

GB – UNITED KINGDOM

EUROPEAN COLLECTION OF AUTHENTICATED CELL CULTURES (ECACC)

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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 4×10^6 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.

Viruses	21 days (or up to 28 days)
Animal cell cultures	14 days (or up to 21 days)
Recombinant DNA	14 days

(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 Depositor. 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 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, 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

	<u>GBP</u>
1. Cell lines	
(a) Deposit and storage, including certification and viability statement	950
(b) Issuance of a (new or updated) viability statement	80
2. Viruses	
(a) Deposit and storage, including certification and viability statement	1,100
(b) Issuance of a (new or updated) viability statement	150
3. Eukaryotic and viral recombinant DNA either as naked DNA or cloned into a host organism	
(a) Deposit and storage, including certification and viability statement	600
(b) Issuance of a new (or updated) viability statement	80
4. General	
(a) Organisms requiring Level 4 containment	Price on application
(b) ACGM 2 to 4 assessment and HSE registration charge	Price on application
(c) Furnishing of a sample (excluding carriage costs)	100
(d) Issuance of (new or amended) certification	50
(e) Administration fee for amendments	50

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.