



A Guide to the Deposit of Biological Material for Patent Purposes



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

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Patents

Historically, the patenting system was developed to stimulate innovation - offering protection in exchange for disclosure allowed other inventors to understand the latest advances and build on them to develop new technologies.

For many inventions, disclosure requires a written description and drawings. In the case of inventions that are, or require the use of biological material, disclosure includes the deposit of the biological material in a recognised institution.

International Depository Authority

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 website.

Under Rule 9 of the Budapest Treaty, NCIMB will maintain confidentiality. However, it should be noted that third parties can access the deposited biological material through Rule 11 of the Budapest Treaty.

Patent deposits cannot be cancelled.

Materials Accepted

Types of Biological Material Accepted

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NCIMB accepts:



- **Bacteria, fungi (including 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 cryopreservation without significant change to their properties.

They can be deposited as active or frozen cultures.



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

However, we recommend that you make your deposit **as early as possible** to allow time for the required viability checks and paperwork to be completed. The length of time required for a viability test can vary between strains or varieties of material deposited.

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, no deposit has been made. 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.



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Forms

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 to deal with the biological material quickly, correctly, and safely.
- An additional form is required for the deposit of a genetically modified organism (QF70), or alternatively, if the depositor has already prepared a risk assessment, that can be submitted.
- Full and accurate completion of these forms is required for compliance with the Budapest Treaty.



Accession Forms

Use the correct accession form for the type of biological material that you are depositing:

- **QF79A** - Bacteria, yeast, bacteriophage, plasmids
- **QF79B** - Seeds
- **QF79C** - Plant cell tissue culture

All forms are available to download on our website.



Please note

Send material as early as possible to avoid delays to your patent application!

- Viability testing can take a week or more.
- If material is not viable on receipt, a further sample must be sent and the date of deposit will be delayed.

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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.
- For purified plasmids we need 10 ml of a preparation containing at least 20 mcg of DNA/ml, together with a suitable host.
- For cosmid or phage DNA we require 1.5 ml of an aqueous solution containing at least 125 mcg DNA/ml, together with a suitable host.



Phages

- Bacteriophages should be sent as cell-free lysates containing at least 10^8 pfu/ml.
- Two aliquots of 10 ml of lysate are required.
- A suitable host must also be deposited.

Bacteria and Yeasts

- Please send two cultures of each strain to be deposited. Mixed cultures are not accepted by NCIMB.
- We accept freeze dried cultures, agar slopes, stabs or broths.



Please note

We can accept plasmids, phages, bacteria and yeasts as cryopreserved by the depositor. We still have to carry out a viability check on any material preserved by the depositor.

The bacterial host constitutes an additional deposit and instructions for deposits of bacteria should be followed.

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Seeds

- 625 seeds must be deposited. Depending upon the variety, this can sometimes be difficult to achieve. If this is the case we can accept an initial deposit of 250 seeds to allow the application to proceed.
- If the initial deposit is less than 625 seeds, an additional deposit must be made to ensure that 625 seeds have been deposited in total.
- Deposited seeds must be fresh, healthy, undamaged, and free from soil or plant debris.
- The deposit should be less than 5% empty seeds.
- Seeds may be deposited either:
 - **pre-dried** under International Board for Plant Genetic Resources (IBPGR) recommended conditions appropriate to the species and ready for immediate low temperature storage, or
 - **ready to be dried** by NCIMB.
- **Germination rate:**
A germination rate of at least 85% is required for the long term storage of the seeds. Deposits of seeds with a germination rate of less than 85% may be accepted in certain circumstances.
- **Genetically manipulated seeds:**
NCIMB is licensed to accept and import genetically manipulated seeds (Class 1 only), but we must be notified of deposits in advance so that we can ensure the relevant regulations are complied with.
- **Phyosanitary certificate:**
Plant seeds may require a phytosanitary certificate. Seeds of certain plant species that are prohibited may be deposited with a special import license.



Remember

If an initial deposit of less than 625 seeds is made, it is the depositor's responsibility to deposit the additional seeds. There are additional charges for this.

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Additional Seed Deposits

- For initial deposits of less than 625 seeds, additional seeds must be deposited to fulfil this number.
- A separate accession form (QF543) should be completed for this and there will be an additional fee to pay.
- A viability test will be performed, and a further viability statement and receipt issued.

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 preservation of the biological material. Depositor checks may also be carried out at the request of the depositor.

Plant Cell Tissue Cultures

Deposits of frozen or active cultures can be made:

- **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 normally require a phytosanitary certificate.
 - Tissue cultures of certain plant species that are prohibited may be deposited with a special import license.

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Unofficial Notification

We will send an acknowledgment of receipt when we receive your biological material. The acknowledgment will include a provisional NCIMB accession number and the date of deposit pending a successful viability test.



Please note

Please note that this provisional notification is not evidence that you have made a valid deposit. A positive viability test is required before official notification can be made.

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 BP/4 and BP/9). These documents 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.

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 a new accession number.

Release of Cultures

Rule 11 of the Budapest Treaty

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 Budapest Treaty:

- 11.1 Interested industrial property offices
- 11.2 To the original depositor or to third parties with the authorisation of the depositor
- 11.3 Parties legally entitled either as a request from the responsible patent office or if evidence is provided that the patent has been granted.

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Additional services for patent depositors

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NCIMB offers a next-generation sequencing (NGS) service, and we can undertake whole-genome sequencing of microbial samples deposited for patent purposes with full genome annotation and additional bioinformatics analysis.

Whole genome sequencing is the ultimate in organism characterisation, and provides valuable information about microbial strains used in patented processes.

For example, the sequence information provides provenance, and can be used to identify infringement.

Please contact enquiries@ncimb.com for details.



Patent Deposit Process

Inform NCIMB about future deposit

Complete the following forms and send to patents@NCIMB.com prior to shipping.

- Application form QF57
- Accession form:
 - QF79 A (for bacteria, yeasts, bacteriophage or plasmids)
 - QF79 B (for seeds) or
 - QF79 C (for plant tissue culture)
 - GMO form if applicable
- Forms are available on our website: <https://www.ncimb.com/patent-deposit-and-storage-services/patent-deposit-service>

Send biological material to be deposited

- Please ensure biological material is appropriately packaged to avoid damage in transit.
- Any category 2 strains or GMOs must be packaged according to UN model regulations.
- Enclose the completed forms in the package with the material to be deposited.
- For seeds, a phytosanitary certificate may be required.

Receive unofficial acknowledgement of receipt

- We will contact you to let you know that we have received your biological material.
- This acknowledgement includes a provisional NCIMB accession number for the material, and date of deposit.
- It is not evidence of a valid deposit for patenting purposes.
- You have not made a valid deposit until viability testing has been successfully completed.

Viability testing

- We will undertake viability testing of your deposit. If your biological material proves to be non-viable or contaminated, we will inform you immediately so that you can send a replacement as soon as possible.
- A valid patent deposit has not been made until viability testing has been successfully completed.
- The time required for viability testing can vary depending on the material deposited.

Don't forget additional seed deposits if required

- If an initial deposit of less than 625 seeds is made, it is the depositor's responsibility to deposit additional seeds. Additional seeds can be deposited at any time before the patent is issued.
- A separate accession form (QF543), which is available on our website, should be completed for this and there will be an additional fee.
- A viability test will be performed, and a further viability statement and receipt issued.

Official notification

- When we have completed viability testing of your deposit you and/or your patent agent will be sent an official receipt and viability statement (Budapest Treaty forms BP/4 and BP/9), which state the accession number, date of deposit and whether your biological material was found to be viable.
- No valid patent deposit has been made until you receive an official receipt from us stating that your biological material has been found to be viable.

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Fees for Patent Deposit Services

For up to date information on fees for our patent deposit service visit our website at:

<https://www.ncimb.com/patent-deposit-and-storage-services/patent-deposit-service>

or contact patents@ncimb.com

Issues That Commonly Arise

We find that depositors can sometimes underestimate the time required for viability testing. It is important to remember that viability testing can take up to a week for bacteria and longer for seeds. Moreover, if the samples sent are not viable or contaminated, the process will have to be repeated, so it is important to allow plenty of time for this stage of the process.



NCIMB Limited
Ferguson Building
Craibstone Estate
Bucksburn
Aberdeen AB21 9YA
United Kingdom

t. +44 (0) 1224 009333
e. enquiries@ncimb.com
w. www.ncimb.com

 @ncimb
 ncimb-ltd
 ncimbltd