#### **BG – BULGARIA**

# NATIONAL BANK FOR INDUSTRIAL MICROORGANISMS AND CELL CULTURES (NBIMCC)

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#### 1. Requirements for Deposit

# (a) Kinds of Microorganisms that May Be Deposited

Bacteria, actinomycetes, filamentous fungi, yeasts, animal cell lines, animal and plant viruses, microorganisms containing plasmids.

The NBIMCC accepts for deposit only those microorganisms which, pursuant to the Regulation No. 4 on the protection of workers from risks related to exposure to biological agents at work (SJ No. 105 dated 08.11.2002) or Directive 2000/54/EC, belong to hazard groups 1 and 2.

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

#### (i) Form and Quantity

The NBIMCC has the following requirements for the form and the quantity of the culture in which the microorganisms should be submitted for deposit:

Bacteria and fungi (including those containing plasmid) should be deposited in the form of three active cultures. Lyophilized cultures are also accepted but at least 10 samples.

Animal cell lines and hybridomas should be deposited in 12 frozen in liquid nitrogen cryotubes, each containing minimum  $5 \times 10^6$  cells.

Animal viruses are accepted as 20 frozen or freeze-dried samples.

In the case of plant viruses, at least 5 g fresh infected leaves should be deposited.

## (ii) Time Required for Viability Testing

The minimum and maximum lengths of time required for testing the viability of the various kinds of microorganisms accepted by the NBIMCC are as follows:

Bacteria from 3 to 14 days

Yeasts from 3 to 14 days

Microorganisms containing plasmid from 3 to 14 days

Fungi from 5 to 21 days

Animal cell lines and hybridomas from 7 to 14 days

Animal viruses 30 or more days

Plant viruses 30 or more days

## (iii) Depositor Checks and Renewal of Stocks

The NBIMCC prepares its own lyophilized and/or frozen batches of bacteria, actinomycetes, yeasts, fungi and microorganisms containing plasmids by subculturing material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. Nevertheless, the NBIMCC always keeps original material supplied by the depositor.

The NBIMCC does not prepare own batches of animal cell lines as well as animal and plant viruses. New batches are prepared from the depositor's original material for the renewal of stocks.

The depositor is required to test for authenticity samples from all batches after the preservation in NBIMCC.

#### (c) Administrative Requirements and Procedures

# (i) General

*Language*. The official language of the NBIMCC is Bulgarian. Communications are also accepted in English.

*Contract*. The NBIMCC does not enter into a written contract with the depositor defining the liabilities of either party.

*Import and/or Quarantine Regulations*. The kinds of microorganisms accepted by the NBIMCC are not subject to quarantine regulations. However, import regulations must be observed in respect of certain kinds of microorganisms accepted by the NBIMCC.

#### (ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the NBIMCC accession form equivalent of model form BP/1. The NBIMCC uses separate forms for the deposit of microorganisms (including those containing plasmid), animal cell lines, animal viruses and plant viruses.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, both in Bulgarian and English. The NBIMCC uses its own standard letters for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NBIMCC will telephone or e-mail the date of deposit and accession number before the official receipt is issued, but only after the viability test has been done and has given a positive result. Similarly, the NBIMCC will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NBIMCC does not ask the depositor for the name and address of his patent agent. However, if requested, the NBIMCC will supply copies of the receipt and the viability statement to either the depositor or his patent agent.

# (iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted to deposits under the Budapest Treaty. 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 are issued on mandatory "international forms" BP/5 and BP/9, respectively.

#### 2. Furnishing of Samples

#### (a) Requests for Samples

The NBIMCC advises third parties of the correct procedures to follow to make a valid request.

The NBIMCC furnishes a sample of a potentially hazardous microorganism under patent regulations to requesting parties after receiving a written statement proving that they are allowed to work with such organisms.

When responding to requests from overseas, the NBIMCC assumes the requesting party has met the import requirements of his own country.

# (b) <u>Notification of the Depositor</u>

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 NBIMCC does not list Budapest Treaty deposits in its published catalogue. If the depositor or a competent patent office instructs the NBIMCC to make samples of a microorganism available to anyone, that organism is listed in the next published NBIMCC catalogue.

# 3. Schedule of Fees

	BGN
(a) Storage- Deposit under the Budapest Treaty	1,200
(b) Issuance of a viability statement	120
(c) Furnishing of a sample	120
(d) Extension of storage duration (per year)	60

# 4. Guidance for Depositors

The NBIMCC does not have specific written notes for the guidance of depositors, but is always ready to offer advice by telephone or correspondence.