



## Resume of the deposit procedure

Depositor should:

- 1) Fill out the deposit documents (Form, Addendum and Contract).
- 2) Provide **12 samples from a single preparation, frozen** (conditioned in 1.8 or 2 ml cryotubes) **or freeze-dried**. Each sample containing at least  $10^6$  viable units (CFUs, PFUs, viable cells, etc.). This biological material is intended to be used as the primary batch and internal reference for the entire shelf-life deposit (which is at least 30 years).

*Furthermore, depositors are asked to supply the CNCM with any viable material which is not available at the CNCM and which is needed to propagate, to test and/or to store the microorganism. For the same purposes depositors are also asked to furnish any ingredient which is not free or is hard to access.*

- Within some hours after receiving the samples in due form, the registration number will be sent to the depositor.
- When the microorganism is officially accepted later on, the accession number will be identical to the registration number and the date of deposit will be the date of registration of this material.
- The CNCM can prepare its own batch from one of these original samples, named access batch (or secondary batch), under conditions that allow it to ensure the maintenance of the integrity of the microorganism. These samples are all maintained in liquid nitrogen.

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## Detailed Deposit Procedure

The CNCM provides any requester with copies of the appropriate deposit documents and is always pleased to give information and advice, within the range of its competence, by mail or e-mail.

### Preparing the Deposit

- The depositor should ensure that he meets all the requirements as to the form and quantity of the biological material to be transmitted for the purposes of deposit of the microorganism and should fill in the documents and give all the information asked for.
- The documents should be signed by the scientist responsible for the biological material and by the legal representative of the depositing organization.
- Depositors must send to the CNCM by e-mail ([cncm@pasteur.fr](mailto:cncm@pasteur.fr)) the deposit documents (form, addendum and contract) BEFORE the shipment of the biological material, so that the CNCM verifies that all the necessary information is given and that it is technically and legally able to accept the microorganism.
- The CNCM communicates by e-mail, as soon as possible, its agreement, or disagreement, with the necessary questions, comments and recommendations.
- The sending of the originals of the deposit documents, duly completed and signed, must precede or accompany the sending of the biological material.



### **Transfer of the biological material**

- Depositors are strongly advised to inform the CNCM when they plan to ship the biological material and to provide essential shipping information.
- Depositors must comply with any safety requirement for the transport/export of the material, particularly they must comply with the specific requirements for the packaging and for the labelling according to the hazard group of the microorganism and of the refrigerant, make sure that the package is accompanied by any documentation required by the relevant international and national Regulations concerning the transport and, where appropriate, the export of the material (export permit).

### **Registration of the microorganism**

As soon as the microorganism is received in a condition which does not preclude for evident reasons its acceptance, the CNCM registers the biological material in the exercise book and promptly communicates in writing the registration number to the depositor. THE COMMUNICATION OF THE REGISTRATION NUMBER OF THE BIOLOGICAL MATERIAL DOES NOT IMPLY THAT THE CNCM IS STRICTLY OBLIGED TO ACCEPT THE MICROORGANISM.

### **Acceptance of the microorganism**

The CNCM accepts the microorganism if:

1. all the requirements are complied with,
2. and the examination of the content of at least one of the transmitted samples has provided confirmation that by no fact the CNCM is precluded from performing the tasks relating to the microorganism that it must perform under the Treaty.

The receipt referred to in Rule 7.1 of the Regulations under the Treaty testifies to the acceptance of the microorganism. The receipt is issued on the international form BP/4. If the microorganism is accepted, its accession number is identical to the registration number of the relevant biological material.

The average time of acceptance of a microorganism is 90 days.

The notification of the acceptance, or of the refusal, is issued within a six-month time period after the date on which the depositor has complied with all the requirements concerning the deposit, except in some cases, where the growth of the microorganism is particularly slow, where the known conditions for propagation, tests and/or storage are not satisfactory, where some ingredients are difficult to access, or where irregularities or unexpected facts are noticed and need confirmation.

### **Validation of the deposit**

Once all tests have been performed by the CNCM to be sure that it is in a position to comply with the requirements under the Treaty, the first viability statement referred to in Rule 10.2.a)i) is issued on the international form BP/9. The first viability statement indicating a positive result testifies to the validity of the deposit. This statement is issued at the same time as the receipt.

**Request for authenticity check**

The CNCM can prepare its own batches by subculturing original material at the time of deposit and/or at any time during the period of the storage, if needed. Samples of those batches are sent to the depositor so that he can test them for all known properties and verify that these properties are preserved under the conditions used by the CNCM for growth and storage.

**Period of storage**

The duration of storage of any microorganism deposited under the Treaty is of at least 30 years after the date of deposit and at least five years after the most recent request for a sample.

The deposit cannot be cancelled during this period, neither by the depositor nor by the CNCM, regardless of the status of the applications involving the microorganism or the use of it.

The fee for deposit and storage is a single fee which includes tests and storage for the whole duration of the deposit. This fee is subject to Value Added Tax (VAT) according to French Law and must be paid after receipt of the relevant invoice.

**Fees for deposit**

Bacteria, filamentous fungi, yeasts .....	701.27 €
Virus propagated on cell lines .....	1 086.96 €
Cell lines .....	1 448.27 €