

## ES – SPAIN

### COLECCIÓN ESPAÑOLA DE CULTIVOS TIPO (CECT)

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#### 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, mycoplasmas, 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 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

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

	<u>EUR</u>
(a) Original deposits	700
(b) New deposits	80
(c) Extension of the duration of the storage beyond the period provided for in Rule 9, per year	105
(d) Issuance of a viability statement:	
(i) Where a viability test is requested	111
(ii) On the basis of the most recent viability test	50
(e) Furnishing of samples (plus postage and packaging costs)	130
(f) Communication of information	130
(g) Issuance of an attestation under Rule 8.2	50
(h) Duplicate or translation of Form BP/4	50
(i) Surcharge to cover bank and administrative costs	5-40

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.