GB – UNITED KINGDOM

NATIONAL COLLECTION OF INDUSTRIAL, FOOD AND MARINE BACTERIA (NCIMB)

NCIMB Ltd
Wellheads Place
Dyce
Aberdeen
AB21 7GB

Telephone: +44 (0) 1224 009333
E-mail: patents@ncimb.com
Internet: http://www.ncimb.com

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

NCIMB accepts bacteria (including actinomycetes), yeasts, non-pathogenic fungi and bacteriophages up to and including ACDP Group 2 and Class 1 genetically modified microorganisms (GMOs).

Class 2 GMOs may be accepted for deposit but this is on a case by case basis only. In these instances the period for completion of a deposit would be much longer (minimum 45 days) and additional expenses will be incurred for administration charges in fulfilling regulatory requirements.

All deposits should be able to withstand preservation by either freeze-drying or freezing over liquid nitrogen without any significant change to their properties.

Plasmids, including recombinants, either

(i) cloned into a bacterial or actinomycete host, or

(ii) as naked DNA preparations

As regards (i), above, the hazard category of the host with or without its plasmid must be no higher than ACDP Group 2.

As regards (ii) above, the phenotypic markets of the plasmids must be capable of expression in a bacterial or actinomycete host and must be readily detectable. In all cases, the physical containment requirements must not be higher than level II as defined by the UK Genetic Manipulation Advisory Group (GMAG) and the properties of the deposited material must not be changed significantly by liquid nitrogen freezing or freeze-drying;

NCIMB also accepts orthodox seeds i.e. those can be dried to a low moisture content and stored at - 20o C (or lower) 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.

The acceptance of seeds by NCIMB and the furnishing of samples thereof are subject at all times to the provisions of the Plant Health (Great Britain) Order 1987, including any future amendments or revisions of the Order. Wherever possible, NCIMB should be notified, in advance, of all intended deposits of seeds, so that it can ensure that all relevant regulations are complied with. Any seeds received without prior notification could be delayed by customs and, possibly, returned to the depositor by them.

In addition to seeds, NCIMB also accepts plant cell tissue cultures, either frozen or as active cultures. As with seeds, all relevant regulations should be complied with.

In all cases, NCIMB reserves the right to refuse to accept any material for deposit which, in the opinion of the Curator, presents an unacceptable hazard or is technically too difficult to handle.

In exceptional circumstances, NCIMB may accept deposits which can only be maintained in active culture, but acceptance of such deposits, and relevant fees, must be decided on an individual basis by prior negotiation with the prospective depositor.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The preferred number of replicates to be supplied by the depositor when making a deposit is as follows:

Material	**Form and quantity required**
Bacteria and yeasts	Two active cultures for production of replicates by NCIMB or 20 freeze dried / frozen replicates for immediate storage.
Non-pathogenic fungi	Two active cultures for production of replicates by NCIMB or 20 freeze dried / frozen replicates for immediate storage.
Bacteriophages (at least 10^8 pfu/ml)	2 x 0.5ml cell free lysate for production of replicates by NCIMB or 1 x 10ml cell free lysate for immediate storage. Host must also be supplied.
Plasmids as isolated DNA (DNA at least 20 mcg/ml)	1 x 10ml for immediate storage. Host must also be supplied.

Seeds	A minimum of 625 seeds are required. Seeds may be deposited either: (a) pre-dried under the IBPGR (International Board for Plant Genetic Resources) 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 dispatched 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 rate is impossible to achieve.
Plant cell tissue cultures	Plant cell tissue cultures may be deposited as frozen or active cultures. These can be in the form of undifferentiated cell cultures, embryogenic plant cell cultures and tissues and as in vitro shoot cultures. Plant tissue cultures may be deposited as: (a) Frozen as 25 cryovials of appropriate cultures. NB: frozen shoot tips should, preferably, have 100 surviving apices, or (b) Active with 3 cultures of suspension cultures or 5 cultures of undifferentiated cell or tissue cultures or 10 in vitro plantlets or shoots etc.

(ii) Time Required for Viability Testing

The time required for viability testing will depend upon the material deposited and the testing procedures required.

(iii) Depositor Checks and Renewal of Stocks

If required, NCIMB will prepare lyophilized and frozen batches of bacteria and yeasts at the time of deposit by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks.

NCIMB prepares frozen batches of bacteriophages by subculturing material supplied by the depositor in those cases where insufficient lysate has been provided for large enough batches to be prepared by direct freezing of the depositor's material. New batches are prepared from these as necessary for the renewal of diminishing stocks.

NCIMB prepares frozen batches of naked plasmids and dries batches of seeds directly from material supplied by the depositor. Diminishing stocks are renewed by asking the depositor to make a further deposit. Depositors are responsible for ensuring that there are sufficient stocks to make the deposit available during the life of the patent; this applies particularly to seeds.

Frozen plant cell tissue cultures are prepared from active culture (or plant material) where this is deposited.

The depositor may request a sample from lyophilized or frozen batches of their deposit, which have been prepared by NCIMB, for an authenticity check.

Whichever method is used for preparing batches of samples for distribution, NCIMB nevertheless freezes and stores a portion of the original material supplied by the depositor, wherever possible.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of NCIMB is English. Communications in any other language are not accepted.

Contract. The NCIMB application form which the depositor is required to complete constitutes a contract by which they are bound:

- to provide all necessary information requested by NCIMB;

- to pay all necessary fees;

- to indemnify NCIMB against any claims which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of NCIMB;

- not to withdraw their deposit during the required storage period;

- to authorize NCIMB to furnish samples according to the applicable patent requirements.

When a microorganism has been accepted for deposit, NCIMB notifies the depositor to remind them that they are bound by the terms and conditions of its contract.

Import and/or Quarantine Regulations. Most of the kinds of microorganisms accepted by NCIMB are not subject to import or quarantine regulations. However, non-indigenous plant pathogens and certain seeds require a plant health license to manipulate and store this material in Scotland. Prospective depositors of plant pathogens or seeds should contact

NCIMB in advance so that the necessary arrangements can be made. Failure to comply with this requirement may result in the immediate destruction of the material by NCIMB. Further details can be found on the Science and Advice for Scottish Agriculture (SASA) website (www.sasa.gov.uk).

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are to fill in an NCIMB application form, accession form and a GMO risk assessment (if applicable) for each microorganism deposited. These forms can be found on the NCIMB website.

NCIMB 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 NCIMB has received such information. However, a BP/7 can be completed for this.

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 BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. NCIMB has its own standard forms for notifying the depositor of acceptance of a microorganism or of refusal to accept a microorganism, and for notifying the depositor of the inability of NCIMB to furnish samples. Individual emails, rather than standard forms, are used for other official notifications.

Unofficial Notifications to the Depositor. NCIMB will email the date of deposit and the provisional accession number after the microorganism has been received, but before the official receipt is issued. However, the depositor is informed that the accession number is provisional, pending the outcome of the viability test. NCIMB will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. NCIMB routinely asks the depositor for the name and address of their patent agent and, if requested, will supply copies of the receipt, viability statement and any other information to both the depositor and their 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 made for patent purposes. However, in the case of deposits previously made for scientific purposes and which are already generally available from NCIMB, the depositor is requested to authorize NCIMB to continue to make them so available and to waive their right to be notified of the release of samples. If the depositor is unwilling to accede to this request, they must make another deposit of the same organism under the Budapest Treaty. These constraints do not apply to deposits previously made for patent purposes or to deposits made confidentially for safekeeping. Any deposit previously made free of charge is subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. With the

exceptions noted above, the administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is 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 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

NCIMB advises third parties of the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, NCIMB will provide requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices (where it has been supplied with such forms).

Notwithstanding any entitlement of third parties to receive samples under patent regulations, samples of plant pathogens or seeds requiring a permit to be worked with are not released to requesting parties in the United Kingdom until NCIMB has confirmed that such parties have obtained the necessary permit. Samples of all microorganisms are delivered only to recognized microbiological laboratories and not to private addresses. When responding to requests from abroad, NCIMB assumes that the requesting party has met the import requirements of their own country.

Samples of microorganisms furnished by NCIMB are from material supplied by the depositor or from material prepared by NCIMB.

(b) Notification of the Depositor

Depositors are notified on model form BP/14 when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

NCIMB lists Budapest Treaty deposits in its published catalogue only with the specific written authorization of the depositor.

3. Schedule of Fees

		GBP
1.	**Storage**	
1.1.	Storage according to the Budapest Treaty (comprising of the initial viability check, the preservation and storage of biological material):	
	- Orthodox seeds, bacteria, fungi, plasmids, bacteriophages (plus the host as a separate deposit)	1'164
	- Plant cell cultures	1'835
1.2.	Storage according to the Budapest Treaty (comprising of the initial viability check of biological material preserved by the depositor and the storage of biological material) or conversion of a deposit made outside of the Budapest Treaty into a deposit according to the Budapest Treaty:	
	- Bacteria, fungi, plasmids, bacteriophages (plus the host as a separate deposit)	907
	- Plant cell cultures	1'227
2.	**Viability**	
	Issuance of a viability statement according to Rule 10.2 of the Budapest Treaty:	
2.1.	Where viability test is requested	156
2.2.	On the basis of most recent viability test	62
3.	**Furnishing of a sample**	
3.1.	To the depositor according to Rule 11.2 (i) of the Regulations under the Budapest Treaty	121
3.2	To a third party according to Rule 11.2 (ii) and 11.3 of the Regulations under the Budapest Treaty	187
4.	**Communication** of information under Rule 7.6 of the Regulations under the Budapest Treaty	183
5.	**Attestation** referred to in Rule 8.2 of the Regulations under the Budapest Treaty	183
6.0	**Additional Charges**	
6.1	Custom inspection fees	at current rate
6.2	Additional or replacement BP/4 or BP/9	156
6.3	Phytosanitary certificates (for furnishing of seeds)	135
6.4	Extending the duration of storage over the one provided by Rule 9 of the Budapest Treaty	52 per year

Fees are payable to NCIMB Ltd. and do not include, where applicable, VAT, handling charges, customs inspection fees (if applicable) or postage and packing.

4. Guidance for Depositors

A guidance for depositors is available on the NCIMB website or by contacting patents@ncimb.com.