

DEPOSIT OF BIOLOGICAL MATERIAL FOR PATENT PURPOSES: INFORMATION SHEET

NCIMB offers a patent deposit service for biological material. This document explains the procedures involved in making a deposit, how much it costs, and the conditions whereby the deposited biological material is made available to third parties.

INTERNATIONAL RECOGNITION OF DEPOSITS

NCIMB holds the status of International Depository Authority under the Budapest Treaty on the International Recognition of the Deposit of Biological Material for the Purposes of Patent Procedure (1977) and Implementing Regulations (1981).

- This means that biological material deposited with NCIMB under the Treaty meets the deposit requirements of patent offices in all countries party to the Treaty. A full list of these countries is available on the WIPO web site.
- Patent deposits can also be made outside of the Budapest Treaty.

TYPES OF BIOLOGICAL MATERIAL ACCEPTED

NCIMB accepts:

- *Bacteria, yeasts, bacteriophages and plasmids* (either cloned into a bacterial host or as purified DNA preparations), including recombinants, provided that:
 - their hazard rating and physical containment requirements are no greater than ACDP Group 2 or ACGM class 1
 - they can be preserved by freeze-drying or liquid nitrogen freezing without significant change to their properties.
- *Orthodox plant seeds*, i.e. those that can be dried to a low moisture content and stored at temperatures lower than -20°C without damage. All arable crops and many small seeded tree species produce orthodox seeds. Please note that recalcitrant seeds, which cannot be dried without damage, are not accepted.
- *Plant cell tissue cultures*: these can be deposited as active cultures, e.g. shoot tips and callous tissue, or as frozen cultures.

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WHEN TO DEPOSIT

Your patent agent will tell you the latest date by which a deposit must be made.

- We recommend that you make your deposit as early as possible to allow time for the required viability checks and relevant paper work to be completed. Viability testing can take up to a week from date of receipt for bacteria, and longer for seeds or plant cell tissue cultures, depending on the variety.
- The date of deposit is defined as the date on which we receive a viable sample of your biological material. If your biological material is not viable when we receive it, there is no deposit. To make a valid deposit, a further sample must be sent. It is therefore important to allow time for viability testing of more than one sample to be undertaken.

HOW TO DEPOSIT

Application (QF57) and accession forms (QF79 A, B or C) must be completed and returned to us before, or with, the biological material to be deposited.

- The application form gives our terms and conditions for the acceptance of deposits and constitutes our contract with you.
- The accession form records the information that we need in order to deal with the biological material quickly, correctly and safely.
- Additional forms are required for the deposit of a GMO (QF 70), or a depositor's own risk assessment may be used.
- Full and accurate completion of these forms is required for compliance with the Budapest Treaty.

BACTERIA AND YEASTS

- Please send two cultures of each strain to be deposited.
- We accept freeze dried cultures, agar slopes, stabs or broths.

PHAGES

- Bacteriophages should be sent as cell-free lysates containing at least 10⁸ pfu/ml.
- Two aliquots of 10ml of lysate are required.
- A suitable host must also be deposited.

PLASMIDS

- Plasmids may be deposited either already transformed into hosts or as purified DNA preparations.
- Our requirements for the former are the same as for any other bacterial strains (see above).
- For purified plasmids we need 10ml of a preparation containing at least 20 mcg of DNA/ml, together with a suitable host.
- For cosmid or phage DNA we require 1.5ml of an aqueous solution containing at least 125 mcg DNA/ml, together with a suitable host.

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Seeds

- A minimum of 250 seeds are required for an initial deposit. The US Patent and Trademark Office requires a minimum of 2500 seeds to be deposited prior to the issue of a patent. Note: the International Board of Plant Genetic Resources recommends a minimum of 4000 seeds for long term storage.
- Deposited seeds must be fresh, healthy, undamaged, and free from soil or plant debris.
- Less than 5% of the deposit should contain empty seeds.
- Seeds may be deposited either pre-dried under IBPGR recommended conditions appropriate to the species and ready for immediate low temperature storage, or ready to be dried by NCIMB, in which case they should be despatched as soon as possible after harvesting in a sealed container.
- A germination rate of at least 85% is normally required, but deposits may be accepted in certain circumstances where this is impossible to achieve.
- NCIMB is licensed to accept and import genetically manipulated seeds (class 1 only), but we must be notified in advance of all deposits so that we can ensure that the relevant regulations are complied with.
- Plant seeds from outside of Europe normally require a phytosanitary certificate. Seeds of certain plant species that are prohibited may be deposited with a special import license.

ADDITIONAL SEED DEPOSITS

- For deposits of less than 2500 seeds, additional seeds can be deposited to fulfil this number at any time before the patent is issued. A separate accession form (QF543) should be completed for this.
- A viability test will be performed and a further viability statement and receipt issued.

PLANT CELL TISSUE CULTURES

- Frozen deposits: 25 ampoules of appropriate cultures are required. Frozen shoot tips should have 100 surviving apices.
- Active deposits: three vials of suspension cultures, five vials of undifferentiated cell or cell tissue cultures, or ten *in vitro* plantlets or shoots etc (e.g. shooting structures).
 - Plant cell tissue cultures from outside of Europe normally require a phytosanitary certificate. Tissue cultures of certain plant species that are prohibited may be deposited with a special import license.

ACKNOWLEDGEMENT OF DEPOSIT

UNOFFICIAL NOTIFICATION

We will contact you or your patent agent as soon as we receive your deposit, with an NCIMB accession number and a provisional date of deposit. Please note this provisional notification is not evidence that you have made a valid deposit. Results of viability testing are required before official notification can be made.

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NON-VIABLE DEPOSITS

If your biological material proves to be non-viable, we will inform you immediately so that you can send a replacement as soon as possible. This replacement will have a new date of deposit, and if it is a Budapest Treaty deposit, a new accession number.

OFFICIAL NOTIFICATION

When we have tested the viability of your deposit, you and/or your patent agent will be sent an official receipt and viability statement (Budapest Treaty forms BP4 and BP9), which state the accession number, date of deposit and whether your biological material was found to be viable.

These are important documents that you may be requested to produce for examination by a patent office. You will also need them if you have to make a new deposit of the same biological material at a later date.

DEPOSITOR CHECKS

We may ask you to check a culture for authenticity, and to inform us of the result. If we do not hear from you within three months, we assume you are satisfied with the cultures. Depositor checks may also be carried out at the request of the depositor.

RELEASE OF CULTURES

BUDAPEST TREATY DEPOSITS

Every time a sample of your biological material is released, you will be officially notified of the name and address of the recipient. Biological material is only made available to those entitled to receive it under Rule 11 of the Treaty, i.e.

- the patent office(s) with which your application has been filed;
- anyone having your specific written authorisation to receive a culture;
- anyone making their request on an official form on which the relevant patent office has certified that they are entitled to receive a culture;
- In certain cases, where a patent has been granted and published (e.g. in the US), no certification is required. In these circumstances, incontrovertible evidence that the patent has been issued is required before a sample is released.

OTHER PATENT DEPOSITS

Biological material deposited outside of the Budapest Treaty is released on your authorisation or on the authorisation of the patent offices that you specify. Some patent offices, notably in the USA and Germany, may require you to obtain a declaration from us as to the permanence and availability of non-Budapest Treaty deposits. We supply these for a small charge. Samples will be made available according to the terms of those declarations.

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FEES FOR PATENT DEPOSIT SERVICES

VAT is payable where appropriate

MATERIAL TYPE	SERVICES INCLUDED	COST
Bacteria, yeasts, plasmids, bacteriophages, seeds	<ul style="list-style-type: none"> • The first viability test. • Storage for at least 30 years, and thereafter for at least five years after the most recent request for a sample. • Issue of all official notifications, except additional viability statements. 	£675
Frozen plant tissue cultures	<ul style="list-style-type: none"> • The first viability test. • Storage for at least 30 years, and thereafter for at least five years after the most recent request for a sample. • Issue of all official notifications, except additional viability statements. 	£1000
Active plant tissue cultures	<ul style="list-style-type: none"> • The first viability test. • Storage for at least 30 years, and thereafter for at least five years after the most recent request for a sample. • Issue of all official notifications, except additional viability statements. 	£1500
Phage or cosmid DNA	Packaging for transformation	£60 per deposit
Seeds	Additional deposits	£200 per deposit
All material	Additional viability statements	£100 per statement

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