

FR – FRANCE

COLLECTION NATIONALE DE CULTURES DE MICRO-ORGANISMES (CNCM)

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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 a 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 email 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.

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 inform by email 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.

(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

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

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 from the CNCM, which moreover is always available to provide additional information and guidance by telephone within the limits of its competence.