necessary procedures.
(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the IMI application form CC PF1 referred to in (i), above, depositors are required to complete the IMI accession form (CC PF2) for Budapest Treaty deposits. The IMI 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 IMI has received such information.

Official Notifications to the Depositor. The receipt is issued on form CC PF3, which is the IMI version of the mandatory “international form” BP/4. The viability statement is issued on form CC PF5, which is the IMI version of the mandatory “international form” BP/9. A standard form (CC PF4) is used for notifying the depositor of refusal to accept a microorganism for deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The IMI acknowledges delivery of cultures, but this does not constitute acceptance. The IMI does not assign an accession number to the microorganism until it has been shown to be viable. After a positive result of the viability test has been obtained, the IMI will, if requested, telephone or telex this information along with the accession number before the issue of the official documentation.

Supply of Information to a Patent Agent. The IMI does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the IMI will supply copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The IMI does not permit the conversion of deposits not originally made for patent purposes to Budapest Treaty deposits. Deposits previously made for patent purposes outside the provisions of the Treaty may be converted provided that the depositor supplies the IMI with a new sample of the deposited microorganism and checks the authenticity of all batches prepared from it. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fees had been paid previously in respect of those deposits.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to send with it copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on forms CC PF3 and CC PF5, which are the IMI versions of mandatory “international forms” BP/5 and BP/9, respectively.
2. Furnishing of Samples

(a) Requests for Samples

The IMI advises third parties of the correct procedures to follow in order to make a valid request. However, in the case of requests requiring proof of entitlement, the IMI does not supply copies of request forms; these must be obtained from the relevant industrial property office.

Notwithstanding any entitlement to receive samples under patent regulations, the IMI will furnish samples of plant pathogens that require a permit to be worked with in the United Kingdom only to third parties in the United Kingdom who have such a permit. The IMI will supply requesting parties who do not hold a permit with the necessary application form and will furnish samples when the requesting party confirms that he has obtained a permit. When responding to requests from overseas (other than from the United States of America), the IMI assumes that the requesting party has met the import requirements of his own country. In the case of requests from the United States of America, samples of plant pathogens are sent via the United States Department of Agriculture quarantine authority.

All samples furnished by the IMI are from batches of its own preparations which, whenever possible, have been made direct (i.e., without subculture) from material supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The IMI does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage of each strain</td>
<td>600</td>
</tr>
<tr>
<td>Issuance of a viability statement</td>
<td>80</td>
</tr>
<tr>
<td>Furnishing of a sample</td>
<td>55</td>
</tr>
<tr>
<td>Issuance of an attestation</td>
<td>25</td>
</tr>
<tr>
<td>Communication of information</td>
<td>25</td>
</tr>
</tbody>
</table>

The fees paid in the United Kingdom are subject to Value Added Tax at the current rate.

4. Guidance for Depositors

The IMI makes available detailed notes for the guidance of depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

- Freshwater and terrestrial algae and free living protozoa, and
- Marine algae, other than large seaweeds.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms should be submitted for deposit as liquid or agar slope cultures. The minimum number of replicates that must be provided by the depositor when making his deposit is six. Algal cultures must contain a minimum of $10^2$ to $10^3$ cell/ml, depending on the species, and three plants in the case of seaweeds. The minimum number of cells in cultures of protozoa must be decided by negotiation.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of algae and protozoa accepted by the CCAP is seven days, but depositors should realize that in some cases viability testing may take as long as 35 days.

(iii) Depositor Checks and Renewal of Stocks

Except where the depositor’s original material is preserved by freezing, as is the case with some algae, the CCAP prepares its own batches of the microorganism at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. In cases where original material has been cryopreserved, stocks are renewed by subculturing these or by asking the depositor for a new deposit. The depositor is required to test for authenticity samples from the first (but not any subsequent) batch of his microorganism prepared by the CCAP.
Except for cryopreserved strains, the CCAP does not store original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCAP is English. Communications in any other language are not accepted.

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

- to provide all necessary information requested by the CCAP;
- to replace the microorganism at his expense if the CCAP is no longer able to furnish samples of it;
- to pay all necessary fees;
- to indemnify the CCAP against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of the CCAP;
- not to withdraw his deposit during the required storage period;
- to authorize the CCAP to furnish samples according to the applicable patent requirements.

When a microorganism has been accepted for deposit, the CCAP notifies the depositor and reminds him that he is bound by the terms and conditions of its contract.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the CCAP are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the CCAP application form referred to in (i), above, depositors are required to complete the CCAP accession form for patent deposits. The CCAP 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 CCAP has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. The CCAP has its own standard forms notifying the depositor of acceptance of a microorganism (see (i), above) or of refusal to accept a microorganism, but standard forms are not used for other official notifications.
Unofficial Notifications to the Depositor. If requested, the CCAP will telephone or e-mail the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CCAP will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The CCAP routinely asks the depositor for the name and address of his patent agent. If requested, the CCAP will supply copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The CCAP does not have any deposits made for patent purposes outside the provisions of the Budapest Treaty and does not consider Rule 6.4(d) applicable in other cases.

(iv) Making a New Deposit

The CCAP does not require the depositor to complete a standard form when making a new deposit, but he must supply copies of the relevant documents and declarations required by Rule 6.2. The receipt and viability statement 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 CCAP 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 CCAP 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).

The CCAP furnishes samples in the belief that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the CCAP assumes that the requesting party has met the import requirements of his own country.

Except where material originally supplied by the depositor has been cryopreserved, as is the case with some algae, samples of microorganisms furnished by the CCAP are from batches of its own preparations of the microorganism.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The CCAP does not list Budapest Treaty deposits in its published catalog.
3. Schedule of Fees

(a) Storage:
   - cryopreserved strains 1’500
   - other methods of maintenance fee case-by-case basis

(b) Issuance of a viability statement 100

(c) Furnishing of a sample (plus expedition cost) 200

(d) Issuance of an attestation 20

The fees are subject to Value Added Tax where applicable.

4. Guidance for Depositors

The CCAP does not yet have notes available for the guidance of prospective depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Animal cell lines, human cell lines, genetically modified cell lines, and hybridomas that can be preserved without significant change to or loss of their properties by freezing and long-term storage. Viruses capable of assay in cell culture, eukaryotic and viral recombinant DNA as naked DNA or cloned in a host organism.

Organisms up to and including Advisory Committee on Dangerous Pathogens (ACDP) Category 4 and Advisory Committee on Genetic Modification (ACGM) Activity Class 4 are accepted for deposit.

Note that:

- No patent deposit should be sent to ECACC without a Biohazard Risk Assessment having been first received and reviewed by ECACC. Following favorable review of a Risk Assessment the customer will be invited to ship the material for deposit. Risk Assessment forms can be accessed from the ECACC website.

- Processing of material that requires handling at Containment Level 4 may require a longer period to completion depending on the availability of high containment facilities. The price charged for such high containment processing is necessarily higher to reflect the increased cost to ECACC.

- Genetically modified organisms evaluated as Activity Class 2 to 4 cannot be accepted until ECACC has obtained authorization from the UK Health and Safety Executive (HSE). ECACC has to pay a fee for this authorization and this will be charged to the customer (see below). A time of several weeks should be allowed for this approval process.

- ECACC reserves the right to refuse to accept any material for deposit that, in the opinion of the curator, presents an unacceptable risk or is technically unsuitable to handle.
ECACC will only accept organisms that do not significantly change after long-term storage at the appropriate temperature.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Animal Cell Cultures. Material submitted to the ECACC for deposit must be in the form of frozen cultures. The ECACC may refuse deposits which have not been packed in sufficient dry ice to keep them frozen during transit. The minimum number of replicates that must be provided by the depositor when making his deposit is 12. All animal cell cultures must contain at least $4 \times 10^6$ cells/ampoule. Any requests to deposit human embryo stem cell lines will be subject to current UK regulations and guidelines.

Recombinant DNA. Deposits are accepted in the form of frozen ampoules of a host organism containing plasmid or phage or naked plasmid or phage DNA. Plasmids and bacteriophage are accepted on condition that they can be preserved without significant change or loss of properties by freezing and long term storage. The minimum number of ampoules (all prepared at the same time) that must be provided by the depositor is 12, containing a culturable quantity of organisms which must be replaced, if required. Naked DNA should be deposited frozen in an appropriate solution e.g. 10mM, 1mM EDTA (pH7.5) in quantities suitable for electrophoretic analysis.

(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 ECACC is given below, but depositors should realize that, in some cases, viability testing may take longer. Customers will be advised of this prior to deposit being accepted.

<table>
<thead>
<tr>
<th>Organism Type</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viruses</td>
<td>21 days (or up to 28 days)</td>
</tr>
<tr>
<td>Animal cell cultures</td>
<td>14 days (or up to 21 days)</td>
</tr>
<tr>
<td>Recombinant DNA</td>
<td>14 days</td>
</tr>
</tbody>
</table>

(iii) Depositor Checks and Renewal of Stocks

The ECACC generally does not prepare its own batches of the deposited organisms, and when stocks are depleted by the furnishing of samples, the depositor will be asked to make a new deposit. The depositor is asked to check for authenticity samples of batches prepared by the ECACC.
(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the ECACC is English. Communications in any other language are not accepted.

Contract. The ECACC application form, which the depositor is required to complete, binds the depositor:

- to provide material only in the required form and quantity;
- to provide a biohazard statement;
- to pay all necessary fees including all charges for the transportation of deposits to the ECACC;
- to observe the terms and conditions of the Budapest Treaty;
- to accept the terms and conditions of deposit in the ECACC.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. The customer will be advised to obtain the regulatory documentation once ECACC has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Deppositor. As well as the ECACC application form referred to in (i), above, the depositor must complete an ECACC deposit form and biohazard statement. Different sets of forms are used for different kinds of microorganisms and the depositor should ask the ECACC for the set of forms appropriate to the microorganism he wishes to deposit.

At least 48 hours before the microorganism is dispatched the ECACC must be informed of the number of ampoules being sent, the method of transportation and the estimated time of arrival. If dispatch is by air, the ECACC must be told the flight number and destination, waybill number and handling agent for delivery.

The ECACC 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 ECACC has received such information.

Official Notifications to the Deppositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.
Unofficial Notifications to the Depositor. If requested, the ECACC will telephone or fax the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. The ECACC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, it will send 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 the 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, except that requirements relating to shipping procedures do not, of course, apply.

(iv) Making a New Deposit

The depositor is required to complete the ECACC deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform with the procedures mentioned previously in respect of shipping requirements.

2. Furnishing of Samples

(a) Requests for Samples

The ECACC does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the ECACC will withhold samples of potentially hazardous microorganisms until it has confirmed that the requesting party has the appropriate containment facilities to handle such organisms. When responding to requests from overseas, the ECACC assumes that the requesting party has met the import requirements of his own country, and the customer is responsible for provision of the relevant documentation to do so.

Samples furnished by the ECACC are usually from preparations supplied by the depositor.
(b) **Notification of the Depositor**

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) **Cataloguing of Budapest Treaty Deposits**

The ECACC does not list Budapest Treaty deposits in its published catalog.

### 3. Schedule of Fees

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>GBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Cell lines</td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>Deposit and storage, including certification and viability statement</td>
<td>950</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a (new or updated) viability statement</td>
<td>80</td>
</tr>
<tr>
<td>2.</td>
<td>Viruses</td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>Deposit and storage, including certification and viability statement</td>
<td>1,100</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a (new or updated) viability statement</td>
<td>150</td>
</tr>
<tr>
<td>3.</td>
<td>Eukaryotic and viral recombinant DNA either as naked DNA or cloned into a host organism</td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>Deposit and storage, including certification and viability statement</td>
<td>600</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a new (or updated) viability statement</td>
<td>80</td>
</tr>
<tr>
<td>4.</td>
<td>General</td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>Organisms requiring Level 4 containment</td>
<td>Price on application</td>
</tr>
<tr>
<td>(b)</td>
<td>ACGM 2 to 4 assessment and HSE registration charge</td>
<td>Price on application</td>
</tr>
<tr>
<td>(c)</td>
<td>Furnishing of a sample (excluding carriage costs)</td>
<td>100</td>
</tr>
<tr>
<td>(d)</td>
<td>Issuance of (new or amended) certification</td>
<td>50</td>
</tr>
<tr>
<td>(e)</td>
<td>Administration fee for amendments</td>
<td>50</td>
</tr>
</tbody>
</table>

Fees plus VAT, where applicable, are payable to the Health Protection Agency – Porton Down.

### 4. Guidance for Depositors

Guidance for depositors is provided on the ECACC application form.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria that can be preserved without significant change to their properties by freeze-drying and which are pathogenic to man and/or animals.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of bacteria are accepted by the NCTC either lyophilized or in agar slabs. The depositor is required to provide only one culture when making his deposit.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of bacteria accepted by the NCTC is four days, but depositors should realize that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The NCTC prepares its own lyophilized batches of bacteria at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples of the first batch of his microorganism (but not subsequent batches) prepared by the NCTC.

The NCTC does not store material originally supplied by the depositor.
(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NCTC is English. Communications in any other language are not accepted.

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

- to provide all necessary information requested by the NCTC;
- to replace the microorganism at his expense if the NCTC is no longer able to furnish samples of it;
- to pay all necessary fees;
- to indemnify the Health Protection Agency or the NCTC 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 NCTC;
- not to withdraw his deposit during the required storage period;
- to authorize the NCTC to furnish samples according to the applicable patent requirements.

A supplement to the NCTC application form requires the depositor to state whether he is acting on his own behalf or on behalf of the Organisation employing him.

Import and/or Quarantine Regulations. Animal pathogenic bacteria being sent from overseas are subject to import regulations (Importation of Animal Pathogens Order 1980; Statutory Instrument 1980 No. 1212). The HPA Centre for Infections, of which the NCTC is part, has a general license to cover the import of animal pathogens, but the depositor is required to give the NCTC his name and address and the scientific name of the organism to be deposited. Further information about the import of animal pathogens may be obtained from The Pathogens Licensing Team, DEFRA, Area 607, 1A Page Street, London SW1P 4PQ, United Kingdom.

The kinds of microorganisms accepted for deposit by the NCTC are not subject to quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NCTC application form referred to in (i), above, depositors are required to complete the NCTC accession form for Budapest Treaty deposits. The NCTC 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 NCTC has received such information.
Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. Letters, rather than standard forms, are used for all other official notifications.

Unofficial Notifications to the Depositor. The NCTC does not telephone or fax the date of deposit, accession number or result of the viability test in advance of the relevant official notifications.

Supply of Information to a Patent Agent. The NCTC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The NCTC does not accept deposits for patent purposes outside the provisions of the Budapest Treaty, nor does it permit the conversion of deposits previously made for scientific purposes to Budapest Treaty deposits. In the latter case, the NCTC requires the same organism to be redeposited under the terms of the Treaty. Thus Rule 6.4(d) does not apply.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit, and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The NCTC 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 NCTC 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 to receive samples under patent regulations, in the case of potentially dangerous microorganisms of ACDP Hazard Group 3, the requesting party must previously have been authorized by his head of department as being competent to request such organisms. This authorization, which must be made out on a special NCTC form, is required only once in respect of any one individual. When responding to requests from overseas, the NCTC assumes that the requesting party has met the import requirements of his own country.

The NCTC reserves the right to withhold the supply of samples to parties having outstanding debts in respect of any previous transactions with the NCTC until such debts have been settled.

All samples furnished by the NCTC are from batches of its own preparations.
(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCTC does not list deposits made under the Budapest Treaty in its published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Item</th>
<th>Service Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>Storage</td>
<td>GBP 450</td>
</tr>
<tr>
<td>(b)</td>
<td>Issuance of a viability statement</td>
<td>60 GBP</td>
</tr>
<tr>
<td>(c)</td>
<td>Furnishing of a sample (plus expedition cost)</td>
<td>45 GBP</td>
</tr>
<tr>
<td>(d)</td>
<td>30-year declaration for already deposited collection strains</td>
<td>50 GBP</td>
</tr>
</tbody>
</table>

Item (a) refers to Hazard Group 2 (fees for Hazard Group 3 increase by 50%). For items (c) and (d) the fees are subject to Value Added Tax at the current rate where appropriate.

4. Guidance for Depositors

The NCTC makes available to prospective depositors copies of *Industrial Property*, 1982, pp. 219 and 220, which contains information furnished by the United Kingdom Government in respect of the NCTC immediately prior to its acquisition of IDA status.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Yeasts, other than known pathogens, that can be preserved without significant change to their properties by freeze drying or storage in liquid nitrogen.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of yeasts are accepted by the NCYC either lyophilized or on agar slopes. The minimum number of replicates that must be provided by the depositor when making his deposit is two for lyophilized preparations and two for agar slope cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of yeasts accepted by the NCYC is five days, but depositors should be aware that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The NCYC prepares its own lyophilized batches of the microorganism at the time of deposit, by subculturing material supplied by the depositor. New batches are prepared from these whenever necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the NCYC.

The NCYC stores material originally supplied by the depositor only until its own procedures have been completed.
Administrative Requirements and Procedures

(i) General

Language. The official language of the NCYC is English. Communications in any other language are not accepted.

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

- to provide all necessary information requested by the NCYC;
- to replace the microorganism at his expense if the NCYC is no longer able to furnish samples of it;
- to pay all necessary fees;
- to indemnify the NCYC against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of the NCYC;
- not to withdraw his deposit during the required storage period;
- to authorize the NCYC to furnish samples according to the applicable patent requirements.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the NCYC are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NCYC application form referred to in (i), above, depositors are required to complete the NCYC accession form for patent deposits. The NCYC 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 NCYC has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. A standard form is used for notifying the depositor of refusal to accept a microorganism for deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NCYC will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The NCYC will similarly communicate the result of the viability test before the viability statement is issued.
Supply of Information to a Patent Agent. The NCYC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the NCYC will supply copies of the receipt and viability statement to either the depositor or his patent agent, but not to both.

(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 Treaty.

(iv) Making a New Deposit

The NCYC does not require the depositor to complete a standard form when making a new deposit, but he must supply copies of the relevant documents and declarations required by Rule 6.2. The receipt and viability statement 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 NCYC 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 NCYC 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). When responding to requests from overseas, the NCYC assumes that the requesting party has met the import requirements of his own country.

All samples furnished by the NCYC are from batches of its own preparations.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCYC does not list Budapest Treaty deposits in its published catalog.
3. **Schedule of Fees**

<table>
<thead>
<tr>
<th>Description</th>
<th>GBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Storage – Deposit under the Budapest Treaty</td>
<td>700</td>
</tr>
<tr>
<td>(b) Extension of the duration of the storage beyond the period provided for</td>
<td>70</td>
</tr>
<tr>
<td>in Rule 9 of the Regulations under the Budapest Treaty, per year</td>
<td></td>
</tr>
<tr>
<td>(c) Issuance of a viability statement</td>
<td>100</td>
</tr>
<tr>
<td>(d) Furnishing of a sample (plus postage and packaging costs)</td>
<td>225</td>
</tr>
</tbody>
</table>

The fee is payable to National Collection of Yeast Cultures (NCYC) and subject to VAT at the current rate, where applicable.

4. **Guidance for Depositors**

The NCYC does not produce a standard letter or guidance notes for prospective depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

NCIMB accepts bacteria (including actinomycetes), yeasts, non-pathogenic fungi and bacteriophages up to and including ACDP Group 2 and Class 1 genetically modified microorganisms (GMOs).

Class 2 GMOs may be accepted for deposit but this is on a case by case basis only. In these instances the period for completion of a deposit would be much longer (minimum 45 days) and additional expenses will be incurred for administration charges in fulfilling regulatory requirements.

All deposits should be able to withstand preservation by either freeze-drying or freezing over liquid nitrogen without any significant change to their properties.

Plasmids, including recombinants, either

(i) cloned into a bacterial or actinomycete host, or
(ii) as naked DNA preparations

As regards (i), above, the hazard category of the host with or without its plasmid must be no higher than ACDP Group 2.

As regards (ii) above, the phenotypic markets of the plasmids must be capable of expression in a bacterial or actinomycete host and must be readily detectable. In all cases, the physical containment requirements must not be higher than level II as defined by the UK Genetic Manipulation Advisory Group (GMAG) and the properties of the deposited material must not be changed significantly by liquid nitrogen freezing or freeze-drying;

NCIMB also accepts orthodox seeds i.e. those can be dried to a low moisture content and stored at -20°C (or lower) without damage. All arable crops and many small seeded tree species produce orthodox seeds.
Recalcitrant seeds, such as those of cocoa, rubber, some tropical fruits and large seeded woody species, which cannot be dried without damage, are not accepted.

The acceptance of seeds by NCIMB and the furnishing of samples thereof are subject at all times to the provisions of the Plant Health (Great Britain) Order 1987, including any future amendments or revisions of the Order. Wherever possible, NCIMB should be notified, in advance, of all intended deposits of seeds, so that it can ensure that all relevant regulations are complied with. Any seeds received without prior notification could be delayed by customs and, possibly, returned to the depositor by them.

In addition to seeds, NCIMB also accepts plant cell tissue cultures, either frozen or as active cultures. As with seeds, all relevant regulations should be complied with.

In all cases, NCIMB reserves the right to refuse to accept any material for deposit which, in the opinion of the Curator, presents an unacceptable hazard or is technically too difficult to handle.

In exceptional circumstances, NCIMB may accept deposits which can only be maintained in active culture, but acceptance of such deposits, and relevant fees, must be decided on an individual basis by prior negotiation with the prospective depositor.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria and yeasts (including those containing plasmids) are accepted in any form; agar plate cultures should be avoided where possible, as these are too easily damaged in transit. Bacteriophages should be supplied as cell-free lysates along with a suitable host. NCIMB prefers to receive sufficient lysate for direct freezing and distribution but, where this is not possible, smaller volumes from which NCIMB may produce its own lysates are acceptable (see below).

Naked plasmids should be submitted as DNA solutions.

Seeds may be deposited either:

- pre-dried under the IBPGR (International Board for Plant Genetic Resources) recommended conditions appropriate to the species and ready for immediate low-temperature storage, or

- freshly harvested for drying by NCIMB, in which case they should be dispatched immediately after harvesting by express delivery in a hermetically sealed container.

In all cases, seeds should be fresh, healthy, undamaged, and free from soil or plant-derived debris. Less than 5% of the deposit should contain empty seeds.

Normally, a germination rate of at least 85% is required, but deposits may be accepted in certain circumstances where such a regeneration rate is impossible to achieve.
Plant cell tissue cultures may be deposited as frozen or active cultures. These can be in the form of undifferentiated cell cultures, embryogenic plant cell cultures and tissues and as in vitro shoot cultures.

The preferred number of replicates to be supplied by the depositor when making a deposit is as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Replicates</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria and yeasts</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Non-pathogenic fungi</td>
<td>2 active cultures or 20 free-dried/frozen replicates</td>
<td></td>
</tr>
<tr>
<td>Bacteriophages (at least 10^8 pfu/ml)</td>
<td>2 x 0.5 ml or 1 x 10 ml of cell-free lysate</td>
<td></td>
</tr>
<tr>
<td>Plasmids (DNA at least 20 mcg/ml)</td>
<td>1 x 10 ml</td>
<td></td>
</tr>
<tr>
<td>Seeds</td>
<td>250 seeds are required. It is in the depositor’s responsibility to ensure that there are enough seeds to make the deposit available throughout the life of the deposit. The IBPGR recommends a minimum of 4,000 for long-term storage and the United States Patent and Trademark Office requires a minimum of 2,500.</td>
<td></td>
</tr>
<tr>
<td>Plant cell tissue cultures</td>
<td>25 ampoules of appropriate cultures. NB: frozen shoot tips should, preferably, have 100 surviving apices</td>
<td></td>
</tr>
<tr>
<td>- Frozen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Active</td>
<td>3 cultures of suspension cultures or 5 cultures of undifferentiated cell or tissue cultures or 10 in vitro plantlets or shoots etc (eg. Shooty structures)</td>
<td></td>
</tr>
</tbody>
</table>

(ii) **Time Required for Viability Testing**

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria and yeasts</td>
<td>3 days (or up to 14 days)</td>
</tr>
<tr>
<td>Bacteriophages</td>
<td>3 days (or up to 5 days)</td>
</tr>
<tr>
<td>Plasmids(^1)</td>
<td>5 days (longer in slow growing hosts)</td>
</tr>
<tr>
<td>Seeds(^2)</td>
<td>depends entirely on the kind of seed</td>
</tr>
<tr>
<td>Plant cell tissue cultures</td>
<td>depends entirely on type or culture/material deposited</td>
</tr>
</tbody>
</table>

\(^1\) For plasmids, ‘viability’ testing consists of inserting the plasmid into a host. If the host is transformed, the ‘viability test’ is regarded as positive.

\(^2\) For seeds, ‘viability’ testing means testing for germination.
(iii) Depositor Checks and Renewal of Stocks

NCIMB prepares its own lyophilized and frozen batches of bacteria and yeasts at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. NCIMB prepares its own frozen batches of bacteriophages by subculturing material supplied by the depositor in those cases where insufficient lysate has been provided for large enough batches to be prepared by direct freezing of the depositor’s material. New batches are prepared from these as necessary for the renewal of diminishing stocks.

NCIMB prepares frozen batches of naked plasmids and dried batches of seeds direct from material supplied by the depositor. Diminishing stocks are renewed by asking the depositor to make a further deposit. Depositors are responsible for ensuring that there are sufficient stocks to make the deposit available during the life of the patent; this applies particularly to seeds. Frozen plant cell tissue cultures are prepared from active culture (or plant material) where this is deposited.

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

Whichever method is used for preparing batches of samples for distribution, NCIMB 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 NCIMB is English. Communications in any other language are not accepted.

Contract. The NCIMB application form which the depositor is required to complete constitutes a contract by which he is bound:

- to provide all necessary information requested by NCIMB;
- to pay all necessary fees;
- to indemnify NCIMB against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of NCIMB;
- not to withdraw his deposit during the required storage period;
- to authorize NCIMB to furnish samples according to the applicable patent requirements.

When a microorganism has been accepted for deposit, NCIMB notifies the depositor and reminds him that he is bound by the terms and conditions of its contract.
Import and/or Quarantine Regulations. Most of the kinds of microorganisms accepted by NCIMB are not subject to import or quarantine regulations. However, non-indigenous plant pathogens and certain seeds require a license to be worked with in Scotland, and prospective depositors of plant pathogens or seeds should contact NCIMB in advance so that the necessary arrangements can be made. Failure to comply with this requirement may result in the immediate destruction by NCIMB of the material submitted. Further information may be obtained from the Department of Agriculture and Fisheries for Scotland, Agricultural Scientific Services, East Craigs, Edinburgh EH12 8NJ, Scotland, United Kingdom.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as NCIMB application form referred to in (i), above, depositors are required to complete the NCIMB accession form for patent deposits. NCIMB 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 NCIMB has received such information.

Official Notifications to the Depositor. The receipt and viability statement 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 model BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. NCIMB has its own standard forms for notifying the depositor of acceptance of a microorganism (see (i), above) or of refusal to accept a microorganism, and for notifying the depositor of the inability of NCIMB to furnish samples. Individual letters, rather than standard forms, are used for other official notifications.

Unofficial Notifications to the Depositor. If requested, NCIMB will telephone, fax or email the date of deposit and the accession number after the microorganism has been received, but before the official receipt is issued. However, the depositor is informed that such information is provisional, pending the outcome of the viability test. NCIMB will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. NCIMB routinely asks the depositor for the name and address of his patent agent and, if requested, will supply copies of the receipt, 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 made for patent purposes. However, in the case of deposits previously made for scientific purposes and which are already generally available from NCIMB, the depositor is requested to authorize NCIMB to continue to make them so available and to waive his right to be notified of the release of samples. If the depositor is unwilling to accede to this request, he must make another deposit of the same organism under the Budapest Treaty. These constraints do not apply to deposits previously made for patent purposes or to deposits made confidentially for safekeeping. Any deposit previously made free of charge is subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. With the exceptions noted above, the administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.
(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. The receipt and 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

NCIMB 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, NCIMB 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, samples of plant pathogens or seeds requiring a permit to be worked with are not released to requesting parties in the United Kingdom until NCIMB has confirmed that such parties have obtained the necessary permit. Also, samples of all microorganisms are delivered only to recognized microbiological laboratories and not to private addresses. When responding to requests from abroad, NCIMB assumes that the requesting party has met the import requirements of his own country.

All samples of bacteria furnished by NCIMB are from batches of its own preparations; samples of bacteriophages may be from its own preparations or from material supplied by the depositor; samples of plasmids and seeds are from material supplied by the depositor.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

NCIMB lists Budapest Treaty deposits in its published catalog only with the specific written authorization of the depositor.

3. Schedule of Fees

<table>
<thead>
<tr>
<th></th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Storage according to the Budapest Treaty (comprising of the initial viability check, the preservation and storage of biological material):</td>
</tr>
<tr>
<td>1.1</td>
<td>Orthodox seeds, bacteria, fungi, plasmids, bacteriophages (plus the host as a separate deposit)</td>
</tr>
</tbody>
</table>

(GB) NCIMB/2019
1.2 Storage according to the Budapest Treaty (comprising of the initial viability check biological material preserved by the depositor and the storage of biological material) or conversion of a deposit made outside of the Budapest Treaty into a deposit according to the Budapest Treaty:
   - Bacteria, fungi, plasmids, bacteriophages (plus the host as a separate deposit)
   - Plant cell cultures

2 Viability
   Issuance of a viability statement according to Rule 10.2 of the Budapest Treaty:
   2.1 Where viability test is requested
   2.2 On the basis of most recent viability test

3 Furnishing of a sample
   3.1 To the depositor according to Rule 11.2 (i) of the Regulation under the Budapest Treaty
   3.2 To a third party according to Rule 11.2 (ii) and 11.3 of the Regulations under the Budapest Treaty

4 Communication of information under Rule 7.6 of the Regulations under the Budapest Treaty

5 Attestation referred to in Rule 8.2 of the Regulations under the Budapest Treaty

6 Additional charges
   6.1 Custom inspection fees At current rate
   6.2 Additional or replacement BP/4 or BP/9 125
   6.3 Phytosanitary certificates (for furnishing of seeds) 120

Fees are payable to NCIMB Ltd, and do not include, where applicable, VAT, handling charges, customs inspection fees (if applicable) or postage and packing.

4. Guidance for Depositors

NCIMB publishes a leaflet containing guidance notes for prospective depositors.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Animal cell lines, human cell lines and genetically modified cell lines that can be preserved without significant change to or loss of their properties from freezing and/or long-term storage.

Note that:

- No patent deposit should be sent to NIBSC without a Biohazard Risk Assessment having been first received and reviewed by NIBSC. For genetically modified cell lines this will include a formal review by the NIBSC Biological Safety Committee. Following a favourable review of the Risk Assessment the customer will be invited to ship the material for deposit. Risk Assessment forms can be accessed from the NIBSC website.

- Processing of material that requires handling at Containment Levels higher than Level 2 may require a longer period to completion depending on the availability of high containment facilities. The price charged for such high containment processing is necessarily higher to reflect the increased cost to NIBSC.

- NIBSC reserves the right to refuse to accept any material for deposit that, in its opinion, presents an unacceptable risk or is technically unsuitable to handle. NIBSC will only accept organisms that do not significantly change after long-term storage at the appropriate storage temperature.
(b) Technical Requirements and Procedures

(i) Form and Quantity

*Human Cell Cultures.* Human material submitted to NIBSC for deposit must be in the form of cryopreserved cultures. NIBSC may refuse deposits which have not been packed in a manner capable of maintaining the material in its original cryopreserved state during transit. The minimum number of replicates that must be provided by the depositor for deposit is 12. Deposits of human cell lines cultured as monolayers or suspension cultures must contain at least $1 \times 10^6$ cells/ampoule (of viable cells as determined prior to cryopreservation). Deposits of human cell lines, if cultured as colonies from colony fragments, must contain at least 4 colony fragments per ampoule or straw. Where the cell line requires a feeder cell layer to support its growth in culture, a sample of this material must also be provided in a quantity sufficient to support the necessary testing. Any requests to deposit human embryonic stem cell lines will be subject to current UK regulations and guidelines. Any request to deposit human cell lines other than embryonic stem cell lines must conform to EU regulations and guidelines.

*Animal Cell Cultures.* Material of animal origin submitted to NIBSC for deposit must be in the form of cryopreserved cultures. Cells whose distribution is prohibited under the CITES convention will not be accepted by NIBSC. NIBSC may refuse deposits which have not been packed in sufficient dry ice to keep them frozen during transit. The minimum number of replicates that must be provided by the depositor for deposit is 12. Deposits of animal cell lines must contain at least $1 \times 10^6$ cells/ampoule (of viable cells as determined prior to cryopreservation).

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by NIBSC is given below. Depositors should realize that viability testing may, under some circumstances, take significantly longer especially in the case of human embryonic stem cells. Depositors will be advised of this prior to the deposit being accepted.

<table>
<thead>
<tr>
<th>Type</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human embryonic stem cells</td>
<td>28</td>
</tr>
<tr>
<td>Human and animal cell cultures</td>
<td>14</td>
</tr>
</tbody>
</table>

(iii) Depositor Checks and Renewal of Stocks

NIBSC does not prepare its own batch of the deposited microorganisms. When the stock, originally provided by the depositor, has been depleted through furnishing samples, the depositor will be asked to provide a new deposit. In the case of human stem cell lines deposited in the UK Stem Cell Bank at NIBSC, it may be possible to transfer some of the stock held by the UKSCB to NIBSC patent deposit to provide a new stock of microorganisms. In this case, the depositor will be asked to check samples prepared by the UKSCB for authenticity.
(c) Technical Requirements and Procedures

(i) General

Language. The official language of NIBSC is English. Communications in any other language are not accepted.

Contract. The NIBSC deposit form, which the depositor is required to complete, binds the depositor to:

- provide all necessary information requested by NIBSC;
- provide a biohazard statement;
- provide material only in the form and quantity required by NIBSC;
- pay all necessary fees, including all charges for the transportation of deposits to NIBSC;
- observe the terms and conditions of the Budapest Treaty;
- accept the terms and conditions of deposit at NIBSC;
- indemnify NIBSC against any claim which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of NIBSC.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. In the case of human embryonic stem cell lines this may include application to the UK Steering Committee for the UK Stem Cell Bank and the Use of Human Stem Cell Lines. The depositor will be advised to obtain the regulatory documentation once NIBSC has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NIBSC deposit form referred to in (i) above, the depositor must complete a NIBSC biohazard statement. In the case of human embryonic stem cell lines the depositor may also be required to complete the applicable form for the UK Steering Committee. The depositor should request information from NIBSC or the UK Stem Cell Bank concerning the appropriate forms.

At least 48 hours before the microorganism is dispatched the depositor must inform NIBSC of the number of ampoules being sent, the method of transportation and the estimated time of arrival. Dispatch must only be handled by couriers approved by NIBSC. If dispatch is by air, NIBSC must be told the flight number and destination, waybill number and handling agent for delivery together with their contact telephone number.

In the event of a later indication or amendment of the scientific description, and/or proposed taxonomic designation or other information supplied to NIBSC, the depositor must complete a revision form indicating the revised information.

(GB)

NIBSC/2013
Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. NIBSC will notify the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. NIBSC does not routinely ask the depositor for the name and address of their patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and their patent agent for which a charge will be made.

(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 providing an accession number was supplied at the time the original deposit was made. However, any deposits previously made free of charge are subject, on conversion, to the 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, except that requirements relating to shipping procedures do not apply.

(iv) Making a New Deposit

The depositor is required to complete the NIBSC deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform to the procedures mentioned previously in respect of shipping requirements. The receipt and viability statements for any new deposit will also be issued on the "international" forms BP/4 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

NIBSC does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, NIBSC will withhold samples of potentially hazardous microorganisms until it has confirmed that the requesting party has the appropriate containment facilities to handle such organisms. When responding to requests from overseas, NIBSC assumes that the requesting party has met the import requirements of his own country, and the customer is responsible for provision of the relevant documentation to do so.

(GB)
NIBSC/2013
(b) **Notification of the Depositor**

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) **Cataloguing of Budapest Treaty Deposits**

NIBSC does not list Budapest Treaty deposits in its published catalogue.

3. **Schedule of Fees**

Cell Lines

<table>
<thead>
<tr>
<th>Description</th>
<th>GBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Deposits and storage including provision of certification and viability statements</td>
<td>1,000</td>
</tr>
<tr>
<td>(b) Issuance of a new (or updated) viability statement</td>
<td>100</td>
</tr>
<tr>
<td>(c) Furnishing of a sample (excluding carriage costs)</td>
<td>100</td>
</tr>
<tr>
<td>(d) Issuance of (new or updated) certification</td>
<td>50</td>
</tr>
<tr>
<td>(e) Administration fee for amendments</td>
<td>50</td>
</tr>
</tbody>
</table>

Fees plus VAT, where applicable are payable to NIBSC.

4. **Guidance for Depositors**

Guidance for depositors is provided on the NIBSC deposit form.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

1. All strains of agriculturally and industrially important bacteria, yeasts, molds and Actinomycetales, EXCEPT:

(a) Actinobacillus (all species); Actinomyces (anaerobic/microaerophilic, all species); Afrizona (all species); Bacillus anthracis; Bartonella (all species); Bordetella (all species); Borrelia (all species); Brucella (all species); Clostridium botulinum; Clostridium chauvoei; Clostridium haemolyticum; Clostridium histolyticum; Clostridium novyi; Clostridium septicum; Clostridium tetani; Corynebacterium diphtheriae; Corynebacterium equi; Corynebacterium haemolyticum; Corynebacterium pseudotuberculosis; Corynebacterium pyogenes; Corynebacterium renale; Diplococcus (all species); Erysipelothrix (all species); Escherichia coli (all enteropathogenic types); Francisella (all species); Haemophilus (all species); Herellea (all species); Klebsiella (all species); Leptospiro (all species); Listeria (all species); Mima (all species); Moraxella (all species); Mycobacterium avium; Mycobacterium bovis; Mycobacterium tuberculosis; Mycoplasma (all species); Neisseria (all species); Pasteurella (all species); Pseudomonas pseudomallei; Salmonella (all species); Shigella (all species); Sphaerophorus (all species); Streptobacillus (all species); Streptococcus (all pathogenic species); Treponema (all species); Vibrio (all species); Yersinia (all species);

(b) Blastomyces (all species); Coccidioides (all species); Cryptococcus neoformans; Cryptococcus uniguttulatus; Histoplasma (all species); Paracoccidioides (all species);

(c) All viral, Rickettsial, and Chlamydial agents;

(d) Agents which may introduce or disseminate any contagious or infectious disease of animals, humans or poultry and which require a permit for entry and/or distribution within the United States of America;

(e) Agents which are classified as plant pests and which require a permit for entry and/or distribution within the United States of America;

(f) Mixtures of microorganisms;
(g) Fastidious microorganisms which require (in the view of the Curator) more than
reasonable attention in handling and preparation of lyophilized material;

(h) Phages not inserted in microorganisms;

(i) Monoclonal antibodies;

(j) All cell lines;

(k) Plasmids not inserted in microorganisms.

2. Recombinant strains of microorganisms, strains containing recombinant DNA molecules,
strains containing their own naturally occurring plasmid(s), strains containing inserted naturally
occurring plasmid(s) from another host, strains containing inserted constructed plasmid(s), and
strains containing viruses of any kind, excluding those already listed as nonacceptable, only if
the deposit document accompanying the microbial preparation(s) includes a clear statement that
progeny of the strain(s) can be processed at a Physical Containment Level of P1 or less and
Biological Containment requirements meet all other criteria specified by the U.S. Department of
Health and Human Services, National Institutes of Health Guidelines for Research Involving
Recombinant DNA Molecules, December 1978 (Federal Register, Vol. 43, No. 247-Friday,
December 22, 1978) and any subsequent revisions.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, fungi and yeasts are accepted as slant, stab or broth cultures, or as lyophilized
preparations. If the depositor wishes the NRRL to distribute his own lyophilized
preparations, he must supply these preparations in tubes of overall dimensions no greater than
50mm in length and 6mm outside diameter. The minimum number of replicates that must be
provided by the depositor when making his deposit is as follows: for bacteria, fungi and
yeasts, the NRRL requires the deposit of one or more preparations (slants, stabs, or
lyophilized preparations) if the NRRL is to distribute its own preparations. If the NRRL is to
distribute depositor’s preparations, 30 lyophilized preparations must be deposited.

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

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td>3 days (or up to 15 days)</td>
</tr>
<tr>
<td>Fungi</td>
<td>10 days (or up to 15 days)</td>
</tr>
<tr>
<td>Yeasts</td>
<td>10 days (or up to 20 days)</td>
</tr>
</tbody>
</table>
(iii) **Depositor Checks and Renewal of Stocks**

The NRRL stores and distributes lyophilized material supplied by the depositor, if this is his wish, or it makes its own lyophilized preparations 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 NRRL requires the depositor to check the authenticity of its lyophilized preparations. The viability statement issued by the NRRL contains a section in which the depositor can record the result of this test. If the depositor does not inform the NRRL of the results of this test within three months, the NRRL assumes that its preparations are equivalent to the depositor’s original deposit.

The NRRL does not accept plasmids, except when they are contained in a living host microorganism.

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

(c) **Administrative Requirements and Procedures**

(i) **General**

*Language.*** The official language of the NRRL is English. Communications in any other language are not accepted.

*Contract.*** The NRRL does not enter into any written contract with the depositor defining the liabilities of either party. However, by completing the NRRL deposition form, the depositor surrenders any right to withdraw his deposit during the required storage procedure, accepts NRRL policy on the handling and distribution of patent deposits, and accepts responsibility for the authenticity of NRRL preparations of his microorganism.

*Import and/or Quarantine Regulations.* Import and/or quarantine regulations do not apply to the kinds of microorganisms accepted by the NRRL for deposit.

(ii) **Making the Original Deposit**

*Requirements to Be Met by the Depositor.* Depositors are required to complete the NRRL Budapest Treaty Deposition Form. The NRRL 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 NRRL has received such information.

*Official Notifications to the Depositor.* The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively. (NRRL has modified the latter to include a section in which the depositor can record the result of his authenticity check of NRRL preparations of his deposit—see (iv), below.) Notification of furnishing 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 NRRL will telephone or e-mail the date of deposit and accession number after the microorganism has been received,
but before the official receipt is issued. The result of the viability test is not so communicated.

*Supply of Information to a Patent Agent.* If requested, the NRRL will supply copies of the receipt and viability statement to the depositor’s patent agent.

(iii) **Converting a Previous Deposit**

The NRRL does not permit the conversion of deposits not originally made for patent purposes to Budapest Treaty deposits. The administrative requirements for converting a deposit previously made for patent purposes are the same as those to be met with respect to an original deposit made under the Treaty, except that no fee is payable.

(iv) **Making a New Deposit**

The NRRL 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 NRRL does not advise third parties of the correct procedures to follow in order to make a valid request for samples. In the case of requests requiring proof of entitlement, third parties requesting a sample under European Patent Office regulations are supplied with the relevant EPO form, but otherwise the NRRL does not supply copies of model request form BP/12 or request forms used by other individual industrial property offices; these must be obtained from the appropriate industrial property office.

Although the NRRL does not knowingly maintain hazardous microorganisms or those requiring a permit to be worked with in the United States of America, the requesting party must be “skilled in the art” (of microbiological practice) before any microorganisms are shipped. If a microorganism being requested is a known producer of a restricted substance, e.g., a hallucinogen, the requesting party must furnish his drug registration number before he can be supplied with a sample. When responding to requests from overseas, the NRRL assumes that the requesting party has met the import requirements of his own country.

Samples of bacteria, fungi and yeasts furnished by the NRRL may be from batches of its own lyophilized preparations or from lyophilized preparations supplied by the depositor, depending on the wishes expressed by the latter at the time of deposit (see 1(b), above).

(b) **Notification of the Depositor**

Unless he has waived his right to be so notified, the NRRL notifies the depositor on form BP/14 each time a sample of his deposit is furnished to a third party.
(c) Cataloguing of Budapest Treaty Deposits

The NRRL does not publish any catalog.

3. Schedule of Fees

Applicable to all patent cultures deposited with the ARS Culture Collection (NRRL).

<table>
<thead>
<tr>
<th>Description</th>
<th>USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Deposit of each strain (payable at the time of deposit)</td>
<td>670</td>
</tr>
<tr>
<td>(b) Furnishing of a sample</td>
<td>40</td>
</tr>
</tbody>
</table>

Checks, in US dollars, should be made payable to the Agricultural Research Service, United States Department of Agriculture.

4. Guidance for Depositors

The NRRL makes available a detailed statement on policies and procedures and a standard letter of explanation.
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal viruses, animal cell cultures, bacteria (pathogenic and nonpathogenic), bacteriophages, embryos\(^1\), DNA, fungi (pathogenic and nonpathogenic), human cell cultures, hybridomas, oncogenes, plant cell cultures, plant viruses, plasmids (in host and not in host), protozoa (nonparasitic, parasitic and pathogenic), RNA, seeds and yeasts (pathogenic and nonpathogenic).

The highest acceptable containment level for deposits is biosafety level (BSL) 3 as described in the current edition of the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*.

When materials to be deposited cannot be tested for viability *in vitro*, ATCC should be contacted for guidance on whether or not the material can be accepted. In addition, some material may require special permits for transport to ATCC, and ATCC should be contacted in advance for assistance.

CDC = U.S. Centers for Disease Control and Prevention
NIH = U.S. National Institutes of Health

\(^1\) ATCC must be notified before sending.
(b) **Technical Requirements and Procedures**

(i) **Form and Quantity**

ATCC does not accept test tubes or other actively growing cultures. The number of replicates that must be provided by the depositor when making the deposit is as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microorganisms (either containing a plasmid or not containing a plasmid), including bacteriophages, fungi, algae, yeast and protozoa</td>
<td>25 cryopreserved or freeze-dried vials from same harvest (0.5 ml per vial)</td>
</tr>
<tr>
<td>Cell lines and hybridomas</td>
<td>25 cryopreserved vials from same harvest (2 – 6 million cells per vial)</td>
</tr>
<tr>
<td>Plasmids(^1) and vectors not in host (e.g., purified DNA, libraries associated rDNA material)</td>
<td>25 vials (100 ng per vial)</td>
</tr>
<tr>
<td>Animal and plant viruses</td>
<td>25 cryopreserved or freeze-dried samples (1 ml per vial)</td>
</tr>
<tr>
<td>Plant tissue cultures</td>
<td>25 cryopreserved vials. Must be callus tissue. Seed preferred</td>
</tr>
<tr>
<td>Seeds</td>
<td>25 packets (25 seeds per packet)</td>
</tr>
</tbody>
</table>

(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 ATCC will differ dependent on the type of material and the testing procedures provided by the depositor.

(iii) **Depositor Checks and Renewal of Stocks**

The ATCC generally does not prepare its own batches of material. In such cases, the depositor is responsible for replenishing the stock to ensure that there is sufficient stock to make the deposit available to the general public for the required period of deposit. However, ATCC may prepare additional samples whenever necessary for the renewal of distribution stocks.

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\(^1\) For plasmids, “viability” testing consists of inserting the plasmid into a host. If the host is transformed, the “viability test” is regarded as positive.
(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the ATCC is English. Communications in any other language are not accepted.

Contract. The ATCC 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, by completing the ATCC BP/1 deposit form, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganism will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The ATCC may need to obtain an import or domestic transfer permit from an US regulatory agency for the import of material into the United States or transfer across state lines. The ATCC will advise prospective depositors about import and quarantine regulations and the procedures that must be followed. Information may also be obtained from the Veterinary Services and/or the Plant Protection and Quarantine Biological Assessment Support Staff both at the US Department of Agriculture, Animal and Plant Health Inspection Service, and from the Department of Health and Human Services, Public Health Service, Office of Biosafety at the Centers for Disease Control.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete ATCC form BP/1 “Budapest Treaty Deposits” in all cases. 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 ATCC has received such information, the depositor must complete ATCC form BP/7-8.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and 9, which are combined in form BP/4-9. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/7-8. 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.

Supply of Information to a Patent Agent. The ATCC asks that the depositor supply the name, address, phone, fax number and email of the patent attorney or agent. The ATCC sends copies of the certificates and notifications to the depositor’s attorney or agent as indicated on the form BP/1.

(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

(US)

ATCC/2019
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 required for 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

New Deposit

In the event that the ATCC determines that a biological material is no longer viable, although originally found viable upon initial deposit, the depositor may replace the nonviable deposit with a new deposit. The deposit will retain its initial deposit number and date as long as (1) the replacement deposit is viable, (2) the ATCC receives the replacement deposit within three months of receipt by the depositor of the notification of nonviability, and (3) the ATCC receives a statement signed by the depositor alleging that the newly deposited biological is the same as that originally deposited. The only charges are for viability testing.

Supplemental Deposits

In the event that the ATCC determines that the deposit, although still viable, no longer retains the characteristics as originally thought, the depositor will be asked to provide a Supplemental Deposit. This deposit will obtain a new date and a new accession number. All the normal forms for deposit must be filled out and the regular fees for an original deposit apply.

2. Furnishing of Samples

(a) Requests for Samples

Generally, availability of the biological material is required only after the issuance of a pertinent patent. Prior to that time, the deposit need only be made available to a requesting party if (1) the Commissioner of the United States Patent and Trademark Office, in accordance with 35 U.S.C. paragraph 122, issues a decision to release such deposit; (2) the patent office of another country signatory to the Budapest Treaty issues such a decision to release the deposit to a particular requesting party; or (3) the original depositor requests in writing that the deposit be released to a particular requesting party. The ATCC will provide requesting parties with form BP/12 or request forms used by an individual industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the ATCC 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. For organisms considered potentially very dangerous, the requesting party must sign an assurance of acceptance of responsibility. Also, in some cases a permit is required to work with certain material in the United States of America, and a requesting party in the United States of America must obtain such a permit before he can receive a sample. If a valid request is received from overseas for a sample of a microorganism that would require a permit to be worked with in the United States of America, the ATCC advises the requesting party to check the import requirements of his own country. If the ATCC knows that a country requires an import permit for a microorganism (even if the United States of America does not), it will so advise a requesting party in that country.
(b) Notification of the Depositor

The ATCC offers a notification service in which a depositor is notified on form BP/14 of the deposit furnished to a third party. For the fee relating to this service, see below under 3 (Schedule of Fees).

3. Schedule of Fees

(a) Storage and issuance of a viability statement:
- 30 years of storage and notification of request
- Issuance of a viability statement

USD 2,500

(b) Furnishing of a sample
- All ATCC Cultures
- US Non-Profit Institutions
- Foreign Non-Profit Institutions
- Other US and Foreign Institutions

<table>
<thead>
<tr>
<th>Type</th>
<th>Fee per item</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ATCC Cultures</td>
<td>USD 86 - 281</td>
</tr>
<tr>
<td>US Non-Profit Institutions</td>
<td>USD 86 - 281</td>
</tr>
<tr>
<td>Foreign Non-Profit Institutions</td>
<td>USD 107 - 330</td>
</tr>
<tr>
<td>Other US and Foreign Institutions</td>
<td>USD 107 - 330</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biosafety Level</th>
<th>Fee range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>21 to 107</td>
</tr>
<tr>
<td>Level 2</td>
<td>90 to 310</td>
</tr>
<tr>
<td>Level 3</td>
<td>90 to 310</td>
</tr>
</tbody>
</table>

Because of the diversity of ATCC holdings, and the requirements for complicated and varied culture media and growth conditions, the fees for furnishing ATCC cultures vary. Therefore, the current fees have been listed as a range representing all currently available ATCC cultures.

4. Guidance for Depositors

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

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1 Additional handling and processing – dependent on destination and hazard level.

(US) ATCC/2019
1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Any algae (including single-celled microalgae and multicellular algae), eukaryotic protists, bacteria, archaea, or viruses from any aquatic environments (including freshwater, brackish, marine and hyper-saline), plant tissue cultures (terrestrial or aquatic) and seeds, and bacteria and fungi from terrestrial environments.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Deposited biological material is accepted by the NCMA in any form. However, the NCMA prefers viable frozen (2 mL) or lyophilized (freeze-dried) cultures. If the depositor is uncertain if the biological material can be cryopreserved, then the NCMA can determine an appropriate cryopreservation protocol via a separate contractual negotiation. For example, since many marine algae species cannot be cryopreserved, they must be maintained in perpetual culture to remain viable. The depositor must provide a minimum of six replicates for deposit (frozen or lyophilized) or duplicate 15 mL cultures (for live perpetual culturing). Algal cultures must contain a minimum of $10^2 - 10^5$ cells mL$^{-1}$ (depending on the species), a minimum of three plants are required for macroalgae (seaweeds), a minimum of $10^4 - 10^6$ cells mL$^{-1}$ are required for bacteria, a minimum of $10^4 - 10^6$ cells mL$^{-1}$ are required for archaea and protozoa, a minimum of $10^5 - 10^7$ particles mL$^{-1}$ are required for marine viruses, 2500 seeds (10 packs of 250) are required for orthodox crop seeds, and 20-40 shoots are required for vegetatively propagated plant tissue (depending upon plant type).

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of algae accepted by the NCMA is 30 days, but depositors must realize that, in some cases, viability testing of certain marine algae can take as long as 90 days. Bacteria, archaea and marine viruses can take up to 30 days (viruses require a viable host on which to propagate). Orthodox crop seeds can take <30 days and vegetatively propagated plant tissue can take between 30 and 40 days depending
on plant type. Note that all of these estimates are dependent on volume and NCMA’s workload at the time of deposit; in some cases testing timeline might be extended. When the deposited organisms cannot be tested for viability in vitro, the NCMA should be contacted to determine if the organism can be accepted for deposit.

(iii) Depositor Checks and Renewal of Stocks

Except where the depositor provides the original deposit in preserved state (by freezing or lyophilization), the NCMA prepares its own batches of the deposited biological material at the time of deposit by subculturing or freezing the biological material supplied by the depositor and then preserving the material using appropriate methods. Additional samples are prepared from the original deposit whenever necessary for the renewal of distribution stocks. In cases where the original deposit has been cryopreserved by the depositor, stocks are renewed by requesting that the depositor provide a new deposit or are renewed by thawing and subculturing (via a separate contractual negotiation). Perpetually-cultured biological material is transferred into fresh growth medium on average once every 21-90 days depending on the individual species.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NCMA is English.

Contract. The NCMA will enter into a specific contractual arrangement with the depositor. Among other things, the contract will outline the terms of payment, deposition details, relevant patent requirements and any specific arrangements for the term of the deposit.

Import and/or Quarantine Regulations. The kinds of deposits accepted by the NCMA are typically not subject to import or quarantine regulations; however, if this situation should change, then the depositor will be responsible for adhering to the import and quarantine regulations that must be followed, as well as any additional financial requirements, prior to deposit. If any special permits are required for shipment to the NCMA, then the NCMA should be contacted in advance for guidance.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. To make a deposit, please contact the NCMA by e-mail or phone so they can learn more about your proposed deposit. Following that conversation, depositors are required to complete the NCMA deposit form(s) for patent deposits and NCMA’s Terms and Conditions form. The NCMA 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 NCMA has received such information. Depositors will be invoiced upon acceptance of a completed deposit form (BP/1 or BP/AF1) and the NCMA Patent Deposit Terms and Conditions form. Payment must be received by the NCMA prior to the Depositor shipping NCMA its biological material. For safe arrival of your material, NCMA strongly encourages the Depositor to use a reputable courier service. After receiving and accepting your biological material, the NCMA will issue an official receipt (BP/4) for your deposit. Your first viability statement (BP/9) will also be furnished once the viability test is completed.
Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” NCMA BP/4 and BP/9, respectively. The NCMA has its own standard forms notifying the depositor of acceptance of a deposit or refusal to accept a deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, then the NCMA will telephone or e-inform the depositor of the date of deposit and accession number after the deposit has been received, but before the official receipt is issued. The NCMA will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NCMA routinely asks the depositor for the name, mailing address, telephone number and e-mail address of their patent attorney or agent.

If requested, then the NCMA will supply copies of the receipt and viability statement to both the depositor and the patent attorney or agent.

(iii) Converting a Previous Deposit

The NCMA does not have any deposits made for patent purposes outside the provisions of the Budapest Treaty and does not consider Rule 6.4(d) of the Budapest Treaty applicable in other cases.

(iv) Making a New Deposit

The NCMA requires the depositor to supply copies of the relevant documents and declarations required by Rule 6.2 of the Budapest Treaty. The receipt and viability statement for a new deposit are issued on mandatory “international forms” NCMA BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The NCMA will advise third parties of the correct procedures to follow to make a valid request. In the case of requests requiring proof of entitlement, the NCMA will provide requesting parties with copies of model request form NCMA BP/12 and/or request forms used by individual patent offices (where it has been supplied with such forms).

The NCMA furnishes the samples in the belief that it is the responsibility of the requesting party to ensure it complies with any relevant health and safety requirements. When responding to requests from outside of the United States, the NCMA assumes that the requesting party has met the import requirements of their home country.

(b) Notification of the Depositor
Depositors will be notified by either letter or electronic communication when samples of their deposit have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCMA usually does not list Budapest Treaty deposits in its published catalog; however, if the depositor or a competent patent office instructs the NCMA to make samples of a deposit available to the public, then that deposit will be listed in the then-current NCMA published catalog.

3. Schedule of Fees

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage of non-seed deposits – frozen or lyophilized for 30 years</td>
<td>3,000</td>
</tr>
<tr>
<td>Storage of seed deposits – dried and frozen for 30 years</td>
<td>1,500</td>
</tr>
<tr>
<td>Perpetual culturing of non-seed deposits for 30 years</td>
<td>25,000</td>
</tr>
<tr>
<td>Additional viability statement fee</td>
<td>500</td>
</tr>
<tr>
<td>Furnishing of Microorganisms sample fee</td>
<td>200</td>
</tr>
</tbody>
</table>

4. Guidance for Depositors

Upon request, the NCMA will provide an e-brochure that describes the NCMA’s requirements and practices for patent-related deposits.