

DEPOSIT OF ORGANISMS FOR PATENT PURPOSES

INFORMATION SHEET

This leaflet describes the patent depositor services available from **NCIMB**; for many years one of the world's leading culture collections. It explains in straightforward terms the few simple procedures involved in making a deposit, how much it costs, and the conditions whereby the deposited strain is made available to the public.

International Recognition of Deposits

NCIMB is recognised throughout the world as a depository for organisms that are the subject of patent applications. The Collections hold the status of **International Depository Authority** under the **Budapest Treaty**^{*}, which means that an organism deposited under the Treaty with **NCIMB** meets the deposit requirements of patent offices in all countries party to the Treaty. These include patent offices in the United Kingdom, the United States of America, Japan, the Soviet Union, most European countries, and the European Patent Office itself.

Organisms accepted

NCIMB accepts **bacteria** (including actinomycetes), **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 as the case may be, and provided that they can be preserved by freeze-drying or liquid nitrogen freezing without significant change to their properties.

* Budapest Treaty on the International recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977) and Implementing Regulations (1981).

** Advisory Committee on Dangerous Pathogens and Advisory Committee on Genetic Manipulation.

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NCIMB also accepts 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.

Recalcitrant seeds, such as those of cocoa, rubber, some tropical fruits and large seeded woody species, which cannot be dried without damage, are not accepted.

When to deposit

Your patent agent will tell you the latest date by which a deposit must be made. As a general rule most patent offices require a deposit to be made no later than the filing date of the relevant patent application (or the priority date if priority is being claimed from an earlier application). However, it is advisable to make your deposit as early as possible and not to leave it until just before the deadline. This applies particularly to seeds deposits for which we have to obtain a licence before receiving them (see below). Always remember that as far as the patent office concerned, **the date of deposit is the date on which we physically receive a viable sample** of your organism. If your organism is not viable when we receive it (three or four days are needed to check it, longer for seeds), there is no deposit; you have to start again, although we shall not charge you again. If there is not enough time for a replacement to reach us before the deadline for deposit, there is nothing you or we can do about it. The same applies if your organism is delayed in the post. Therefore, above all, **do not wait until the last minute to make your deposit**.

How to deposit

You may make a deposit with **NCIMB** under the Budapest Treaty or not as you wish. The fee is the same in either case and the same forms must be completed. However, for deposits made outside the Budapest Treaty, it is your responsibility to tell us when and to whom cultures are to be released. Organisms deposited under the Treaty, on the other hand, are released according to Rule 11 of the Treaty (see below) and you do not have to worry about giving us specific instructions.

A deposit made outside the provisions of the Budapest Treaty can later be converted at no extra cost to one made under the Treaty. At present the Japanese patent office will recognise deposits made outside Japan **only** if they have been made (or converted into) deposits under the Budapest Treaty.

Forms. Our Application and Accession Forms (available on request or via our website) must be completed for all patent deposits. The Application Form gives our terms and conditions for the acceptance of deposits and constitutes our contract with you. We ask you to fill in two copies, one of which is for your own files. The Accession Form asks mainly for technical information about the organism itself and one copy should be completed for each organism being deposited. By completing these forms fully and accurately you automatically comply with all the administrative requirements of the Budapest Treaty and at the same time gives us all the information we need to enable us to deal with the organisms quickly, correctly and safely.

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It is often helpful for us to receive the completed forms in advance of the cultures themselves, particularly if special growth media are required, so that we can carry out the all-important viability test as quickly as possible. In the case of seeds, we **must** be notified in advance of deposit.

Deposit of bacteria and yeasts. We prefer to be sent two cultures of each strain to be deposited. One of these will be sub-cultured to make freeze dried and liquid nitrogen frozen preparations; the other will be kept in reserve. We will accept cultures in most forms - freeze dried, agar slopes, stabs, broths - but not on agar plates because they are so easily damaged in transit.

Deposit of phages. Bacteriophages should be sent to us as cell-free lysates containing at least 10^8 pfu/ml. We need 10ml of lysate which we can dispense directly into vials for freezing. A suitable host must also be deposited.

Deposit of 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, however, 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.

Deposit of seeds. Seeds may be deposited either:

- a) pre-dried under the **IBPGR*** recommended conditions appropriate to the species and ready for immediate low-temperature storage,
- or
- b) freshly harvested for drying by NCIMB, in which case they should be despatched immediately after harvesting by express delivery in a hermetically sealed container.

In all cases seeds should be fresh, healthy, undamaged, and free from soil or plant-derived debris. Less than 5% of the deposit should contain empty seeds.

Normally a germination rate of at least 85% is required, but deposits may be accepted in certain circumstances where such a regeneration standard is impossible to achieve.

At least 250 seeds are required, but it is in your own interest to send as many more as can be spared. (The IBPGR recommend a minimum of 4000 for long term storage). You should bear in mind that the US Patent and Trademark Office now normally requires a minimum of 2500 seeds to be deposited in connection with a US application. The US office will give an applicant the opportunity to justify a deposit of fewer seeds in a particular case. However, if you deposit fewer than 2500 seeds and if you intend to file a US application, it will be your responsibility to provide such justification to the US office.

NCIMB is licensed to accept and to import genetically manipulated seeds (class 1 only), but we **must** be notified in advance of all intended deposits of seeds so that we can ensure that all relevant regulations are complied with. It will also be

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necessary to complete additional forms to deposit a GMO. Any seeds received without prior notification may be destroyed immediately. Certain plant species may require a phytosanitary certificate or other declaration and some species may be refused on the grounds of plant health. NCIMB must therefore be notified in advance of all seed deposits, the name and origin of seed materials.

*International Board for Plant Genetic Resources

Acknowledgement of deposit

Unofficial notification. If asked, we will telephone or email the NCIMB accession number and date of deposit of your organism to your or your patent agent immediately we receive it, provided everything appears to be in order. We do not make a charge for this service, but it is important to understand that such a notification is both provisional and unofficial. It is **not** evidence that you have made a valid deposit; only when we have found your organism to be acceptable and viable can you be sure of that. If your organism proves to be non-viable, we will inform you immediately by telex or telephone, so that you can send a replacement as soon as possible. This replacement will, however, have a new date of deposit, and, if it is a Budapest Treaty deposit, a new accession number also. Under no circumstances can we assign an NCIMB accession number to an organism before we have received it.

Official notification. When we have tested the viability of your deposit, you will be sent a **receipt** and **viability statement**, which inform you officially of the accession number, date of deposit and whether your organism was found to be viable. These are important documents which (assuming your organism was viable when tested) you may be required to produce to a patent office as evidence that you have made a viable deposit on a particular date. Because of this, it is often essential that your patent agent receives copies as soon as they are issued. If you give us the name and address of your patent agent at the time of deposit, we shall be pleased to send him copies of the receipt and viability statement at no extra cost at the same time as we send them to you.

Do not lose the receipt and viability statement. You will need them again if for any reason you have to make a new deposit of the same organism at a later date.

Depositor checks

We make both freeze dried and frozen preparations of bacteria and yeasts, and frozen preparations of phages and plasmids. Because we are concerned that the cultures we maintain and eventually send out are representative of what was originally deposited, we may occasionally ask you to check a culture from each of our freeze dried and frozen batches 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 our preparations. Depositor checks may also be carried out at the request of the depositor.

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Release of cultures

Budapest Treaty deposits. Organisms are made available only to those entitled under Rule 11 of the Treaty to receive them, i.e. to the following:

- a) the patent office(s) with which your application has been filed;
- b) anyone having your specific written authorisation to receive a culture;
- c) anyone making his request on an official form on which the relevant patent office has certified that he is entitled to receive a culture;
- d) anyone requesting under US patent law an organism which is the subject of a granted and published US patent, provided that we are supplied with incontrovertible evidence that the patent has in fact been issued.

You are officially notified by us at no extra charge of the name and address of the recipient every time a sample of your organism is sent out.

Other patent deposits. Organisms deposited outside the provisions of the Budapest Treaty are 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 are happy to supply such declarations (at a small charge) in which case samples will be made available according to the terms of those declarations.

Fees

A once and for all fee of £650 (plus VAT where applicable) is payable for each organism deposited for patent purposes. This covers 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, and the issue of all official notifications except viability statements subsequent to the first. These are charged at £90. In the case of phage or cosmid DNA, a charge of £60 per deposit will be levied for packaging the DNA for transformation.

We normally invoice you as soon as the deposit procedures have been completed.

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