JP – JAPAN

NITE PATENT MICROORGANISMS DEPOSITARY (NPMD),
NATIONAL INSTITUTE OF TECHNOLOGY AND EVALUATION (NITE)

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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	12 tubes

(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.

Plasmids	1 day
Bacteria	3 days
Yeasts	5 days
Actinomycetes, fungi and bacteriophages	7 days
Embryos	7 days
Animal cell cultures (including hybridomas and human cell cultures)	3 to 4 weeks

(iii) Depositor Checks and Renewal of Stocks

The NPMD stores samples originally supplied by the depositor, and doest 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

	JPY
(a) Storage	
(i) refrigerated or frozen	
- original deposit (for 30 years)	113,700
- new deposit	50,500
- extension of storage duration (per year)	13,700
(ii) subculturing of active culture	
- original deposit (for 30 years)	2,496,900
- new deposit	50,500
- extension of storage period (per year)	93,100
(b) Issuance of an attestation under Rule 8.2	2,900
(c) Issuance of a viability statement	
(i) when a viability test is carried out	35,100
(ii) based on the last viability test	2,900
(d) Furnishing of a sample (shipping fee excluded)	52,100
(e) Issuance of a communication under Rule 7.6	2,900
(f) Issuance of some kinds of certification	2,900

Fees do not include tax.
For each of the above items, a transaction fee of 4,300 JPY will be applied to all orders placed outside Japan.

4. Guidance for Depositors

The NPMD provides pamphlets for the guidance of prospective depositors.