NL – NETHERLANDS (KINGDOM OF THE)

WESTERDIJK FUNGAL BIODIVERSITY INSTITUTE (CBS)

Uppsalalaan 8 3584 CT Utrecht

Mailing address: P.O. Box 85167 3508 AD Utrecht

Telephone: (31-30) 212 26 00 Facsimile: (31-30) 212 26 01

E-mail: patent@wi.knaw.nl Internet: www.wi.knaw.nl

Requirements for Deposit

(a) <u>Kinds of Microorganisms that May Be Deposited</u>

Fungi, yeasts, bacteria, plasmids in pure form or in a host of the kinds accepted by CBS and phages that can be maintained with routine laboratory techniques without significant modification during appropriate storage at low temperature, in liquid nitrogen or during storage in the lyophilized state. Strains requiring special cultural conditions can be accepted under special conditions and are subject to additional fees (on request). In cases of microorganisms considered to belong to a specific hazardous group, please contact us before sending them.

Mixtures of microbial cultures of more than two components will not be accepted. Mixtures of two components will only be accepted if these a) cannot be cultivated separately as pure cultures, (b) can easily be distinguished macroscopically and/or microscopically and (c) after a positive authenticity check by depositor.

Bacteriophages and plasmids need to be sent together with a suitable host, if such a host is not available in the public CBS collection. The non-publicly available host provided by the depositor needs to be deposited separately in the public CBS collection or as a separate deposit under the Regulations of the Budapest Treaty.

Genetically Modified Microorganisms (GMOs) are accepted by CBS when we are allowed to work with them in accordance with our national GMO regulations, please contact us before sending them.

The CBS collection reserves the right to refuse to accept for deposit, material, which in its view, represents an unacceptable hazard or which it is not in a position to process.

(b) <u>Technical Requirements and Procedures</u>

(i) Form and Quantity

The minimum number of replicates (active cultures growing in or on a suitable nutrient medium) that must be supplied by the depositor when making his deposit is as follows:

| Fungi | 2 agar cultures or 12 Iyophilized cultures plus 1 agar culture | |
|-------------------------|--|--|
| Yeasts | 2 agar cultures or 12 lyophilized cultures plus 1 agar culture | |
| Bacteria | 2 agar cultures or 12 lyophilized cultures plus 1 agar culture | |
| Plasmids (in hosts) | 2 (agar) cultures or 12 lyophilized cultures plus 1 agar culture | |
| Plasmids (purified DNA) | minimum quantity of 50 μ g | |
| Phages | 10 ml with a titre of at least 10° pfu/ml | |

The CBS prepares its own lyophilized and/or frozen batches of bacteria, fungi and yeast at the time of deposit by subculturing material supplied by the depositor at a fee of Euro 150 for bacteria or Euro 200 for fungi and yeast. A batch of 10 ampoules of freeze-dried material and/or a batch of 10 frozen straws of material are made, depending on the organism deposited. Plasmids deposited in pure form will be placed first in their suitable host before a batch of 10 ampoules freeze-dried material can be prepared. The preparation of a phage lysate with a sufficiently high titre can be done at a fee of Euro 500.

Whichever method is used for preparing batches of samples for distribution, the CBS keeps a portion of the original material supplied by the depositor if possible only.

(ii) <u>Time Required for Viability Testing</u>

The average length of time required for testing viability of the various kinds of microorganisms accepted by the CBS is given below, but depositors should realize that occasionally viability testing may take longer. This is especially likely for slow growing microorganisms or if unusual antibiotics or other additives are necessary in the medium.

Fungi, yeasts, bacteria, plasmids in hosts or purified DNA¹, phages weeks

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(iii) Depositor Checks and Renewal of Stocks

¹ A "viability test" for plasmids consists of transforming a suitable host with the plasmid. If the host is transformed, the "viability test" is regarded as positive.

The depositor is required to check the authenticity of a sample of the batch prepared by the CBS from the originally deposited material, and to inform the CBS on the result.

New batches of cultures are prepared by the CBS whenever it is necessary to renew diminishing stocks. The CBS can ask the depositor to check the authenticity of these new batches.

(c) Administrative Requirements and Procedures

(i) <u>General</u>

Language. The official language of the CBS is English. Communications are also accepted in Dutch.

Contract. The CBS does not enter into any written contract with the depositor defining the liabilities of either party but, by signing the CBS deposit forms, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganism will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. Certain microorganisms are subject to import and/or quarantine regulations. The CBS will advise depositors about these and will assist the depositor to make the necessary arrangements for transportation and, if necessary, licenses (fees on request). The CBS should be contacted for precise instructions in this regard, and, in cases of plant pathogens, further information may be obtained from: **National Plant Protection Organization of the Netherlands (NPPO-NL), NVWA,** Geertjesweg 15, Postbus 9102, 6700 NC Wageningen, The Netherlands.

The CBS should be contacted in advance if deposit of any plant pathogenic microorganism as listed in the Plant Health Regulation (EU) 2016/2031 is intended.

(ii) <u>Making the Original Deposit</u>

Requirements to Be Met by the Depositor. The depositor is required to complete the CBS-BP/1 form (the equivalent of model form BP/1) which is the deposition form used for making an Original Deposit under the regulations of the Budapest Treaty. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete the CBS-BP/7 form (the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, both in English. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/8. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. CBS will communicate by e-mail or by letter the date of deposit and unique CBS deposition number as soon as possible after the microorganism has been received, but before the official notification of receipt is issued. The

date of deposit and the CBS deposition number will only become official after the viability test has been done and has given a positive result.

Supply of Information to a Patent Agent. The CBS does not ask the depositor to give the name and address of his patent agent. Depending on the wishes of the depositor, the CBS will supply copies of the receipt and viability statement either to the depositor or to his patent agent, but not to both.

(iii) <u>Converting a Previous Deposit</u>

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. All converted deposits, even when the first previous deposit was made free of charge, are subject to the storage fee normally levied for Budapest Treaty deposits, with the exception of deposits previously made under the European Patent Convention. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete the CBS-BP/2 form (the equivalent of model form BP/2) which is the deposition form used for making a New Deposit under the regulations of the Budapest Treaty. The depositor is also required to supply copies of the relevant BP/4 and BP/9 forms in accordance with Rule 6.2 of the Budapest Treaty; otherwise the procedure is similar to that when making an Original Deposit. The receipt and viability statement for a New Deposit are issued on the mandatory "international" BP/5 and BP/9 forms.

2. <u>Furnishing of Samples</u>

(a) <u>Requests for Samples</u>

The CBS 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, the CBS 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, in the case of potentially hazardous microorganisms, the CBS will first ask the requesting party to confirm that he is competent to work with and allowed to handle them. Samples are not released to private persons not engaged in a relevant profession. When responding to requests from overseas, the CBS will ask the requesting party to inform if an import permit is required for that particular country. The requesting party must provide an import permit when needed to meet the import requirements of his own country.

Samples of fungi, yeasts and of bacteria furnished by the CBS are usually from batches of its own preparations, but samples of other microorganisms are usually from preparations supplied by the depositor.

(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

The CBS does not list Budapest Treaty deposits in its online published catalog.

3. <u>Schedule of Fees</u>

| (a) | Storage (30 years) | 650 |
|-----|---|----------|
| (b) | Conversion of a deposit | 650 |
| (c) | Preservation of stock material for the deposition of 30 years: | |
| | – bacteria | 150 |
| | – fungi and yeast | 200 |
| (d) | Prolongation of the duration of the storage over the one provided b of the Regulations under the Budapest Treaty | y Rule 9 |
| | – prolong for 15 years | 325 |
| | – prolong for 30 years | 600 |
| (e) | Issuance of a viability statement, except where Rule 10.2(e) of the Regulations of the Budapest Treaty applies: | |
| | if the viability test is to be carried out | 100 |
| | based on the last viability test | 50 |
| (f) | Communication of information | 50 |
| (g) | Issuance of an attestation | 35 |
| (h) | Furnishing of a sample: | |
| | - in accordance with Rule 11.2(ii), 11.3(a) and 11.3(b) of the Regu | ulations |
| | of the Budapest Treaty | 200 |
| | in accordance with Rule 11.2(i) of the Regulations of the Budape Treaty: | est |
| | – agar slant | 100 |
| | – freeze-dried ampoule | 50 |
| (i) | Surcharge to cover bank and administrative costs | 10 |

According to Dutch Tax Law, 21 % VAT will be added for customers within The Netherlands. For customers within Europe 21 % VAT will be added when no VAT number is given or when not applicable. For customers outside Europe no VAT will be added.

EUR

4. <u>Guidance for Depositors</u>

The CBS does not produce a standard letter or guidance notes for prospective Depositors. The specific requirements of Westerdijk Fungal Biodiversity Institute (CBS) can be found on the internet site: www.wi.knaw.nl. For more information, you can contact our Patent administration: patent@wi.knaw.nl.