Guide to the Deposit of Microorganisms under the Budapest Treaty

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NOTE

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as the "Budapest Treaty" or the "Treaty") was concluded on April 28, 1977, and entered into force on August 19, 1980.

The fundamental principle of the Budapest Treaty is that all States party to it recognize a deposit made in any one of certain culture collections ("international depositary authorities") as sufficient for the purposes of their own patent procedure. The Treaty and the Regulations thereunder establish rules on deposits with international depositary authorities, storage and furnishing of samples of deposited microorganisms.

The purpose of this Guide is to present in a systematic manner information on the procedures and requirements concerning the deposit of microorganisms and to give practical advice to persons depositing microorganisms for patent purposes, on the one hand, and to anyone wishing to obtain samples of such microorganisms, on the other hand.

Following an introduction and a summary of the main features of the Budapest Treaty, the Guide is divided into two parts dealing, respectively, with the general requirements of the Treaty as they relate to the deposit of microorganisms and the furnishing of samples thereof (Part I), and the specific requirements of each of the international depositary authorities and of each of the industrial property offices of the States party to the Budapest Treaty as well as the African Regional Intellectual Property Organization (ARIPO), the Eurasian Patent Organization (EAPO) and the European Patent Organization (EPO) (Part II). Appendices to the Guide give a checklist of the points to be attended to when depositing microorganisms or requesting the furnishing of samples (Appendix 1); the full text of the Budapest Treaty and the Regulations (Appendix 2) and copies of the models of forms used under the Budapest Treaty and the Regulations (Appendix 3).

It is hoped that this Guide will assist depositors of microorganisms, international depositary authorities, industrial property offices and in general all concerned with the protection of biotechnological inventions to better understand and take advantage of the system of deposit of microorganisms provided for under the Budapest Treaty.

With the exception of Part II, which has been prepared by the International Bureau, the original text of the Guide has been written by Dr. Ivan Bousfield, former Executive Director and Curator of the National Collections of Industrial, Food and Marine Bacteria (NCIMB), Aberdeen, United Kingdom, to whom WIPO expresses its sincere appreciation.

Geneva, March 2006

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Australia (AU)
Lady Mary Fairfax CellBank Australia (CBA)
The National Measurement Institute (NMI)

Belgium (BE)
Belgian Coordinated Collections of Microorganisms (BCCM™)

Bulgaria (BG)
National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)

Canada (CA)
International Depositary Authority of Canada (IDAC)

Chile (CL)
Colección Chilena de Recursos Genéticos Microbianos (CChRGM)

China (CN)
China Center for Type Culture Collection (CCTCC)
China General Microbiological Culture Collection Center (CGMCC)

Czech Republic (CZ)
Czech Collection of Microorganisms (CCM)

Finland (FI)
VTT Culture Collection (VTTCC)

France (FR)
Collection nationale de cultures de micro-organismes (CNCM)

Germany (DE)
Leibniz-Institut DSMZ – Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)

Hungary (HU)
National Collection of Agricultural and Industrial Microorganisms (NCAIM)

India (IN)
Microbial Culture Collection (MCC)
Microbial Type Culture Collection and Gene Bank (MTCC)

Italy (IT)
Advanced Biotechnology Center (ABC)
Collection of Industrial Yeasts DBVPG
Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini" (IZSLER)

Japan (JP)
International Patent Organism Depositary (IPOD),
National Institute of Technology and Evaluation (NITE)
National Institute of Technology and Evaluation,
Patent Microorganisms Depositary (NPMD)

Latvia (LV)
Microbial Strain Collection of Latvia (MSCL)

Netherlands (NL)
Centraalbureau voor Schimmelcultures (CBS)

Poland (PL)
IAFB Collection of Industrial Microorganisms
Polish Collection of Microorganisms (PCM)

Republic of Korea (KR)
Korean Agricultural Culture Collection (KACC)
Korean Cell Line Research Foundation (KCLRF)
Korean Collection for Type Cultures (KCTC)
Korean Culture Center of Microorganisms (KCCM)

Russian Federation (RU)
National Research Center of Antibiotics (NRCA)
Russian Collection of Microorganisms (VKM)
Russian National Collection of Industrial Microorganisms (VKPM)

Slovakia (SK)
Culture Collection of Yeasts (CCY)

Spain (ES)
Banco Español de Algas (BEA)
Colección Española de Cultivos Tipo (CECT)

United Kingdom (GB)
CABI Bioscience, UK Centre (IMI)
Culture Collection of Algae and Protozoa (CCAP)
European Collection of Cell Cultures (ECACC)
National Collection of Type Cultures (NCTC)
National Collection of Yeast Cultures (NCYC)

National Collections of Industrial, Food and Marine Bacteria (NCIMB)
National Institute for Biological Standards and Control (NIBSC)

United States of America (US)
Agricultural Research Service Culture Collection (NRRL)
American Type Culture Collection (ATCC)
Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA)

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Introduction

(i) General

(ii) Information on Industrial Property Offices

AL Albania
AM Armenia
AT Austria
AU Australia
AZ Azerbaijan
BA Bosnia and Herzegovina
BE Belgium
BG Bulgaria
BH Bahrain
BN Brunei Darussalam
BY Belarus
CA Canada
CH Switzerland
CL Chile
CN China
CR Costa Rica
CU Cuba
CZ Czech Republic

Note: The two-letter code after each country name conforms with WIPO Standard ST.3 (Recommended Standard Two-Letter Code for the Representation of Countries).

DE Germany
DK Denmark
DO Dominican Republic
EE Estonia
ES Spain
FI Finland
FR France
GB United Kingdom
GE Georgia
GR Greece
GT Guatemala
HN Honduras
HR Croatia
HU Hungary
IE Ireland
IL Israel
IN India
IS Iceland
IT Italy
JO Jordan
JP Japan
KG Kyrgyzstan
KP Democratic People’s Republic of Korea
KR Republic of Korea
KZ Kazakhstan
LI Liechtenstein
LT Lithuania
LU Luxembourg
LV Latvia
MA Morocco
MC Monaco
MD Republic of Moldova
ME Montenegro
MK The former Yugoslav Republic of Macedonia

MX Mexico
NI Nicaragua
NL Netherlands
NO Norway
OM Oman
PA Panama
PE Peru
PH Philippines
PL Poland
PT Portugal
RO Romania
RS Serbia
RU Russian Federation
SE Sweden
SG Singapore
SI Slovenia
SK Slovakia
SV El Salvador
TJ Tajikistan
TN Tunisia
TR Turkey
TT Trinidad and Tobago
UA Ukraine
US United States of America
UZ Uzbekistan
ZA South Africa

AP African Regional Intellectual Property Organization (ARIPO)
EA Eurasian Patent Organization (EAPO)
EP European Patent Organization (EPO)

INTRODUCTION TO THE BUDAPEST TREATY

(a) Deposit of Microorganisms for the Purposes of Patent Procedure

(i) Disclosure and the Requirement for Deposit

1. A fundamental requirement of patent law is that the details of an invention must be fully disclosed to the public. For disclosure to be adequate, an invention must be described in sufficient detail to permit a person skilled in the art to repeat the effect of the invention: in other words, the disclosure should enable the average expert with access to the appropriate facilities to reproduce the invention for himself. Disclosure is normally achieved by means of a written description supplemented where necessary by drawings. However, inventions involving the use of new microorganisms (i.e., those not available to the public) present problems of disclosure in that repeatability often cannot be ensured by means of a written description alone. In the case of an organism isolated from soil, for instance, and perhaps "improved" by mutation and further selection, it would be virtually impossible to describe the strain and its selection sufficiently to guarantee another person obtaining the same strain from soil himself. In such a case, the microorganism itself might be considered to be an essential part of the disclosure. Moreover, if the microorganism was not generally available to the public, the written disclosure of the invention might be held to be insufficient. This line of reasoning led to the industrial property offices in an increasing number of countries either requiring or recommending that the written disclosure of an invention involving the use of a new microorganism be supplemented by the deposit of the microorganism in a recognized culture collection. The culture collection would then make the microorganism available to the public at the appropriate point in the patenting procedure.

(ii) Need for a Uniform International Deposit System

2. Although by the early 1970s the depositing of microorganisms in culture collections for patent purposes had become fairly common, there was no uniform system of deposit, or, perhaps more importantly, of *recognition* of deposit. Most countries requiring or recommending deposit required it to be made in a "recognized" collection, but the minimum criteria to be met by such "recognized" collections were vague and ill defined. In most cases, "recognized" probably equated with "internationally known." The culture collections for their part, when confronted with the variety of national patent laws, were often unsure of how to proceed in respect of the furnishing of samples to requesting parties. Lack of firm guidelines led some collections to allow the depositor almost complete control over the furnishing of samples of his microorganism, believing this to be the surest way of protecting themselves from the danger of releasing a sample illegitimately.

3. Faced with the above-mentioned uncertainties, many patent applicants saw no alternative but to deposit the same microorganism in several collections in different countries to guard against the possibility of any of their applications failing on the grounds of insufficient disclosure. Clearly this practice was wasteful, time-consuming and sometimes expensive, and, taken to its logical conclusion, would have resulted in applicants depositing the microorganism in every country in which they wished to file a patent application referring to that microorganism. In order to obviate the need for such multiple deposits, therefore, the

Government of the United Kingdom proposed, in 1973, that the World Intellectual Property Organization (WIPO) should study the possibilities of one deposit serving the purposes of all the deposits that would otherwise be needed. This proposal was adopted by the Governing Bodies of WIPO.

(iii) The Budapest Treaty

4. In 1974, the Director General of WIPO convened a Committee of Experts to discuss the possibilities of international cooperation over the deposit of microorganisms for patent purposes. The essence of the solution prepared in discussions of this Committee was that certain culture collections should be recognized as depositary authorities and that a deposit made with any one of them should be recognized as valid for patent purposes by all the countries in which protection for the relevant invention was sought. The Committee of Experts also found that the conclusion of a treaty would be necessary to put this proposed solution into effect. At two further sessions in 1975 and 1976 the Committee of Experts examined drafts prepared by the International Bureau of WIPO of a Treaty and Regulations on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. A third draft of this Treaty and Regulations served as a basis for the deliberations of a Diplomatic Conference, convened by the Director General of WIPO, organized by him in cooperation with the Government of Hungary, and held in Budapest from April 14 to 28, 1977. The Diplomatic Conference, which was attended by representatives of 29 States[1] members of the Paris Union for the Protection of Industrial Property and observers from two non-member States[2] of the Paris Union, the Interim Committee of the European Patent Organisation, and 11 non-governmental international organizations,[3] adopted a treaty with the title "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure," together with Regulations under the Treaty.

5. The Budapest Treaty came into effect in 1980 when it had been ratified or acceded to by the requisite minimum number (five) of States. The Regulations under the Budapest Treaty were modified in 1981 and in 2002.

[1] Australia, Austria, Bulgaria, Czechoslovakia, Denmark, Egypt, Finland, France, German Democratic Republic, Germany (Federal Republic of), Hungary, Indonesia, Italy, Japan, Mexico, Netherlands, Norway, Philippines, Poland, Portugal, Romania, Senegal, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America, Yugoslavia.

[2] Democratic People's Republic of Korea, Pakistan.

[3] Committee of National Institutes of Patent Agents (CNIPA), European Federation of Agents of Industry in Industrial Property (FEMIPI), Council of European Industrial Federations (CEIF), International Association for the Protection of Industrial Property (AIPPI), International Chamber of Commerce (ICC), International Federation of Patent Agents (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Pacific Industrial Property Association (PIPA), Union of European Patent Attorneys and Other Representatives Before the European Patent Office (UNEPA), Union of Industries of the European Community (UNICE), World Federation for Culture Collections (WFCC).

(b) Main Features of the Budapest Treaty

(i) International Depositary Authorities and Recognition of Single Deposit

6. Under the Treaty, certain culture collections are recognized as "international depositary authorities" (IDAs). Any Contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for those purposes, a deposit made in any IDA, wherever that IDA may be. Similarly, if any intergovernmental industrial property organization (e.g., the European Patent Office) files a formal declaration with the Director General of WIPO to the effect that, for its own patent purposes, it accepts the provisions of the Treaty and the Regulations, then it too must recognize a deposit made in any IDA.

7. Any culture collection can become an IDA provided that it has been formally nominated by the Contracting State on whose territory it is located and that that Contracting State has furnished solemn assurances that the collection complies and will continue to comply with the requirements of the Treaty and the Regulations. The most important of these are that the IDA will be available on the same terms to any depositor, that it will accept and store microorganisms deposited with it for the full period specified by the Treaty, and that it will furnish samples of deposited microorganisms only to those entitled to receive them. An intergovernmental industrial property organization which has filed the declaration referred to in paragraph 6 similarly may furnish assurances in respect of a culture collection located on the territory of one of its member States.

(ii) Deposit and Furnishing of Samples

8. The Regulations under the Treaty lay down in detail the procedures which depositors and IDAs must follow, the duration of storage of deposited microorganisms (at least 30 years or five years after the most recent request for a sample, whichever is later), and the mechanisms for the furnishing of samples. The Regulations do not address the timing of deposit, however; this is left entirely to the relevant national law. So, to a large extent, are the timing and conditions of furnishing of samples. Provision is made for samples to be furnished at any time to the depositor, to anyone having the depositor's written authorization, and to any "interested" industrial property office (i.e., one dealing with a patent application concerning the deposited microorganism and which provides the IDA with a declaration to that effect), but in all other cases national law determines when, to whom and under what conditions samples are to be furnished. However, because IDAs may not be familiar with the national laws of different countries, the Regulations require that a third party requesting a sample from an IDA must make his request on a form on which the relevant industrial property office certifies that he is entitled to receive a sample of that particular microorganism. Alternatively, the industrial property office may, from time to time, notify IDAs of the accession numbers of those microorganisms referred to in patents granted and published by it, in which case such microorganisms become available to anyone without the need for certification.

(iii) Safeguard of Deposits

9. The Treaty and Regulations make various provisions to guard against the loss and consequent non-availability of deposited microorganisms. Thus the IDA must have the expertise and facilities necessary to keep the microorganism viable and uncontaminated

throughout the storage period required by the Treaty. If for any reason an IDA is no longer able to furnish samples of a microorganism, a new deposit of the same organism can be made and can benefit from the date of deposit of the original. If for any reason an IDA ceases to function as such, the Treaty provides for the microorganisms deposited with it to be transferred to another IDA.

(iv) Meaning of the Term "Microorganism"

10. The term "microorganism" is not defined in the Treaty so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

PART I: GENERAL REQUIREMENTS FOR DEPOSIT AND FURNISHING OF SAMPLES

Section A: Making the Original Deposit

(a) Obligations of the Depositor

(i) Universal Requirements

11. When making an original deposit under the Budapest Treaty, the depositor must comply with Rules[1] 6.1(a) and 6.3(a). Rule 6.1(a) specifies the minimum information which the depositor must supply to the IDA when he sends his microorganism for deposit; Rule 6.3(a) lists the additional requirements which the IDA may ask the depositor to meet in respect of its own administrative procedures.

12. According to Rule 6.1(a):

> "The microorganism transmitted by the depositor to the international depositary authority shall...be accompanied by a written statement bearing the signature of the depositor and containing:
>
> (i) an indication that the deposit is made under the Treaty and an undertaking not to withdraw it for the period specified in Rule 9.1;"

The period specified in Rule 9.1 is five years after the most recent request for a sample, and in any case at least 30 years. It is important to realize that a deposit made under the Treaty cannot be cancelled during this period, either by the depositor or the IDA, regardless of whether a patent is eventually granted. This applies even if patent applications relating to the deposit are abandoned or withdrawn.

13. Rule 6.1(a) continues:

> "(ii) the name and address of the depositor;
>
> (iii) details of the conditions necessary for the cultivation of the microorganism, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence;"

This provision ensures that the IDA is given sufficient information to enable it to handle the microorganism correctly. The instructions referring to mixed cultures are intended to ensure that a positive viability statement (see paragraphs 33 to 39) is not issued unless all the components of the co-culture have been shown to be viable.

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[1] Whenever the words "Article(s)" or "Rule(s)" are used in this Guide, they mean Article(s) or Rule(s) of the Budapest Treaty, unless otherwise specified.

14. Rule 6.1(a) continues:

> "(iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism;"

The wording of this clause is sometimes misinterpreted. It does not mean that the depositor should have identified his microorganism in a taxonomic sense; it simply means the designation by which he refers to the organism. The "identification reference" may be a name, of course, but equally it may be merely a strain designation or even just a laboratory code number.

15. Rule 6.1(a) concludes:

> "(v) an indication of the properties of the microorganism which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties."

The provisions of Rule 6.1(a) are fairly obvious requirements which are intended to ensure that the IDA is aware that the deposit is being made under the Budapest Treaty and is able to deal with the microorganism in the laboratory correctly and safely. Nevertheless, the requirements of Rule 6.1(a) are mandatory and may not be varied either by the depositor or the IDA. Indeed if the depositor does not comply with them all, the IDA is obliged by Rule 6.4(b) (see paragraph 29) to ask him to do so before it can accept the deposit.

16. Scientific description and/or taxonomic designation. Whereas Rule 6.1(a) lists the indications that must be contained in the written statement sent by the depositor to the IDA, Rule 6.1(b) states:

> "It is strongly recommended that the written statement...should contain the scientific description and/or proposed taxonomic designation of the deposited microorganism."

Since this Rule is not a requirement but an exhortation, compliance with it is not mandatory. Moreover, if the depositor does decide to submit a scientific description and/or proposed taxonomic designation, he need not do so at the time of deposit. Rule 8.1(a) permits the communication of this information at some later date, and also provides for the amendment of any description/designation indicated previously. The contents of such a communication are regulated by Rule 8.1(b), which states:

> "Any such later indication or amendment shall be made in a written communication, bearing the signature of the depositor, addressed to the international depositary authority and containing:
>
> (i) the name and address of the depositor;
>
> (ii) the accession number given by the said authority;

(iii) the scientific description and/or proposed taxonomic designation of the microorganism;

(iv) in the case of an amendment, the last preceding scientific description and/or proposed taxonomic designation."

When making such a communication, the depositor may ask the IDA to provide him with an attestation containing the information referred to in Rule 8.1(b)(i) to (iv) and the date on which the IDA received the communication (Rule 8.2). The IDA is obliged to meet such a request, but is entitled to charge a fee for so doing (Rule 12.1(a)(ii)).

(ii) Requirements of IDAs

17. As well as the foregoing requirements, the Regulations permit the IDA to impose on the depositor certain conditions of its own. The extent of these conditions is governed by Rule 6.3(a), which states:

"Any international depositary authority may require:

(i) that the microorganism be deposited in the form and quantity necessary for the purposes of the Treaty and these Regulations;"

This provision allows the IDA to require that cultures of microorganisms are submitted to it in a particular state, e.g., on agar slants, in liquid suspension, lyophilized, etc.; that a specified number of replicates is provided; that cultures should not be below a specified minimum titre; and so on.

18. Rule 6.3(a) continues:

"(ii) that a form established by such authority and duly completed by the depositor for the purposes of the administrative procedures of such authority be furnished;"

This means the accession form and any other form routinely used by the IDA and obtainable from it.

19. Rule 6.3(a) continues:

"(iii) that the written statement referred to in Rule 6.1(a) or 6.2(a) be drafted in the language, or in any of the languages, specified by such authority, it being understood that such specification must at least include the official language or languages indicated under Rule 3.1(b)(v);"

This is a provision permitting a Japanese IDA, for example, to ask for information to be supplied to it in Japanese. Rule 3.1(b)(v) refers to the official language(s) of the institution specified in the communication required under Article 7(1) of the Treaty from the Contracting State or intergovernmental industrial property organization nominating that institution for the acquisition of IDA status. Rule 6.2(a) refers to the statement required from the depositor in the event of a new deposit, and is dealt with in Section B of this Guide.

20. Rule 6.3(a) continues:

> "(iv) that the fee for storage referred to in Rule 12.1(a)(i) be paid..."

Rule 12.1(a)(i) permits the IDA to charge the depositor for storing his microorganism in accordance with the Treaty. However, Rule 12.1(b) requires this fee to cover the whole duration of storage; thus it must be a once-and-for-all payment.

21. Rule 6.3(a) concludes:

> "(v) that, to the extent permitted by the applicable law, the depositor enter into a contract with such authority defining the liabilities of the depositor and the said authority."

This provision allows the IDA to make the kind of contractual arrangements with the depositor that would be usual under the laws of contract of the IDA's own country.

22. The provisions of Rule 6.3(a) allow the IDA to apply its normal in-house administrative and technical requirements to the internal processing of deposits. It is entirely a matter of choice for the IDA whether it demands any or all of the requirements permitted under Rule 6.3(a), but if it does, then it must so inform the International Bureau of WIPO (Rule 6.3(b)). The depositor must comply with any such requirements to ensure acceptance of his microorganism. These requirements are dealt with in Section D of this Guide.

(b) Obligations of the IDA

(i) Kinds of Microorganisms Accepted

23. The communication to the Director General of WIPO from a Contracting State or an intergovernmental industrial property organization, referred to in Article 7 and Rule 3, nominating a culture collection for the acquisition of IDA status must specify the kinds of microorganisms that the culture collection will accept for deposit under the Budapest Treaty (Rule 3.1(b)(iii)). From the time of its acquisition of IDA status that culture collection is obliged to accept all such microorganisms for deposit (subject to Rule 6.4(a)(ii) and (iii) - see paragraphs 26 and 27).

(ii) Extension or Limitation of the Kinds of Microorganisms Accepted

24. If the IDA subsequently wishes to limit or extend the list of kinds of microorganisms it accepts, it must do so by notifying the modified list to the Contracting State or intergovernmental industrial property organization under whose assurances it has acquired IDA status. That State or organization in turn must formally notify the Director General of WIPO of the withdrawal of its declaration of assurances either entirely or in respect only of certain kinds of microorganisms (Article 8(2)(a), Rule 4.2(a) and (b)) or of the extension of the list of kinds of microorganisms accepted (Rule 3.3). The changes then come into effect at the earliest three months from the date of notification in the case of a limitation of the list of

the kinds of microorganisms accepted (Rule 4.2(c)) and immediately after publication by the International Bureau of WIPO in the case of an extension (Rule 3.3, Article 7(2)(b)) of such list. In either case, the State or organization may specify a later effective date than that just mentioned.

(iii) Refusal to Accept a Microorganism

25. An IDA may refuse to accept a microorganism sent to it for deposit only in certain circumstances, which are specified in Rule 6.4(a). This Rule states:

> "(a) the international depositary authority shall refuse to accept the microorganism and shall immediately notify the depositor in writing of such refusal and of the reasons therefor:
>
> (i) where the microorganism is not of a kind of microorganism to which the assurances furnished under Rule 3.1(b)(iii) or 3.3 extend;"

Although the reason for this provision may appear self-evident, it is important to note that the IDA is not merely entitled, but is obliged to refuse such a microorganism.

26. Rule 6.4(a) continues:

> "(ii) where the properties of the microorganism are so exceptional that the international depositary authority is technically not in a position to perform the tasks in relation to it that it must perform under the Treaty and these Regulations;"

This provision covers the situation where, on the face of it, the microorganism should be of a kind which the IDA accepts, but where in fact the IDA clearly is unable to handle it. An example would be a strain of an otherwise "acceptable" species, which either naturally or because of genetic manipulation was too difficult for the IDA to cultivate.

27. Rule 6.4(a) concludes:

> "(iii) where the deposit is received in a condition which clearly indicates that the microorganism is missing or which precludes for scientific reasons the acceptance of the microorganism."

This provision again relates to a microorganism that in normal circumstances would be accepted by the IDA. It would apply, for example, where the receptacle containing the culture had been broken in transit, thereby making recovery of the microorganism in an uncontaminated state impossible.

28. Rule 6.4(a) specifies the only circumstances in which an IDA may legitimately refuse to accept a microorganism for deposit, other than by virtue of continued non-compliance by the depositor with the requirements for deposit. Refusal by the IDA in any other case is in contravention of its obligations under the Treaty and could lead to its losing its status as an IDA (Article 8, Rules 4 and 5).

(iv) Acceptance of the Original Deposit

29. The requirements which the IDA must observe when accepting a microorganism for deposit are laid down in Rule 6.4(b), (c) and (d). Rule 6.4(b) and (c) states:

"(b) Subject to paragraph (a), the international depositary authority shall accept the microorganism when all the requirements of Rule 6.1(a) or 6.2(a) and Rule 6.3(a) are complied with. If any of those requirements are not complied with, the international depositary authority shall immediately notify the depositor in writing of that fact and invite him to comply with those requirements.

"(c) When the microorganism has been accepted as an original or new deposit, the date of that original or new deposit, as the case may be, shall be the date on which the microorganism was received by the international depositary authority."

Thus the IDA is obliged to ensure that the depositor has met all the mandatory requirements for deposit (see paragraphs 11 to 22) before it can accept the microorganism. However, deferment of formal acceptance (as opposed to refusal) pending the depositor's compliance with all his obligations does not prejudice the date of deposit. Except in the case of a conversion of a deposit made outside the Budapest Treaty under Rule 6.4(d) (see paragraphs 30 and 31), the date of deposit is held to be the date on which the IDA physically receives the microorganism, even though all procedural requirements for acceptance may not have been met on that date.

(v) Conversion of Deposits Made Outside the Budapest Treaty

30. Rule 6.4(d) allows for a deposit originally made outside the provisions of the Treaty and before the culture collection became an IDA to be converted to a deposit made under the Treaty. This Rule states:

> "The international depositary authority shall, on the request of the depositor and provided that all the requirements referred to in paragraph (b) are complied with, consider a microorganism, deposited before the acquisition by such authority of the status of international depositary authority, to have been received, for the purposes of the Treaty, on the date on which such status was acquired."

The requirements for converting an existing deposit into a "Budapest deposit" are essentially the same as those which must be met when making an original deposit under the Treaty, except that the microorganism itself, of course, will already have been sent and received. However, it must be realized that when a deposit is converted under Rule 6.4(d), for the purposes of the Treaty the date of deposit is held to be the date on which the culture collection acquired IDA status, not the earlier date on which the collection physically received the microorganism. It is important that this "artificial" date of deposit be borne in mind in relation to the filing dates of patent applications referring to the deposited microorganism. Following an "understanding" reached by the Assembly of the Budapest Union (in 1981 and in 1990), the depositor may request that a deposit made with an IDA, but outside the scope of the Budapest Treaty, be converted into a Budapest Treaty deposit. Furthermore, according to such "understanding" in such a case, the date recognized for the purposes of the Treaty as the date of deposit is determined by the applicable national law. In practice this means that

whereas some industrial property offices may recognize the date on which the IDA received the microorganism as the date of deposit, others may recognize only the date of receipt by the IDA of the request for conversion. Depositors should bear this in mind and consider any effects it may have on patent applications or patents referring to the converted deposit.

31. Conversion is a useful facility because it means that an earlier non-Budapest Treaty deposit can be accorded the international recognition which it might not otherwise command. Conversion, for example, is essential for the recognition by the Japanese Patent Office of any non-Budapest Treaty deposit made outside Japan, regardless of its previous availability. At present, however, only the original depositor (or his successor in title) can convert a deposit. In all other cases, a separate deposit of the same organism must be made under the Treaty. Moreover, some IDAs will not agree to the conversion of deposits previously made for purely scientific purposes because of the constraints which the Budapest Treaty system might impose on the hitherto unrestricted distribution of samples. In such cases, separate deposit of the microorganism under the Treaty is again necessary.

(vi) Issuance of Receipt

32. Having received and accepted a microorganism for deposit (or having converted an existing deposit), the IDA must notify the depositor of this fact by issuing to him an official receipt in respect of that deposit (Rule 7.1). The receipt must be made out on the so-called "international form" BP/4 (see Appendix 3). This form is one of four "international forms," a model of which has been established by the Director General of WIPO and the Budapest Union Assembly (Rule 7.2(a)). Wherever the Regulations specify the use of an "international form" by IDAs, such use is mandatory. The receipt must be signed by an authorized representative of the IDA (Rule 7.2(c)) and must contain the specific information required by Rule 7.3 which states:

> "Any receipt referred to in Rule 7.1 and issued in the case of an original deposit shall indicate that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and shall contain at least the following indications:
>
> (i) the name and address of the international depositary authority;
>
> (ii) the name and address of the depositor;
>
> (iii) the date of the original deposit as defined in Rule 6.4(c);
>
> (iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
>
> (v) the accession number given by the international depositary authority to the deposit;
>
> (vi) where the written statement referred to in Rule 6.1(a) contains the scientific description and/or proposed taxonomic designation of the microorganism, a reference to that fact."

The receipt is a very important communication for it constitutes a written attestation by the IDA that the microorganism in question was deposited with it on a particular date, was accepted by it, and was assigned a particular accession number. Moreover, the receipt together with a positive first viability statement (see paragraphs 33 to 39) provide documentary evidence that a deposit meeting the requirements of the Budapest Treaty has been made. Also, by virtue of the obligations imposed on IDAs by the Treaty, these documents are a presumptive indication that the deposited microorganism will be kept in storage and samples thereof will be furnished according to the requirements of the Treaty. Any Contracting State may demand a copy of the receipt (Article 3(1)(b)). (It should be noted in this connection, however, that, notwithstanding the provisions of Article 3(2) and the assurances furnished under Article 7(1)(a) in respect of the IDA, certain industrial property offices may require an additional declaration from the IDA as to the permanence and availability of the deposit.)

(vii) Viability Testing and Statement

33. Viability Testing. As soon as possible after receiving a microorganism for deposit, the IDA must test the viability of the microorganism (Rule 10.1(i)) and must inform the depositor in writing of the results of the test (Rule 10.2(a)(i)), using mandatory "international form" BP/9. The obligations placed on IDAs in respect of the viability testing of an original deposit are laid down in Rule 10.1, which states:

> "The international depositary authority shall test the viability of each microorganism deposited with it:
>
> (i) promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;"

Rule 5.1 refers to the transfer of microorganisms from a defaulting to a substitute IDA and is dealt with in Section B of this Guide.

34. Rule 10.1 continues:

> "(ii) at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary, for technical reasons;"

This provision, while requiring the IDA to pay attention to the viability testing of a microorganism during the storage period, nevertheless leaves the frequency of such testing to the professional judgment of the IDA.

35. Rule 10.1 concludes:

> "(iii) at any time, on the request of the depositor."

This provision acknowledges the right of the depositor to demand on any particular occasion evidence of the viability of his deposit.

36. Viability Statement. The circumstances in which an IDA must provide a written statement in respect of an original deposit are given in Rule 10.2(a), which states:

> "The international depositary authority shall issue a statement concerning the viability of the deposited microorganism:
>
> (i) to the depositor, promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;
>
> (ii) to the depositor, on his request, at any time after the deposit or transfer;
>
> (iii) to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were furnished in conformity with Rule 11, on his or its request, together with or at any time after such furnishing of samples."

This provision entitles anyone who has received a sample of the microorganism also to receive a viability statement, if he so wishes. In such a case, and in the case of Rule 10.2(a)(ii), above, the viability statement must refer to the most recent viability tests (Rule 10.2(c)).

37. The contents of the viability statement are laid down by Rule 10.2(b), which states:

> "The viability statement shall indicate whether the microorganism is or is no longer viable and shall contain:
>
> (i) the name and address of the international depositary authority issuing it;
>
> (ii) the name and address of the depositor;
>
> (iii) the date referred to in Rule 7.3(iii) or, where a new deposit or a transfer has been made, the most recent of the dates referred to in Rules 7.4(iii) and 7.5(iii);"

The two last mentioned dates are the dates of receipt by the IDA of a new deposit or transferred deposit, respectively.

38. Rule 10.2(b) continues:

> "(iv) the accession number given by the said authority;
>
> (v) the date of the test to which it refers;
>
> (vi) information on the conditions under which the viability test has been performed, provided that the said information has been requested by the party to which the viability statement is issued and that the results of the test were negative."

This last provision enables the recipient of the viability statement to check, in the event of a negative result, that the IDA has carried out the viability test correctly. The IDA is entitled to charge for viability statements issued in respect of an original deposit, except for that issued to the depositor immediately after deposit or where the recipient is an industrial property office (Rules 10.2(e) and 12.1(a)(iii)).

39. Viability testing is an extremely important part of the depositing procedure under the Budapest Treaty since the whole point of deposit is to ensure that viable samples of the microorganism are made available at the appropriate time and under the requisite conditions to those entitled. The test carried out immediately after deposit is particularly important because it determines in effect the validity of the date of deposit. Accordingly, the viability statement reporting the result of this test is a very important document. If it reports a negative result, and if all subsequent viability statements report similarly negative results, then even though all procedural requirements may have been met in respect of the deposit, the original date of deposit is lost (see paragraph 67). If, on the other hand, the first viability statement reports a positive result, then, in the event of the microorganism subsequently being lost and in the absence of any later positive statements, it is the key to the recognition of the original date of deposit *vis à vis* any replacement (Article 4(1)(d); see paragraph 66).

(viii) Storage of Microorganisms

40. Having accepted a microorganism for deposit, tested its viability and issued the receipt and viability statement, the IDA is obliged to maintain the microorganism according to the provisions of Rule 9, which states:

> "9.1 Duration of the Storage
>
> "Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit."

This provision is intended to ensure the permanence of the deposit and in effect simply obliges the IDA to do what would be expected of any culture collection in order to minimize the loss of deposited microorganisms.

41. Rule 9 continues:

> "9.2 Secrecy
>
> "No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism under Rule 11 and subject to the same conditions as provided in that Rule."

This provision is intended to ensure that the deposit of a microorganism remains secret until any patent application referring to it has been published. However, by linking the furnishing of information to the provisions of Rule 11 (see paragraphs 87 to 96), which govern the furnishing of samples, Rule 9.2 relieves the IDA of any obligation to ascertain for itself whether publication has taken place. (In practice, there are certain exceptions to this; see paragraphs 92 and 104.)

(c) Guidelines for Making the Original Deposit

(i) General

42. Subsections (a) and (b), above, have listed and explained the general requirements, obligations and procedures which must be observed by the depositor and the IDA when an original deposit is being made under the Budapest Treaty. The purpose of this subsection is to offer practical guidance and suggestions to prospective depositors so that timely and trouble-free deposits may be ensured.

(ii) Problems to Be Avoided

43. Last Minute Deposits. Making a deposit under the Budapest Treaty should be quite straightforward, but problems can and do occur. Most of these arise because the depositor has not left enough time for any unexpected difficulties to be put right. It cannot be emphasized too strongly that however good the intentions of the depositor may be, the industrial property office will recognize only the actuality of the deposit. This actuality is the physical receipt by the IDA of a viable sample of the microorganism. Thus, although in principle a microorganism being sent for deposit need not in most cases reach the IDA until the filing date (or priority date, as the case may be) of the corresponding patent application, in practice the depositor should begin the depositing procedure soon enough to allow for any possible delays or mishaps. Some delays can be anticipated, of course. If, say, the deposit is to be made with a foreign IDA, any import or quarantine regulations should be borne in mind. For instance, it may take several weeks, or even months, to import certain cell-lines and viruses into the United States of America (see Section D of this Guide). However, it is the possibility of unexpected delays that makes depositing at the last minute a risk not worth taking in view of the likely consequence for the patent application itself. None of the following common situations causes a problem if the microorganism has been sent for deposit in good time; all pose a serious threat to the last-minute deposit.

44. Postal Delays. Sometimes the microorganism sent for deposit simply fails to arrive at the IDA in time, either because the package has been mailed too late or because of abnormal delays in the postal system. It should also be noted that the postal authorities in some countries will not accept packages containing certain classes of microorganisms transmitted by airmail and will destroy them on receipt. Usually, an IDA is able to advise a prospective foreign depositor whether it can accept his microorganism sent by airmail.

45. Customs Delays. Microorganisms sent for deposit in IDAs abroad often must be transmitted by air freight. Delays frequently occur because depositors have provided insufficient shipping information to allow the smooth passage of the package through the customs authorities in the country of destination.

46. Damaged Packages. Sometimes depositors do not pack the vessels containing their microorganisms adequately, with the result that the vessels may be broken in transit, rendering the microorganism irrecoverable from the package in an uncontaminated state. In such a case, the IDA will refuse to accept the deposit (Rule 6.4(a)(iii)). If the deposit has been made at the last minute, it may be too late to send a replacement. Prospective depositors should note that the packaging of microorganisms for transmission through the overseas mail and by air freight is governed by the regulations of the Universal Postal Union and the International Air Transport Association, respectively.

47. Non-Viability. Sometimes a microorganism sent for deposit proves to be non-viable when tested by the IDA, necessitating the depositor to send a replacement sample. Such a replacement cannot be treated as a new deposit under the provisions of Article 4 because a positive viability statement was not issued in respect of the original sample (see paragraphs 67 and 68). Thus the replacement must be treated as an original deposit in its own right, which means that the earliest date of deposit is the date on which the IDA receives the replacement sample, not the date on which it received the first sample. If the first sample was sent for deposit at the last minute, the replacement sample may not reach the IDA in time. (It should be borne in mind in this connection that, depending on the kind of microorganism, viability testing may take some time. Thus for most bacteria, fungi, yeasts, algae and protozoa, viability testing usually takes two to five days, for animal cell-lines a week or slightly longer is normal and for animal viruses and plant tissue cells, up to a month is not unusual (see Section D of this Guide).)

48. It is essential to recognize the difference between a new deposit in the sense of Article 4 (see paragraphs 65 to 68) and a replacement deposit as described above, and to realize that if a microorganism is found by the IDA from the outset to be non-viable, the original date of deposit cannot be applied to any replacement.

49. Unacceptable Microorganisms. Occasionally an IDA finds that a microorganism sent to it is not one of the kinds which it accepts under the Treaty, and thus it refuses the deposit (Rule 6.4(a)(i)). Again, if the deposit is being made at the last minute, it may be too late to send the microorganism to another IDA that will accept the deposit.

50. Lack of Communication. Last-minute deposits usually occur through lack of forethought on the part of the depositor or his patent agent, or through lack of communication between the two. And even when the microorganism itself is sent in good time, lack of communication between depositor and agent can cause confusion and delay. In such cases, the date of deposit is not usually jeopardized, but the depositing procedure is made unnecessarily complicated and time-consuming. Thus, for example, the depositor (who is often a scientist with little knowledge of patent procedure) may be told simply to ensure that he sends his microorganism to the IDA by a certain date, without being adequately briefed about the relevant administrative and legal requirements. Consequently, deposits sometimes arrive not only late but also lacking sufficient information to enable the IDA to process them. Furthermore, it is often forgotten that the Treaty speaks always of the depositor and that, unless instructed otherwise, the IDA will communicate only with him. If requested, most IDAs will send copies of receipts and viability statements to both the depositor and his agent, which avoids the common problem of depositors not realizing the importance of the receipt and viability statement and the need to furnish them as evidence of deposit.

51. Problems can also arise when patent agents are inadequately briefed by depositors about possible technical or legal difficulties with their microorganism, with the result that IDAs may be confronted with situations about which they should have been forewarned. There has been at least one case where the patent agent had all the administrative procedures in hand, only to find that the depositor had told neither him nor the IDA that the microorganism had to be handled under special conditions to which the IDA did not have immediate access.

52. Communication between a patent applicant and his patent agent is always considered vital in the drafting of the patent application and in its filing. It is equally essential in the depositing of microorganisms for patent purposes.

(iii) Guide to Procedures

53. The problems and pitfalls described in paragraphs 43 to 52 can largely be avoided if prospective depositors adhere to the following three simple guidelines:

– start the deposit procedure in good time;

– ensure that adequate briefing is received from the patent agent about administrative and legal requirements;

– ensure that the patent agent is briefed about the kind of microorganism and about any possible technical problems there may be with it.

This being said, the following points about practical procedures should be observed.

54. Acceptability of the Microorganism. The depositor should ensure that the IDA he has chosen is able and empowered to accept for deposit the kind of microorganism to be submitted. If there are likely to be technical problems, he should advise the IDA in advance.

55. IDA Requirements and Forms. The depositor should check the administrative and technical requirements of the IDA (Rule 6.3(a)) and should ask for the appropriate forms.

56. Information. The depositor should give all the information asked for on the forms and should ensure that it is correct, and that it is expressed in one of the official languages of the IDA. It is generally recognized that many depositors will not be familiar with the details of the Budapest Treaty and Regulations and thus may not be fully aware of all their obligations in respect of them. Therefore, the forms which the depositor is asked to fill in are so designed that, by completing them correctly, he automatically provides all the information required of him by the Regulations (in particular, Rule 6.1(a)) and by the IDA itself. These forms vary to some extent between IDAs but they all follow a similar general pattern.) Nevertheless, deposit forms are not infrequently returned to IDAs only partially completed or containing incorrect information, thus leading to unnecessary delays.

57. Identity of Depositor. It should be made clear whether the person sending the microorganism is himself the depositor or whether he is acting on behalf of the organization employing him. In the case of the latter, the deposit form should be signed by an authorized official of that organization and it should be made clear to whom the IDA should send any official notifications.

58. Patent Agent. If the depositor's patent agent is likely to be communicating with the IDA, the depositor should inform the IDA, otherwise it may withhold information until it has ascertained the agent's right to receive it. In particular, the depositor should tell the IDA if he wishes copies of the receipt and viability statement to be sent to his patent agent.

59. Form and Quantity of the Microorganism. The depositor should ensure that he meets the requirements of the IDA as to the form and quantity of the microorganism to be deposited (Rule 6.3(a)(i)).

60. Advance Information. Although Rule 6.1(a) states that the microorganism should be accompanied by a written statement (the completed deposit form), in practice it is often helpful to an IDA to receive information in advance of the microorganism itself, so that arrangements can be made to deal with the deposit promptly. This is particularly helpful if, say, a special growth medium containing unusual ingredients has to be prepared by the IDA.

61. Date of Deposit. Notwithstanding paragraph 60, the depositor should bear in mind that the date of deposit is the date on which the microorganism is actually received by the IDA. Therefore, in an emergency (which should not arise, of course, if the depositor is following these guidelines), priority should be given to ensuring that the IDA receives the microorganism itself. However, in such a case the depositor should remember that without the written information, the IDA may not be in a position to test the viability of the microorganism.

62. Authenticity Checks. Depending on its policy and on the kind of material being deposited, an IDA may or may not prepare subcultures for eventual distribution as samples of the deposited microorganism. Thus in the case of cell-lines and naked plasmids, for instance, the depositor is usually required to supply sufficient material for the IDA to distribute direct (see also paragraph 59). On the other hand, for bacteria, yeasts, moulds, etc., it is more usual for the IDA to distribute its own preparations. In this case, many IDAs will ask the depositor to check the authenticity of their preparations (a normal practice of culture collections). The depositor is not obliged by the Treaty to check these preparations, but he is well-advised to do so to ensure that the material sent out by the IDA will in fact correspond to the claims in the patent application.

63. Official Communications. The depositor should expect to receive an official receipt and viability statement from the IDA and should be aware of their importance and of the fact that he may be required to furnish them as evidence of deposit. Technically, the receipt should be issued first but in practice, where the viability test takes only a few days, many IDAs find it more convenient to await the result of this test and then send out the receipt and viability statement together. If asked, most IDAs will communicate the accession number and date of deposit when they have accepted the deposit. However, it must be remembered that these communications are unofficial and have no standing under the Treaty.

64. Conversions. If an existing deposit is being converted to one made under the Budapest Treaty (Rule 6.4(d)), the depositor should first inform the IDA of the accession number of the microorganism and obtain confirmation that the conversion is, in fact, permissible (if it is not, he will have to make another deposit). He should then attend to the points contained in paragraphs 55, 56, 58, 62 and 63, above).

Section B: Making a New Deposit

(a) Circumstances in Which a New Deposit May Be Made

65. Article 4 of the Treaty states:

> "(1)(a) Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular,
>
> (i) where such microorganism is no longer viable, or
>
> (ii) where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions, that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited.
>
> "(b) The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that:
>
> (i) it shall be made with another international depositary authority where the institution with which the original deposit was made has ceased to have the status of international depositary authority.or discontinues.the performance of its functions in respect of deposited microorganisms;
>
> (ii) it may be made with another international depositary authority in the case referred to in subparagraph (a)(ii)."

These provisions are intended to ensure, as far as possible, the continued availability of a deposited microorganism in the event of the IDA not being in a position to furnish samples. In this way, the depositor's patent rights are not jeopardized by circumstances that are not of his making and which are beyond his control. It should be noted, however, that according to Article 4(2) these provisions cannot be applied to microorganisms previously transferred to another IDA, unless that IDA is also unable to furnish samples.

(b) Requirements to Be Met

(i) Statement by the Depositor

66. Article 4(1) continues:

> "(c) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited microorganism is the same as that originally deposited. If the allegation of the depositor is contested, the burden of proof shall be governed by the applicable law."

The contents of the signed statement which the depositor must submit with his new deposit are laid down in Rule 6.2, and may be summarized thus (the following is a summary, not a quotation, of Rule 6.2):

> (i) where the new deposit is being made with a different IDA, all the indications required under Rule 6.1(a) (see paragraphs 12 to 15);
>
> (ii) the reason for making the new deposit, a statement alleging that the microorganism being submitted is the same as that deposited previously, and an indication of the date on which notification was received from the IDA of its inability to furnish samples (or, as the case may be, the date of publication of the fact that the IDA has lost its status or discontinued its function--Article 4(1)(e); see paragraph 70);
>
> (iii) the most recent scientific description and/or proposed taxonomic designation submitted to the IDA in respect of the previous deposit. (Rule 6.2(c) defines "previous deposit" as either the latest of a succession of earlier new deposits, or the original deposit, as the case may be.)

This signed statement must be accompanied by a copy of the receipt of the previous deposit and a copy of the most recent positive viability statement.

(ii) Date of Deposit

67. Article 4(1) continues:

> "(d) Subject to subparagraphs (a) to (c) and (e), the new deposit shall be treated as if it had been made on the date on which the original deposit was made where all the preceding statements concerning the viability of the originally deposited microorganism indicated that the microorganism was viable and where the new deposit was made within three months after the date on which the depositor received the notification referred to in subparagraph (a)."

This subparagraph is central to the concept of continuity of deposit in that it allows the original date of deposit to stand, regardless of the actual date of the new deposit, provided that this latter date falls within the stated three-month time limit.

68. It should be noted that, as mentioned earlier (see paragraphs 39 and 47), the original date of deposit can be applied to a new deposit only if at least one positive viability statement had been issued in respect of the previous deposit. Article 4 does not apply to replacements for deposits that have never been shown to be viable.

(iii) Time Limit

69. The exact dates that circumscribe the three-month time limit are calculated according to Rule 12bis.2, which states:

> "When a period is expressed as one month or a certain number of months, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire in the relevant subsequent month on the day which has the same number as the day on which the said event occurred, provided that if the relevant subsequent month has no day with the same number the period shall expire on the last day of that month."

Thus if the depositor receives notification from the IDA on, say, January 15, he must make his new deposit no later than April 15; or if he receives notification on, say, January 31, the new deposit must be made no later than April 30. (The same formula is applied, mutatis mutandis, when calculating time periods expressed in years (Rule 12bis.1).)

70. This three-month time limit does not begin until the depositor has received notification from the IDA of its inability to furnish samples, except where the IDA has ceased to function as such or has lost its status (Article 4(1)(b)(i)) and has not notified the depositor of this fact. In this case, Article 4(1)(e) states that if the IDA has not notified the depositor within six months of the publication by the International Bureau of WIPO of its loss of status, the three-month time limit starts from the date of that publication. However, in practice Article 4(1)(e) should not need to be invoked since, in the event of loss of status or discontinuance of function by the IDA, the Contracting State is required to ensure the transfer of all deposits to another IDA and to ensure that the defaulting IDA notifies depositors (Rule 5.1; see paragraph 84).

(iv) Receipt and Viability Statement

71. Having received and accepted a new deposit, the IDA must test its viability and must issue to the depositor a receipt and viability statement. The latter is identical with that which would be issued in the case of an original deposit (see paragraphs 36 to 38), but the receipt (Rule 7.4), which must be made out on "international form" BP/5, is not. Indications in Rule 7.4(i) to (v) are the same as in the receipt for an original deposit (see paragraph 32), except that they refer instead to "new deposit," but Rule 7.4 goes on to state:

> "(vi) an indication of the relevant reason and the relevant date as stated by the depositor in accordance with Rule 6.2(a)(ii);"

This refers to the reason for making the new deposit and the date on which the depositor received notification of the inability of the IDA to furnish samples.

72. Rule 7.4 continues:

> "(vii) where Rule 6.2(a)(iii) applies, a reference to the fact that a scientific description and/or a proposed taxonomic designation has/have been indicated by the depositor;"

Rule 6.2(a)(iii) refers to the last description/designation submitted in respect of the previous deposit.

73. Rule 7.4 concludes:

> "(viii) the accession number given to the previous deposit..."

Unless the new deposit is being made with another IDA, the accession number is likely to be the same as that accorded the previous deposit.

74. If the new deposit is being made with another IDA, the receipt must also give the name and address of the IDA with which the previous deposit was made, although Rule 7.4 does not mention this. When the IDA issues a receipt for a new deposit it must send with it to the depositor copies of the receipt and of the last positive viability statement issued in respect of the previous deposit.

(c) Guidelines for Making a New Deposit

75. If the original date of deposit is to be retained, a viable sample of the newly deposited microorganism must have been received by the IDA no later than the last day of the three-month time limit referred to in Article 4(1)(d) (see paragraph 69). If a viable sample is not received until later, the earliest date of deposit that can be applied to the new deposit is the date on which it was actually received by the IDA. Since loss of the original date of deposit can have serious implications for any patents or applications relating to the particular microorganism, timely action by the depositor when making a new deposit is just as important as when making an original deposit. New deposits made at the last minute are subject to the same risks as are last-minute original deposits (see paragraphs 43 to 49).

76. Most of the suggestions and guidelines discussed in Section A in respect of original deposits are equally applicable to new deposits, but the depositor should also bear the following points in mind when making a new deposit.

77. Notification from the IDA. The depositor should be aware of the significance of a notification from the IDA that it can no longer furnish samples and he should act promptly when he receives it. He should, of course, immediately note the date on which he received the notification and from it calculate the latest date by which any new deposit must be made.

78. Possibility of Transfer. If the IDA is unable to furnish samples because of loss of status or discontinuance of function, the depositor should ascertain (if the IDA has not so informed him) whether his deposited microorganism(s) will be transferred under the aegis of the Contracting State to another IDA in accordance with Rule 5.1(a)(i) (see paragraph 54). If this is to be the case, the right to make a new deposit under Article 4 does not exist (Article 4(2)).

79. Deposit with a Different IDA. If the new deposit is to be made with another IDA, the depositor should ensure that the IDA he chooses will accept his microorganism and he should determine its administrative and technical requirements (see Section D of this Guide), since they may differ from those of the original IDA. However, the depositor has the right to make a new deposit in another IDA only in the case of discontinuance or loss of status (Article 4(1)(b)(i)) or because of export/import restrictions (Article 4(1)(b)(ii)).

80. Identity of the New Deposit. The depositor should take care to ensure that the microorganism he is submitting as a new deposit is the same as that deposited previously, since there is always the possibility of the allegation he makes under Article 4(1)(c) being contested.

81. Statement. Unless the forms from the IDA provide space for it, the depositor should ensure that he has appended a signed statement giving the reason for making a new deposit, the date on which he received notification from the IDA of its inability to furnish samples, and a declaration that the microorganism he is submitting is the same as that previously deposited (Article 4(1)(c) and Rule 6.2(a)(ii)). Some IDAs use WIPO model forms BP/2 and BP/3 (see Appendix 3) for new deposits, which ask for these indications. In such cases, a separate statement is not necessary.

82. Additional Documentation. The depositor should remember that, in addition to the appropriate forms and declaration, he must also submit to the IDA (a) a copy of the receipt for the previous deposit, (b) a copy of the latest positive viability statement issued in respect of the previous deposit, and, if applicable, (c) the latest scientific description/taxonomic designation sent to the IDA in respect of the previous deposit.

(d) Transfer of Deposited Microorganisms

(i) Reasons for Transfer

83. Although they are not, strictly speaking, new deposits, it is appropriate to deal here with the case of deposited microorganisms which are necessarily transferred from one IDA to another. This situation can arise as a consequence of any of the following:

– the IDA temporarily or permanently ceases to carry out its functions in respect of the microorganisms deposited with it;

– the Contracting State or intergovernmental industrial property organization which originally furnished the assurances (Article 6(1)) leading to the IDA acquiring its status withdraws those assurances with the result that the status of the IDA is terminated (Article 8(2)).

– the IDA fails to meet its obligations under the Treaty and Regulations with the result that a Contracting State or intergovernmental industrial property organization successfully petitions the Budapest Union Assembly to terminate or limit the status of the IDA (Article 8(1));

– the IDA loses its status as a consequence of the Contracting State or intergovernmental industrial property organization which furnished the assurances in respect of it under Article 6(1) ceasing to be a party to the Treaty (Article 17(4)) or ceasing to recognize the provisions of the Treaty (Article 9(4)), respectively.

Except in the case of the last of these reasons, which inevitably must be absolute, the foregoing can apply either to all the microorganisms deposited with the IDA or only to certain kinds.

(ii) Obligations of the Contracting State

84. In the event of any of the foregoing, the Contracting State or intergovernmental industrial property organization which furnished the assurances under Article 6(1) is obliged by Rule 5.1 to ensure the prompt transfer of all affected deposits and all relevant files, etc., to another IDA. The State or intergovernmental industrial property organization must also ensure, as far as possible, that the defaulting IDA notifies all affected depositors of such transfers. In these circumstances, the State or the organization decides on the substitute IDA to which deposits are to be transferred, but the depositor may, if he so wishes, ask the defaulting IDA to send, in addition, a sample of any of his deposits and copies of any relevant files, etc., to another IDA. In this case, however, he must bear the expenses of any such additional transfer himself (Rule 5.1(e)).

(iii) Obligations of the Substitute IDA

85. The substitute IDA must issue to the depositor a receipt in respect of any microorganism transferred to it under Rule 5.1 and, after testing their viability, a viability statement. The viability statement is identical with that which would be issued in the case of the original or new deposit, but the contents of the receipt in the case of a transferred deposit (which must be made out on "international form" BP/6) are governed by Rule 7.5. This Rule requires the following particulars:

"(i) the name and address of the international depositary authority;

(ii) the name and address of the depositor;

(iii) the date on which the transferred sample was received by the international depositary authority (date of transfer);

(iv) the identification reference...given by the depositor to the microorganism;

(v) the accession number given by the international depositary authority;

(vi) the name and address of the international depositary authority from which the transfer was effected;

(vii) the accession number given by the international depositary authority from which the transfer was effected;

(viii) where the written statement referred to in Rule 6.1(a) or 6.2(a) contained the scientific description and/or proposed taxonomic designation of the microorganism, or where such scientific description and/or proposed taxonomic designation was/were indicated or amended under Rule 8.1 at a later date, a reference to that fact."

(iv) Position of the Depositor

86. Transfer of deposits in the case of loss of status or cessation of function of the IDA occurs in circumstances over which the depositor has no control, and, therefore, his active participation in the process is minimal. He should, however, be aware that it may be necessary, depending on the applicable patent procedure, for him to notify the new accession number to any industrial property office with which he has filed an application referring to the original deposit (Rule 5.1(c)). It might be prudent for him to do this in any case. Furthermore, it should be noted that Rule 5.1 requires the Contracting State or intergovernmental industrial property organization to ensure the transfer of deposits "to the fullest extent possible." There is thus no absolute guarantee that transfer of a particular deposit would in fact be effected. Therefore, when the depositor is notified by the IDA of its inability to furnish samples (as he must be under Article 4) because of loss of status or cessation of function, it is in his own interest to ascertain from the IDA whether his deposits will be transferred according to Rule 5.1. If the answer is negative, he can exercise his right under Article 4(1)(b)(i) to make new deposits with another IDA.

Section C: Furnishing of Samples

(a) General Conditions for Requesting Samples

87. The whole point of depositing a microorganism for patent purposes is to make it available to entitled parties according to the requirements of patent law. The purpose of this section is to inform depositors of the general conditions under which samples of their deposit will be furnished under the Budapest Treaty and to advise third parties of the requirements they must comply with when requesting a sample. This section should be read with reference to Section E, which gives the requirements of individual countries as to the furnishing of samples of deposited microorganisms.

88. It is widely acknowledged that IDAs cannot be expected to be familiar with the patent laws of countries throughout the world. Thus to require an IDA to judge for itself whether a particular third party is legally entitled to receive a sample of a particular deposit is generally considered to be undesirable. Many industrial property authorities also consider it unreasonable to expect an IDA to ascertain from the relevant industrial property office (which it may not even know) the legitimacy of every request for a sample. Therefore, the solution provided by the Budapest Treaty is to permit an IDA to furnish a sample of a particular microorganism only if the request is accompanied by the written authorization of the depositor or by a certificate from a competent industrial property office indicating the legitimacy of the request, or, alternatively, if a competent industrial property office has already notified the IDA

that the microorganism may be distributed without the need for such authorization. These matters are governed by Rule 11, which recognizes three different situations in which samples may be furnished, viz. to interested industrial property offices (Rule 11.1), to or with the authorization of the depositor (Rule 11.2), or to parties legally entitled (Rule 11.3).

(b) Requests from Interested Industrial Property Offices

89. When the industrial property office of a Contracting State or an intergovernmental industrial property organization requests a sample of a deposited microorganism, Rule 11.1 states that the request must be accompanied by a declaration to the effect that:

> "(i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;
>
> (ii) such application is pending before that office or has led to the grant of a patent;
>
> (iii) the sample is needed for the purposes of a patent procedure having effect in the said Contracting State or in the said organization or its member States;
>
> (iv) the said sample and any information accompanying or resulting from it will be used only for the purposes of the said patent procedure."

This Rule clearly indicates that an "interested" industrial property office is one that either is processing a patent application or has granted a patent in respect of the deposited microorganism. The above provisions also prohibit such an office from using a sample of the microorganism (or information about it) for any purposes other than its own procedures.

(c) Requests from or with the Authorization of the Depositor

90. Rule 11.2 states:

> "Any international depositary authority shall furnish a sample of any deposited microorganism:
>
> (i) to the depositor, on his request;
>
> (ii) to any authority, natural person or legal entity (hereinafter referred to as 'the authorized party'), on the request of such party, provided that the request is accompanied by a declaration of the depositor authorizing the requested furnishing of a sample."

These provisions recognize the right of the depositor both to obtain a sample of his own deposited microorganism whenever he wishes and to permit the furnishing of a sample to whomever he pleases, regardless of whether that person is otherwise "legally entitled."

However, the depositor does not have the right to prevent the furnishing of samples to parties legally entitled, whatever his personal wishes may be.

(d) Requests from Parties Legally Entitled

(i) Requests Requiring Industrial Property Office Certification

91. The furnishing of samples in the vast majority of cases is governed by Rule 11.3, which provides two alternative mechanisms. The first of these is given by Rule 11.3(a), which states:

> "(a) Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as 'the certified party'), on the request of such party, provided that the request is made on a form whose contents are fixed by the Assembly and that on the said form the industrial property office certifies:
>
> (i) that an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;
>
> (ii) that, except where the second phrase of (iii) applies, publication for the purposes of patent procedure has been effected by that office;
>
> (iii) either that the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled or that the certified party has affixed his signature on a form before that office and that, as a consequence of the signature of the said form, the conditions for furnishing a sample to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before that office; where the certified party has the said right under the said law prior to publication for the purposes of patent procedure by the said office and such publication has not yet been effected, the certification shall expressly state so and shall indicate, by citing it in the customary manner, the applicable provision of the said law, including any court decision."

These provisions are intended to protect both the depositor and the IDA from the danger of samples being furnished illegally or mistakenly. They ensure that not only must the requesting party obtain certification of entitlement from the industrial property office, but also that the industrial property office must effectively state that it is competent to provide such certification, i.e., that it is actually processing an application referring to the microorganism (either in its capacity as a national office or, in the case of an international application filed under the Patent Cooperation Treaty (PCT), as a "designated Office" within the meaning of that Treaty (Rule 11.5)), and that the requesting party meets all the conditions required by the applicable law. Moreover, where the requesting party is entitled to receive a sample before publication of the patent application, the industrial property office must refer to the actual provision of the law which grants such entitlement. Except where Rules 11.1, 11.2 or 11.3(b)

apply, any request not made out on the appropriate form or endorsed as above by the industrial property office will automatically be refused by an IDA. In the case of an international application filed under the PCT, the certification of publication required by Rule 11.3(a)(ii) can, at the option of the industrial property office, certify either international publication under the PCT or publication by that office in its own right (Rule 11.5). It should also be noted that some industrial property offices (see Section E of this Guide) may require a form additional to that just mentioned to be completed by the requesting party and may have to provide additional certification to comply with their own national law.

(ii) Requests not Requiring Industrial Property Office Certification

92. The alternative mechanism for the furnishing of samples to parties legally entitled is given by Rule 11.3(b), which states:

> "(b) In respect of patents granted and published by any industrial property office, such office may from time to time communicate to any international depositary authority lists of the accession numbers given by that authority to the deposits of the microorganisms referred to in the said patents. The international depositary authority shall, on the request of any authority, natural person or legal entity (hereinafter referred to as 'the requesting party'), furnish to it a sample of any microorganism where the accession number has been so communicated. In respect of deposited microorganisms whose accession numbers have been so communicated, the said office shall not be required to provide the certification referred to in Rule 11.3(a)."

By notifying the IDA of the accession numbers of microorganisms cited in published patents, industrial property offices in countries whose laws require that such organisms must be available without restrictions to anyone once the relevant patents have been granted and published are able to circumvent the certification procedures of Rule 11.3(a). In practice, however, such notification is provided by very few industrial property offices and IDAs are often left to ascertain for themselves whether the relevant patents have been issued.

(e) Common Procedures

93. Procedures that must be followed in respect of all requests for the furnishing of samples are laid down in Rule 11.4(a) to (e). Rule 11.4(a) and (b) deals with the languages in which any request, declaration, certification or other communication referred to in Rules 11.1, 11.2 and 11.3 must be written. Such communications must be in English, French, Russian or Spanish where they are addressed to an IDA whose official language is or whose official languages include English, French, Russian and Spanish, respectively. However, where the official language of the IDA is Russian or Spanish, any communication addressed to it may still be in English or French, in which case the International Bureau of WIPO will provide, on request and free of charge, a certified translation into Russian or Spanish. Conversely, where a request for a sample is made by an industrial property office (Rule 11.1) whose official language is Russian or Spanish, the request may be made in Russian or Spanish regardless of the official language of the IDA. In this case, the International Bureau will provide, on request and free of charge, a certified translation into English or French.

94. Rule 11.4(c) requires any request, etc., made under Rules 11.1, 11.2 or 11.3 to be in writing and to be signed and dated. Rule 11.4(d) states that any request, etc., made under Rules 11.1, 11.2 or 11.3(a) (not 11.3(b)) must contain:

> "(i) the name and address of the industrial property office making the request, of the authorized party or of the certified party, as the case may be;
>
> (ii) the accession number given to the deposit;
>
> (iii) in the case of Rule 11.1, the date and number of the application or patent referring to the deposit;
>
> (iv) in the case of Rule 11.3(a), the indications referred to in (iii) and the name and address of the industrial property office which has made the certification referred to in the said Rule."

In the case of any request made under Rule 11.3(b), only the name and address of the requesting party and the accession number of the deposit need be given (Rule 11.4(e)). However, as already mentioned (paragraph 92), Rule 11.3(b) is rarely invoked and in practice delays can be avoided if the request is also accompanied by evidence of the issuance of a patent referring to the particular microorganism.

(f) Procedures for Furnishing Samples

(i) Indications Provided by the IDA

95. Rule 11.4(f) to (h) deals with the procedures to be followed by the IDA when actually furnishing samples. Rule 11.4(f) states:

> "The container in which the sample furnished is placed shall be marked by the international depositary authority with the accession number given to the deposit and shall be accompanied by a copy of the receipt referred to in Rule 7, an indication of any properties of the microorganism which are or may be dangerous to health or the environment and, upon request, an indication of the conditions which the international depositary authority employs for the cultivation and storage of the microorganism."

Except for the requirement to supply a copy of the receipt, these are obvious provisions which most culture collections apply in any case when sending out cultures of microorganisms.

(ii) Notification of the Depositor

96. Rule 11.4(g) states:

> "The international depositary authority having furnished a sample to any interested party other than the depositor shall promptly notify the depositor in writing of that fact, as well as of the date on which the said sample was furnished and of the name and address of the industrial property office, of the authorized party, of the certified party or of the requesting party, to whom or to which the sample was furnished. The said

notification shall be accompanied by a copy of the pertinent request, of any declarations submitted under Rules 11.1 or 11.2(ii) in connection with the said request, and of any forms or requests bearing the signature of the requesting party in accordance with Rule 11.3."

This Rule recognizes the right of the depositor to be informed in every case when, to whom and under what conditions samples of his microorganism have been furnished. In practice, however, some depositors indicate in writing to the IDA that they wish to waive their right to be so informed. In such cases, most IDAs will comply with the depositor's wish; in fact, some charge a lower fee for storage if the depositor waives this right (see Section D of this Guide).

(iii) Fees

97. A fee may be charged by the IDA for the furnishing of samples (Rule 12.1(a)(iv)) in all cases except where the recipient is an industrial property office, in which case the sample must be supplied free of charge (Rule 11.4(h)).

98. Any party entitled under Rules 11.1, 11.2 or 11.3 to receive a sample of a deposited microorganism is also entitled to be supplied, on request, with a copy of the most recent scientific description and/or proposed taxonomic designation relating to the microorganism (Rule 7.6), provided, of course, that the IDA has previously received such information from the depositor under Rules 6.1(b), 6.2(a)(iii) or 8.1(b)(iii) (see Section A of this Guide). The IDA is permitted to charge a fee for the communication of the description/designation in such cases (Rule 12.1(a)(v)). This fee, like all fees charged by the IDA, cannot be varied according to the nationality or residence of the party paying it (Rule 12.1(c)).

(g) Guidelines to Making a Valid Request for a Sample

(i) General

99. Subsections (a) to (f) have detailed and explained the requirements that must be met to effect the furnishing of a sample of a microorganism deposited under the Budapest Treaty. The purpose of this subsection is to translate these requirements into the practical steps that a third party (other than an industrial property office) should take in order to obtain a sample of such a microorganism.

100. Except where Rule 11.3(b) applies, anyone making a simple request for a sample of a particular microorganism, without any authorization or certification, can expect the IDA to ask him to do one of the following:

– obtain the authorization of the depositor (Rule 11.2(ii); see paragraph 101);

– obtain certification from the appropriate industrial property office, in which case the IDA may or may not supply him with the relevant forms (Rule 11.3(a); see paragraphs 102 and 103);

– provide evidence of the issuance of a US patent. (This is necessary because samples must be available without restriction when a US patent has issued, but IDA may not be aware of the patent; see paragraph 105.)

(ii) Obtaining Samples with the Authorization of the Depositor

101. The procedure which the requesting party should follow to obtain a sample with the authorization of the depositor is self-evident. He should approach the depositor, ask him for a written, dated, signed declaration authorizing the IDA to furnish to him a sample of the microorganism in question (if he wishes, he can use form BP/11 for this, which can be obtained from the IDA, although it is not essential). He should then send this declaration along with his request (and a purchase order) to the IDA. However, Rule 11.2(ii) presupposes that the requesting party knows who the depositor is. If he does not, he cannot expect the IDA to divulge this information to him (Rule 9.2; see paragraph 41). Thus there is little point in anyone who does not already know the identity of the depositor attempting to obtain a sample by this route.

(iii) Obtaining Samples with Industrial Property Office Certification

102. A request for a sample with industrial property office certification must be made on a form corresponding to form BP/12 (see Appendix 3), which ensures that the indications required by Rules 11.3(a) and 11.4(d) are given. Commonly, form BP/12 itself is used, although certain offices may have their own version of it. For example, the European Patent Office uses a form which combines the requirements of Rules 11.3(a) and 11.4(d) of the Budapest Treaty with those of Rule 33 of the European Patent Convention. Also, some offices may require additional forms to be completed in respect of their own national procedures. The equivalent of form BP/12, and any other appropriate forms, obviously can be obtained from the relevant industrial property office(s). Also many IDAs (see Section D of this Guide) keep stocks of them and will supply copies on request. Rule 11.3(a) assumes, however, that the requesting party knows which industrial property offices are competent to provide certification (i.e., where applications have been filed) in respect of the particular microorganism being asked for. If he does not, he should not assume that because the IDA can provide him with form BP/12, it can also tell him where to send it. In many cases, IDAs do not know where applications have been filed in respect of microorganisms deposited with them.

103. To obtain a sample of a microorganism under Rule 11.3(a), the requesting party should:

(a) ask the competent industrial property office, or the IDA, for a copy of the form to be used for requesting samples of microorganisms according to Rule 11.3(a) of the Budapest Treaty;

(b) complete that part of the form to be filled in by “the requesting party;”

(c) send the entire form to the industrial property office, not to the IDA, along with any fee that may be payable;

(iv) Obtaining Samples of Deposits Cited in US Patents

104. In the United States of America, in general, after grant any microorganism referred to in the published patent must be available to the public without restriction.

105. Before the patent has been granted, however, access to the deposit will be available during the pendency of the patent application with the reference to the microorganism only to one determined by the US industrial property Office to be entitled to the deposit under U.S. law and regulations. Because of this, the certification procedures of Rule 11.3(a) are relevant to US practice to establish a right to access to the deposit before a patent has been granted. The IDA may not know that a particular microorganism is the subject of a US patent and hence freely available. Thus, anyone requesting a microorganism which is referred to in a published US patent should ascertain whether the IDA is aware of such publication. If it is not, he should accompany his request with the number and date of the patent, the name(s) of the applicant(s) and a copy of the page referring to the accession number of the microorganism as evidence of publication. If the requesting party is not able to supply such evidence, he must expect the furnishing of a sample to be delayed until the IDA has verified that publication has occurred (not all IDAs, however, do conduct this type of verification). If the IDA is already aware of such publication, however, it is likely to furnish the sample in accordance with Rule 11.3(b).

(v) Obtaining Samples under Rule 11.3(b)

106. To obtain a sample pursuant to Rule ll.3(b), a requesting party merely needs to give his name and address and quote the accession number of the microorganism. Some IDAs, however, request use of WIPO model form BP/13.

(vi) Health and Safety Requirements

107. It should be noted that the procedures described in this subsection relate only to the right to receive samples of microorganisms according to patent law. They do not override any requirements to be met in respect of import and quarantine regulations, health and safety procedures, plant disease regulations, etc. Thus as well as obtaining any certification required by the Budapest Treaty, anyone requesting a sample must ensure that he has obtained any permit or license and complies with any safety requirements necessary for handling the organism in question.

PART II: SPECIFIC REQUIREMENTS OF INDIVIDUAL INTERNATIONAL DEPOSITARY AUTHORITIES AND INDUSTRIAL PROPERTY OFFICES

Section D: Requirements of International Depositary Authorities (IDAs)

(a) Culture Collections Currently Holding IDA Status

The following 44 depositary institutions in 23 countries have acquired the status of IDA:

Australia (AU)
Lady Mary Fairfax CellBank Australia (CBA)
The National Measurement Institute (NMI)

Belgium (BE)
Belgian Coordinated Collections of Microorganisms (BCCM™)

Bulgaria (BG)
National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)

Canada (CA)
International Depositary Authority of Canada (IDAC)

Chile (CL)
Colección Chilena de Recursos Genéticos Microbianos (CChRGM)

China (CN)
China Center for Type Culture Collection (CCTCC)
China General Microbiological Culture Collection Center (CGMCC)

Czech Republic (CZ)
Czech Collection of Microorganisms (CCM)

Finland (FI)
VTT Culture Collection (VTTCC)

France (FR)
Collection Nationale de Cultures de Micro-organismes (CNCM)

Germany (DE)
Leibniz-Institut DSMZ – Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)

Hungary (HU)
National Collection of Agricultural and Industrial Microorganisms (NCAIM)

India (IN)
Microbial Culture Collection (MCC)
Microbial Type Culture Collection and Gene Bank (MTCC)

Italy (IT)
Advanced Biotechnology Center (ABC)
Collection of Industrial Yeasts (DBVPG)
Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini" (IZSLER)

Japan (JP)
International Patent Organism Depositary (IPOD),
National Institute of Technology and Evaluation (NITE)
National Institute of Technology and Evaluation,
Patent Microorganisms Depositary (NPMD)

Latvia (LV)
Microbial Strain Collection of Latvia (MSCL)

Netherlands (NL)
Centraalbureau voor Schimmelcultures (CBS)

Poland (PL)
IAFB Collection of Industrial Microorganisms
Polish Collection of Microorganisms (PCM)

Republic of Korea (KR)
Korean Agricultural Culture Collection (KACC)
Korean Cell Line Research Foundation (KCLRF)
Korean Collection for Type Cultures (KCTC)
Korean Culture Center of Microorganisms (KCCM)

Russian Federation (RU)
Russian Collection of Microorganisms (VKM)
National Research Center of Antibiotics (NRCA)
Russian National Collection of Industrial Microorganisms (VKPM)

Slovakia (SK)
Culture Collection of Yeasts (CCY)

Spain (ES)
Banco Español de Algas (BEA)
Colección Española de Cultivos Tipo (CECT)

United Kingdom (GB)

CABI Bioscience, UK Centre (IMI)
Culture Collection of Algae and Protozoa (CCAP)
European Collection of Cell Cultures (ECACC)
National Collection of Type Cultures (NCTC)
National Collection of Yeast Cultures (NCYC)
National Collections of Industrial, Food and Marine Bacteria (NCIMB)
National Institute for Biological Standards and Control (NIBSC)

United States of America (US)
Agricultural Research Service Culture Collection (NRRL)
American Type Culture Collection (ATCC)
Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA)

(b) List of Kinds of Microorganisms Accepted by IDAs*

	ABC (IT)	ATCC (US)	BCCM™ (BE)	BEA (ES)	CBA (AU)	CBS (NL)	CCAP (GB)	CChRGM (CL)	CCM (CZ)	CCTCC (CN)	CCY (SK)	CECT (ES)
Algae		X		X			X			X		
Animal viruses		X								X		
Animal cell cultures	X	X	X		X					X		
Bacteria (pathogenic)		X	X			X			X	X		X
Bacteria (non-pathogenic)		X	X			X		X	X	X		X
Bacteriophages		X				X				X		
Embryos		X										
Eukaryotic DNA		X								X		
Fungi (pathogenic)		X	X			X			X	X		
Fungi (non-pathogenic)		X	X			X		X	X	X		X
Human cell cultures	X	X	X		X					X		
Hybridomas	X	X	X		X					X		
Molds		X						X		X		
Murine embryos		X										
Mycoplasma		X								X		
Nematodes										X		
Oncogenes		X								X		
Plant cell cultures		X								X		
Plant viruses		X								X		
Plasmids (in hosts)		X	X			X		X	X	X		X
Plasmids (not in hosts)		X	X			X				X		X
Protozoa (parasitic)		X										
Protozoa (non-parasitic)		X					X			X		
Protozoa (pathogenic)		X										
RNA		X	X									
Seeds		X								X		
Yeasts (pathogenic)		X	X			X			X	X	X	
Yeasts (non-pathogenic)		X	X			X		X	X	X	X	X

* For information purposes only. For the up-to-date list of microorganisms accepted by IDAs pursuant to Rule 13.2(a) of the Regulations under the Budapest Treaty, please refer to "Information on Kinds of Microorganisms Accepted and Amount of Fees Charged by IDAs" on the Budapest Treaty website (http://www.wipo.int/budapest).

(b) List of Kinds of Microorganisms Accepted by IDAs (continued)

	CGMCC (CN)	CNCM (FR)	DBVPG (IT)	DSMZ (DE)	ECACC (GB)	IAFB (PL)	IDAC (CA)	IMI (GB)	IPOD (JP)	IZSLER (IT)
Algae	X								X	
Animal viruses	X	X			X		X			X
Animal cell cultures	X	X		X	X		X			
Bacteria (pathogenic)	X	X		X			X			X
Bacteria (non-pathogenic)	X	X		X		X	X	X		X
Bacteriophages	X			X			X			
Embryos										
Eukaryotic DNA					X		X			
Fungi (pathogenic)	X	X		X			X			
Fungi (non-pathogenic)	X	X	X	X		X	X	X		
Human cell cultures		X		X	X					
Hybridomas		X		X	X		X			
Molds										
Murine embryos										
Mycoplasma	X			X						
Nematodes								X		
Oncogenes										
Plant cell cultures	X			X					X	
Plant viruses	X			X						
Plasmids (in hosts)	X	X		X			X			
Plasmids (not in hosts)	X			X			X			
Protozoa (parasitic)										
Protozoa (non-parasitic)									X	
Protozoa (pathogenic)										
RNA										
Seeds	X								X	
Yeasts (pathogenic)	X	X		X			X			
Yeasts (non-pathogenic)	X	X	X	X		X	X	X		

(b) List of Kinds of Microorganisms Accepted by IDAs (continued)

	KACC (KR)	KCCM (KR)	KCLRF (KR)	KCTC (KR)	MCC (IN)	MSCL (LV)	MTCC (IN)	NBIMCC (BG)	NCAIM (HU)	NCIMB (GB)	NCMA (US)	NCTC (GB)
Algae				X							X	
Animal viruses		X		X				X				
Animal cell cultures			X	X				X				
Bacteria (pathogenic)					X	X	X			X		X
Bacteria (non-pathogenic)	X	X		X	X	X	X	X	X	X	X	
Bacteriophages		X		X			X			X	X	
Embryos				X								
Eukaryotic DNA			X	X								
Fungi (pathogenic)					X	X	X					
Fungi (non-pathogenic)	X	X		X	X	X	X	X	X			
Human cell cultures			X	X								
Hybridomas			X	X				X				
Molds				X					X			
Murine embryos				X								
Mycoplasma												
Nematodes												
Oncogenes												
Plant cell cultures			X	X						X		
Plant viruses	X	X		X				X				
Plasmids (in hosts)	X	X	X	X	X	X	X	X		X		
Plasmids (not in hosts)		X	X	X	X		X			X		
Protozoa (parasitic)												
Protozoa (non-parasitic)				X							X	
Protozoa (pathogenic)												
RNA				X								
Seeds	X			X						X		
Yeasts (pathogenic)				X	X	X	X					
Yeasts (non-pathogenic)	X	X		X	X	X	X	X	X	X		

(b) List of Kinds of Microorganisms Accepted by IDAs (continued)

	NCYC (GB)	NIBSC (GB)	NMI (AU)	NPMD (JP)	NRCA (RU)	NRRL (US)	PCM (PL)	VKM (RU)	VKPM (RU)	VTTCC (FI)
Algae										
Animal viruses										
Animal cell cultures		X		X					X	
Bacteria (pathogenic)				X			X			
Bacteria (non-pathogenic)			X	X	X	X	X	X	X	X
Bacteriophages				X			X		X	
Embryos				X						
Eukaryotic DNA										
Fungi (pathogenic)				X						
Fungi (non-pathogenic)			X	X	X	X		X	X	X
Human cell cultures		X		X					X	
Hybridomas				X					X	
Molds						X				
Murine embryos										
Mycoplasma										
Nematodes										
Oncogenes										
Plant cell cultures									X	
Plant viruses										
Plasmids (in hosts)				X		X			X	
Plasmids (not in hosts)				X					X	
Protozoa (parasitic)										
Protozoa (non-parasitic)										
Protozoa (pathogenic)										
RNA										
Seeds										
Yeasts (pathogenic)				X						
Yeasts (non-pathogenic)	X		X	X	X	X		X	X	X

(c) Detailed Requirements and Practices of IDAs

(i) General

This subsection describes in detail the requirements and practices of each IDA as they relate to the deposit of microorganisms and the furnishing of samples under the Budapest Treaty. Information is based on communications and notifications published on WIPO's website (http://www.wipo.int/budapest), and on the replies to letters sent to all IDAs by WIPO. The IDAs are listed alphabetically by country and the information on each is arranged in the format given in (ii), below. Reference to "model forms" and "international forms" means those forms designed by the International Bureau of WIPO, published in WIPO documents BP/A/II/12 (1981) and BP/A/VIII/1 (1990), and which are reproduced in Appendix 3.

(ii) Information on IDAs

For each IDA, information is arranged as follows:

country, name of international depositary authority and acronym, address, telephone and fax numbers, electronic and Internet addresses, if any.

IDAs are listed according to the two-letter country code in accordance with WIPO Standard ST.3.

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The different types of biological entities accepted for deposit and any specific exclusions are given. The maximum hazard rating and/or physical containment requirements acceptable to the IDA in respect of microorganisms that may be deposited are stated.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The state in which cultures must be submitted is given, e.g., lyophilized, frozen, liquid suspension, agar slant, etc. The minimum number of replicates that must be supplied by the depositor and the minimum titre of each culture (where appropriate) are stated.

(ii) Time Required for Viability Testing

The average and maximum length of time (in days) needed by the IDA to carry out viability tests is given for each kind of microorganism accepted.

(iii) Depositor Checks and Renewal of Stocks

Information is given whether the IDA subcultures material supplied by the depositor to provide stocks of samples for storage; whether it stores samples originally supplied by the depositor; how it replenishes diminishing stocks; and whether it requires the depositor to test for authenticity samples of its own preparations.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language(s) and any other language(s) in which the IDA accepts communications are given.

Contract. Information is given about the kind of contract (if any) that the IDA enters into with the depositor.

Import and/or Quarantine Regulations. Information is given whether any of the microorganisms accepted by the IDA are subject to import and/or quarantine regulations; the requirements for compliance with such regulations; and the government departments where further advice may be obtained.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Reference is made to any forms that must be completed; any information that must be given to the IDA in advance of deposit; and any special transport and/or delivery arrangements.

Official Notifications to the Depositor. Reference is made to any forms that the IDA uses to issue official notifications to the depositor.

Unofficial Notifications to the Depositor. An indication is given whether the IDA will communicate information to the depositor in advance of any official notifications.

Supply of Information to a Patent Agent. An indication is given whether the IDA will supply copies of documents to the depositor’s patent agent.

(iii) Converting a Previous Deposit

Information is given about the requirements of the IDA that the depositor must meet and the extent to which he is permitted to convert a deposit previously made outside the Budapest Treaty to one made under the Treaty.

(iv) Making a New Deposit

Any requirements of the IDA additional to those that must be met when making an original deposit are indicated.

2. Furnishing of Samples

(a) Requests for Samples

Information is given whether the IDA advises third parties of the correct procedures to follow in order to make a valid request; whether the IDA supplies the requesting party with the appropriate forms; whether the requesting party must meet any health and safety requirements; whether samples furnished by the IDA are from its own preparations or from those supplied by the depositor.

(b) Notification of the Depositor

The means whereby the IDA notifies the depositor of the furnishing of samples is given.

(c) Cataloguing of Budapest Treaty Deposits

It is stated whether, and under what conditions, the IDA lists deposits under the Budapest Treaty in its published catalogs.

3. Schedule of Fees

The fees payable to the IDA for procedures carried out under the Budapest Treaty are listed.

4. Guidance for Depositors

Reference is made to any publications that the IDA makes available for the guidance of prospective depositors.

AU – AUSTRALIA

LADY MARY FAIRFAX CELLBANK AUSTRALIA (CBA)
Children's Medical Research Institute
214 Hawkesbury Road
Westmead NSW 2145

Postal address:
Locked Bag 23
Wentworthville NSW 2145

Telephone: (61-2) 8865 2850
Facsimile: (61-2) 9687 2120
E-mail: info@cellbankaustralia.com
Internet: www.cellbankaustralia.com

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

CBA will accept for deposit, human and animal cell lines and hybridomas that can be preserved in liquid nitrogen vapour without significant damage to or loss of their properties or viability.

CBA will not at this time accept for deposit, genetically modified organisms requiring physical containment level 3 or 4 (PC3 or PC4). Deposits should be accompanied by a favourable Biohazard Risk Assessment statement.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Human and animal cell lines and hybridoma must be submitted to CBA for deposit in the form of frozen cultures. CBA may refuse deposits that have not been packed in sufficient dry ice to keep them frozen during transit.

The minimum number of replicates that must be provided by the depositor when making the deposit is 12. All hybridoma, human and animal cell cultures must contain at least 4×10^6 cells/ampoule.

Any requests to deposit human embryo stem cell lines will be subject to current Australian Government regulations and guidelines.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by CBA is given below, but depositors should realize that, in some cases, viability testing might take longer. Customers will be advised of this prior to deposit being accepted.

Animal cell cultures	10 days (or up to 15 days)
Human cell cultures	10 days (or up to 15 days)
Hybridoma cultures	10 days (or up to 15 days)

(iii) Depositor Checks and Renewal of Stocks

CBA generally does not prepare its own batches of the deposited organisms, and when the furnishing of samples depletes stocks, the depositor will be asked to make a new deposit. The depositor is asked to check the authenticity of samples prepared by CBA.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The CBA application form, which the depositor is required to complete, binds the depositor:

- to provide material only in the required form and quantity;
- to provide a biohazard statement;
- to pay all necessary fees including all charges for the transportation of deposits to CBA;
- to observe the terms and conditions of the Budapest Treaty;
- to accept the terms and conditions of deposit of samples in CBA.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. The customer will be advised to obtain the regulatory documentation once CBA has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the CBA application form referred to in (i), above, the depositor must complete a CBA deposit form and biohazard statement (available on the CBA website).

At least 48 hours before the microorganism is dispatched, CBA must be informed of the number of ampoules being sent, the method of transportation and the estimated time of arrival. If dispatch is by air, CBA must be told the flight number and destination, waybill number and handling agent for delivery.

CBA 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 CBA has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, CBA will telephone, fax or email the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. CBA does not routinely ask the depositor for the name and address of his or her patent attorney. However, if requested, it will send copies of the receipt and viability statement to both the depositor and the patent attorney.

(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 deposited for patent purposes. However, any deposits previously made are subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits.

The administrative requirements for conversion are the same as those to be met in respect of an original deposit, except that requirements relating to shipping procedures do not apply.

(iv) Making a New Deposit

The depositor is required to complete the CBA deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform to the procedures mentioned previously in respect of shipping requirements.

2. Furnishing of Samples

(a) Requests for Samples

CBA does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant intellectual property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations or by written authorization of the depositor, CBA will withhold samples of potentially hazardous microorganisms until the requesting party has confirmed that it has the appropriate containment facilities to handle such organisms.

When responding to requests from overseas, CBA assumes that the requesting party has met the import requirements of their own country, and the customer is responsible for provision of the relevant documentation to do so.

Samples furnished by CBA are usually from preparations supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

CBA does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

1. Cell lines	Australian dollars
For the storage of the microorganism in accordance with the Treaty, including certification and viability statement	2,600
Issuance of a new or updated viability statement	170
2. General	
Furnishing of a sample (excluding shipping costs)	210
Issuance of (new or amended) certification	110
Administration fee for amendments	110

Fees plus GST, where applicable, are payable to CellBank Australia.

4. Guidance for Depositors

Guidance for depositors is provided on the CBA application form and CBA website (*www.cellbankaustralia.com)*

AU – AUSTRALIA

THE NATIONAL MEASUREMENT INSTITUTE (NMI)

1/153, Bertie Street
Port Melbourne, VIC 3207
Australia

Telephone: (61-3) 9644 4841
Facsimile: (61-3) 9644 4999
E-mail: budapest.treaty@measurement.gov.au
Internet: http://www.measurement.gov.au

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes), yeasts and fungi other than known human and animal pathogens, that can be preserved without significant change to their properties by the methods of preservation in use (freezing and freeze-drying).

Nucleic acid preparations and phages may be accepted if the depositor certifies that they pose no hazard when handled by normal laboratory procedures and the depositor supplies suitable material for preservation.

At present, the NMI does not accept for deposit animal, plant, algal and protozoal cultures, cultures of viral, rickettsial and chlamydial agents, microorganisms which may require, in the view of the curator, special attention to handling and preparation for storage.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms must be submitted for deposit as lyophilized preparations or on culture media. The minimum number of replicates that must be provided by the depositor when making his deposit and the form in which they must be submitted are as follows:

Bacteria, fungi and yeasts	6 lyophilized or on culture media
Phages and plasmids	sufficient quantity and titre for preservation

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the NMI is given below:

Bacteria	5 days
Fungi	10 days
Yeasts	10 days

(iii) Depositor Checks and Renewal of Stocks

The NMI prepares its own batches of bacteria, fungi and yeasts by subculturing material supplied by the depositor. New batches are prepared by asking the depositor to make a new deposit under Article 4, by subculturing NMI's own preparation with the approval of the depositor, or by subculturing material originally supplied by the depositor. The depositor is asked to check the authenticity of batches prepared by the NMI from material supplied by him at the time of deposit and thereafter. The NMI stores original material supplied by the depositor.

(c) Administrative Requirements and Procedure

(i) General

Language. The official language of the NMI is English.

Contract. At present, the NMI does not enter into a written contract with the depositor defining the liabilities of either party.

Import and/or Quarantine Regulations. Certain kinds of microorganisms accepted for deposit by the NMI are subject to import and quarantine regulations. The NMI will arrange the necessary permits for importation of biological materials and clearing any quarantine requirements. The depositor must contact the NMI before depositing any microorganisms. The time required to obtain the permit may vary depending on the kinds of microorganisms to be deposited. Further information may be obtained from the Australian Quarantine Inspection Service, GPO Box 858, Canberra, A.C.T., 2601 Australia.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is requested to complete model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and viability statement are issued, respectively, on mandatory "international forms" BP/4 and BP/9. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification to the depositor that a sample of the deposited microorganism has been furnished to an entitled party is issued on model form BP/14. Standard forms are not used for other notifications.

Unofficial Notifications to the Depositor. If requested, the NMI will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. Similarly, the NMI will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NMI asks the depositor at the time of deposit to supply the name and address of his patent agent and, if requested, it will send copies of the receipt and the viability statement to both the depositor and 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, whether or not they were originally deposited for patent purposes. In addition to the administrative requirements for conversion, which are the same as those to be met in respect of an original deposit under the Budapest Treaty, the NMI requests the depositor to verify the authenticity of his deposited material at the time of conversion.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to supply copies of the documents specified under Rule 6.2; otherwise, the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

The NMI advises requesting parties of the correct procedure to follow to make a valid request. In the case of requests requiring proof of entitlement, the NMI will provide requesting parties with copies of model request form BP/12 and/or requests forms used by individual industrial property offices. It will also advise requesting parties on the requirements provided for under the Australian Patent Act.

The NMI furnishes a sample of a dangerous microorganism only after having received confirmation that the requesting party is capable of handling the microorganism safely.

(b) Notification of the Depositor

Depositors are notified when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

At present, the NMI does not publish a catalog.

3. Schedule of Fees

		AUD
(a)	Storage	1,000
(b)	Issuance of a viability statement on an existing deposit	270
(c)	Furnishing of a sample	270

4. Guidance for Depositors

Guidance notes for prospective depositors are in preparation.

BE - BELGIUM

BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS (BCCM™)

BCCM™ is a consortium of complementary service collections. The headquarters and the component collections that accept deposits under the Budapest Treaty are listed hereunder. All applications and/or deposits are to be addressed directly to the appropriate BCCM™ collection.
The Quality Management System of the BCCM™ consortium has been certified according to the ISO 9001 standard for, among others, the following activities:
"Accession, control, preservation, storage and supply of biological material and related information in the frame of public deposits, safe deposits and patent deposits under the Budapest Treaty".

Headquarters
BCCM Coordination Cell
Federal Public Planning Service Science Policy
231, avenue Louise
1050 Brussels

Telephone: (32-2) 238 36 07
Facsimile: (32-2) 230 59 12
E-mail: bccm.coordination@belspo.be
Internet: http://bccm.belspo.be/index.php

Collections

BCCM/IHEM Biomedical fungi and yeasts collection
Scientific Institute of Public Health
Service Mycology and Aerobiology
Rue J. Wytsmanstraat, 14
1050 Brussels

Telephone: (32-2) 642 55 18
Facsimile: (32-2) 642 55 19
E-mail: bccm.ihem@wiv-isp.be

BCCM/LMBP Plasmid and DNA Library collection
Universiteit Gent
Vakgroep Biomedische Moleculaire Biologie
Technologiepark, 927
9052 Zwijnaarde

Telephone: (32-9) 331 38 43
Facsimile: (32-9) 331 35 04
E-mail: bccm.lmbp@irc.UGent.be

BCCM/LMG Bacteria collection
Universiteit Gent
Laboratorium voor Microbiologie
K.L. Ledeganckstraat, 35
9000 Gent

Telephone: (32-9) 264 51 08
Facsimile: (32-9) 264 53 46
E-mail: bccm.lmg@UGent.be

BCCM/MUCL Agro-industrial fungi, yeasts and arbuscular mycorrhizal fungi collection
Université catholique de Louvain
Mycothèque de l'Université catholique de Louvain
Croix du Sud, 2 – box L7.05.06
1348 Louvain-La-Neuve

Telephone: (32-10) 47 37 42
Facsimile: (32-10) 45 15 01
E-mail: bccm.mucl@uclouvain.be

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

BCCM/IHEM: filamentous fungi and yeasts, including pathogenic fungi and yeasts that cause mycosis in man and animals, and actinomycetes.

BCCM/LMBP: genetic material, recombinant or not, cloned in a host or as isolated material (e.g. plasmids); natural or genetically modified human and animal cell lines, including hybridomas. Deposits of genetically modified microorganisms should not exceed containment level 2 as defined by the EU directive 2009/41/EC and its updates concerning the contained use of genetically modified organisms.

BCCM/LMG: bacteria, including actinomycetes, but excepting pathogens belonging to a hazard group higher than Risk group 2 according to the EU directive 2000/54/EC and its updates.

BCCM/MUCL: filamentous fungi, yeasts and arbuscular mycorrhizal fungi, including plant pathogens, but excluding pathogenic fungi causing mycosis in man and animals belonging to a hazard group higher than Risk group 2 according to the EU directive 2000/54/EC and its updates.

As a general rule, the BCCM™ collections accept only samples that can be cultured and preserved under conditions technically feasible for the collection concerned and that can be conserved, other than in continuous vegetative activity, without inducing significant changes in their characteristics.

Exceptionally, the various BCCM™ collections may accept deposits of microorganisms that cannot be conserved other than by active culture. Acceptance as well as the costs of such a deposit will be negotiated case by case with the potential depositor. Exceptionally and following the same case-by-case negotiation procedure, they may also accept deposits of mixtures of microorganisms.

The BCCM™ collections also reserve their right to refuse a deposit of biological material whose manipulation or conservation involves hazards deemed to be excessive, or if they receive the material in a bad condition.

All deposits should be addressed directly to the appropriate BCCM™ collection.

(b) Technical Requirements and Procedures

(i) Form and Quantity

- Bacteria, filamentous fungi, yeasts, actinomycetes:

The depositor must supply 23 ampoules with freeze-dried cells of the same batch.

The freeze-dried cells of one or more of these ampoules will be subjected to a viability test and subsequently serve for the preparation of a stock of 20 cryopreserved samples.

In case the depositor is not able to provide the required 23 ampoules, he must supply at least 3 ampoules of freeze-dried cells of the same batch.

In case the depositor is not able to provide the microorganism under freeze-dried form, he must supply 3 “vials” of frozen cultures, or 3 active cultures, each of the same batch.

The freeze-dried cells of one or more ampoules or the frozen cells of one or more vials, or one or more of the active cultures will be subjected to a viability test and subsequently serve for the preparation of a stock of 20 samples of cryopreserved cells. BCCM™ will prepare a batch of 20 samples of freeze-dried cells for an additional fee.

- Arbuscular mycorrhizal fungi:

Optimally, the depositor must supply 2 *in vitro* (monoxenic) cultures of the same batch.

Otherwise, he must supply an “*inoculum*” containing propagules (i.e. spores and/or mycorrhizal root fragments) from an *in vitro* culture or from a trap plant, or a trap plant culture containing spores[1]. It is mandatory that the “inoculum” is derived from a single monosporal culture. However, a mixture of propagules from more than one culture may also be accepted if the material is derived from the same mother monosporal culture.

Upon request of the depositor, BCCM/MUCL could attempt to grow the arbuscular mycorrhizal fungus under *in vitro* (monoxenic) culture for an additional fee.

[1] Note that in trap plant culture, purity can only be assessed within the Glomeromycota phylum since the trap plant culture are generally not produced in aseptic conditions

- Plasmids in a bacterial host:

The depositor must supply three active, freeze-dried or frozen cultures of the same batch, of which one or more will be subjected to a viability test and subsequently serve for the preparation of a stock of cryopreserved cells.

- Plasmids as isolated material:

Samples must be supplied in freeze-dried or frozen form or precipitated in alcohol. A minimum of 2 x 20 micrograms must be furnished.

The plasmid DNA must have a sufficient degree of purity to ensure successful transformation. The recommended bacterial host strain must be stated and - if not available at the depositary - also be furnished without the plasmid concerned. In the latter case, the storage of the appropriate host strain for the period of at least 30 years will be charged separately.

- Human and animal cells, hybridomas:

The animal and human cell cultures or hybridomas must be checked for contaminants before submitting the mass frozen cultures (containing at least 4 x 10^6 viable cells/vial). BCCM/LMBP may refuse the deposit when cultures are thawed upon arrival. At least 12 samples of the same batch in well-sealed and clearly and durably marked 1-2 ml cryotubes of ± 12 mm diameter must be supplied, of which one or more will be subjected to a viability test.

- Other genetic material: contact BCCM/LMBP.

(ii) Time required for Viability Testing

The minimum periods required by BCCM™ to test the viability of various types of microorganisms are as follows (however, depositors should be aware that the viability test may take longer for certain types of microorganisms):

Bacteria	3 days
Filamentous fungi	3 days
Yeasts	2 days
Arbuscular mycorrhizal fungi	30 days
Plasmids[2]	± 1 week
Human and animal cell cultures, hybridomas[3]	± 3 weeks
Other genetic material	Contact BCCM/LMBP

(iii) Depositor Checks and Renewal of Stocks

At the time of deposit, BCCM™ prepare their own cryopreserved batch and, depending on the form and quantity in which the microorganisms have been supplied, their own freeze-dried batch. From this cryopreserved or freeze-dried batch, the depositor is

[2] The "viability test" includes the preparation of plasmid DNA and restriction enzyme analysis by gel electrophoresis. For genetic material deposited as isolated material, the "viability test" obviously implies the transformation of the suitable host first. If the theoretically expected fragments can be experimentally confirmed, the "viability test" is deemed positive.

[3] The "viability test" includes testing for mycoplasma contamination.

provided with 1 sample with the request to check the authenticity of this sample of his microorganism prepared by BCCM™ and to inform them of the result of his checking.

Also, to renew depleted stocks, BCCM™ will prepare, as needed, new batches starting from one sample of the previous batch.
Only for the renewed freeze-dried batches, and for the cultures maintained by regular sub-cultivation (i.e. the Glomeromycota), the depositor is again asked to check the authenticity.

In general, BCCM™ do not prepare their own batches of animal and human cell lines or hybridomas. Consequently, when stocks of material are depleted following furnishing of samples, they request the depositor to make a new deposit.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of BCCM™ is English. Communications are also accepted in German, French and Dutch.

Contract. The application form BCCM™/acron/DBT1,[4] which must be completed by the depositor, constitutes a contract under which the depositor is required:

- to communicate all information requested by BCCM™;

- to pay all required fees;

- not to withdraw his deposit during the required conservation period;

- to authorize BCCM™ to furnish samples in accordance with the requirements applicable to patents;

- to make a new deposit in the event of BCCM™ not being in a position to supply samples;

- not to make BCCM™ liable for any deterioration of samples during conservation if all the precautions he has described for that conservation have been taken by BCCM™;

- to compensate BCCM™ for any prejudice they may incur as a result of the handling of the microorganism for which they are responsible if all the precautions he has described with respect to such handling have been taken by BCCM™;

- to compensate BCCM™ for any court action that may be taken against them following the supply of samples, unless such action is based on negligence on the part of BCCM™.

[4] All the forms used by BCCM™ bear a reference number of the type BCCM/acron/num; "acron" is replaced by the acronym (IHEM, LMBP, LMG, MUCL) of the Collection concerned; "num" is replaced by the individual number of the form. Numbering of the type "BP/.." indicates that it is a compulsory international form or another standard form.

Once the deposit and acceptance procedure has been completed, the depositor receives a form BCCM/acron/DBT2 to remind him that he is bound by the contract thus concluded. Belgian law applies to any dispute.

Import and/or Quarantine Regulations. Certain types of microorganisms accepted by BCCM™ are subject to import or quarantine regulations. Where that is the case, the depositor must communicate the name of the species of the microorganism to BCCM™ to enable the necessary measures to be taken.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete, in addition to the application form BCCM/acron/DBT1 (see (i) above), a form BCCM/acron/BP/1, which is the deposit form required by the Budapest Treaty.

Preferentially, these two forms are to be sent to the appropriate BCCM™ collection before sending the biological material. The BCCM™ collections reserve the right to refuse a deposit of biological material if these two forms are not filled out correctly.

In the event of a subsequent communication or modification of the scientific description or the proposed taxonomic designation and also for any request for attestation that BCCM™ have received such information, the depositor should preferably complete the form BCCM/acron/BP/7.

Official Notifications to the Depositor. The attestation of receipt and the viability statement are issued on the compulsory "international forms" BCCM/acron/BP/4 and BCCM/acron/BP/9, respectively.

The attestation of receipt of communication or subsequent amendment of the scientific description and/or the proposed taxonomic designation is issued on the form BCCM/acron/BP/8.

The notification on the furnishing of samples to third parties is issued on form BCCM/acron/BP/14.

Unofficial Notifications to the Depositor. Although BCCM™ confirm receipt of the microorganisms sent to them, this does not mean that they have accepted them for deposit. If the viability test gives a positive result, BCCM™ communicate the result, on request, unofficially, together with the deposit number of the microorganism before issuing the official attestations on receipt and viability.

Supply of Information to a Patent Agent. BCCM™ request the depositor to communicate to them, in the interest of all concerned, the name and address of his patent agent. On request, they will provide to the patent agent a copy of the attestation of receipt and of the viability statement.

(iii) Converting a Previous Deposit

Deposits that were not made under the Budapest Treaty may be converted by the original depositor into deposits under that Treaty, whether or not the microorganisms were

originally deposited for the purposes of patent procedure. Any earlier deposit-even if made free of charge-is subject, at the time of conversion, to the storage fee normally charged for deposits made under the Budapest Treaty. The administrative requirements for conversion are the same as those that must be met for an original deposit made under the Budapest Treaty. Both the date of deposit and the date of receipt of the request for conversion are stated on the "international form" BCCM/acron/BP/4.

(iv) Making a New Deposit

When making a new deposit, the depositor must complete form BCCM/acron/BP/2 and furnish copies of the documents referred to in Rule 6.2. The attestation of receipt and the viability statements with respect to a new deposit are issued on the compulsory “international forms” BCCM/acron/BP/5 and BCCM/acron/BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

BCCM^{TM} will inform third parties of the procedure to be followed in order to make a proper request. For those requests requiring proof of the right to receive samples, BCCM^{TM} will supply the requesting parties copies of the standard request form BCCM/acron/BP/12 or of the request forms used by a given industrial property office (insofar as such office has transmitted the relevant forms to BCCM^{TM}).

Notwithstanding any entitlement by a third party to receive samples under patent regulations, BCCM^{TM} will conserve the samples of potentially hazardous microorganisms until the requesting party has proven that it holds an authorization to handle such organisms. Likewise, they will only furnish samples of a microorganism to recognized microbiological laboratories and not to private addresses. In the case of requests from abroad, the requesting party has to satisfy its own country’s requirements with regard to importation.

All samples of microorganisms furnished by BCCM^{TM} will be taken from the batches they have prepared themselves or from the batches furnished by the depositor.

(b) Notification of the Depositor

When BCCM^{TM} furnish a sample of a deposited microorganism to a third party, they will notify the depositor on the standard form BCCM/acron/BP/14, unless the depositor has waived his right to receive such notification.

(c) Cataloguing of Budapest Treaty Deposits

BCCM^{TM} will not list, in the catalogs it publishes, the deposits made under the Budapest Treaty.

3. Schedule of Fees

		EUR
1.	For cultures of bacteria, yeasts, filamentous fungi, including actinomycetes	
(a)	Storage	665
(b)	Preparation of the first batch of 20 freeze-dried samples for long term storage (only in case these are not provided by the depositor)	300
(c)	Issuance of a viability statement:	
	- when a viability test is carried out	60
	- based on the last viability test	25
(d)	Furnishing of a sample	
	- Fungi and yeasts	120
	- Bacteria	90
(e)	Communication of information	25
(f)	Issuance of an attestation	25
2.	For arbuscular mycorrhizal fungi	
(a)	Storage	1,300
(b)	Preparation of a batch of cryopreserved samples for long term storage (20 samples)(if applicable, depending on the species of AMF deposited)	600
(c)	Issuance of a viability statement:	
	- when a viability test is carried out	500
	- based on the last viability test	25
(d)	Furnishing of a sample	120
(e)	Communication of information	25
(f)	Issuance of an attestation	25
3.	For plasmids	
(a)	Storage [5]	665
(b)	Issuance of a viability statement:	
	- when a viability test is carried out	60
	- based on the last viability test	25
(c)	Furnishing of a sample	105
(d)	Communication of information	25
(e)	Issuance of an attestation	25

[5] In case the recommended host strain is not available at BCCM/LMBP, the depositor is encouraged to deposit a plasmid-carrying culture. If this is not possible and the host has to be furnished by the depositor, a one-off fee of 160.00 euros for this host strain will be charged for quality control tests at the time of deposit (purity, viability), batch preparation, cryopreservation, safekeeping at -80°C for min. 30 years, administration.

4.	For human cells, animal cells and hybridomas	
(a)	Storage	1,300
(b)	Issuance of viability statement:	
	- when a viability test is carried out	90
	- based on the last viability test	25
(c)	Furnishing of a sample	110
(d)	Communication of information	25
(e)	Issuance of an attestation	25
5.	For other genetic material	Price offer on request at BCCM/LMBP

Fees do not include VAT, transport costs or bank fees.

4. Guidance for Depositors

Depositors are reminded that all requests or deposits should be dealt directly with the BCCM^{TM} collection concerned. They may also obtain the necessary forms from that collection, or from the BCCM website http://bccm.belspo.be/services/deposit.

The staff of the collections is of course available to potential depositors to provide any detailed information. The contact details of each of the collections are mentioned above.

BG – BULGARIA

NATIONAL BANK FOR INDUSTRIAL MICROORGANISMS AND CELL CULTURES (NBIMCC)

49 St Kliment Ohridski Blvd., Bldg. 3
1756 Sofia

Telephone: (00359-2) 872 08 65
Facsimile: (00359-2) 872 08 65
E-mail: info@nbimcc.org
Internet: http://www.nbimcc.org

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) Technical Requirements and Procedures

(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 5×10^6 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) 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 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

		BGL
(a)	Storage	1,200
(b)	Issurance of a viability statement	120
(c)	Furnishing of a sample	120

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.

CA – CANADA

INTERNATIONAL DEPOSITARY AUTHORITY OF CANADA (IDAC)

National Microbiology Laboratory
Public Health Agency of Canada
Canadian Science Center for Human and Animal Health
1015 Arlington Street
Winnipeg, MB R3E 3R2

Telephone: (1-204) 789 60 30
Facsimile: (1-204) 789 20 18
Internet: http://www.nml-lnm.gc.ca/IDAC-ADI/index-eng.htm (English version)
http://www.nml-lnm.gc.ca/IDAC-ADI/index-fra.htm (French version)

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The IDAC will accept for deposit: animal viruses of Risk Group Levels 1, 2 and 3, which can be propagated in cell culture, Risk Group Levels 1, 2 and 3 bacteria, all bacteriophages, all mammalian cell lines, and all cloned genes. Fungi, hybridomas, yeasts, plasmid and phage vectors, libraries and other rDNA material will also be accepted.

The IDAC will only accept deposits which can be preserved without significant change to their properties by freezing or lyophilization. Deposits which cannot be so preserved or can only be maintained in active culture, may be accepted on an individual basis, with prior negotiation and determination of associated fees.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IDAC will only accept deposits which can be preserved without significant change to their properties by freezing or lyophilization. Deposits which cannot be preserved in this manner or can only be maintained in active culture may be accepted on an individual basis, with prior negotiation and determination of associated fees.

Depositors are encouraged to supply frozen or freeze-dried material. However, when possible, the IDAC will accept actively growing material, and preserve it by freezing or freeze-drying at an additional cost. In these cases a sample of the preserved material will be returned to the depositor for verification of properties. However, if the preserved material is viable but not acceptable (e.g., properties altered), a new deposit must be made, and the original deposit date will be void. Depositors are therefore urged to supply frozen or freeze-dried material prepared in their laboratory in order to avoid the possibility of this occurring.

The quantity of material required for the various types of deposits is as follows:

Microorganisms (including bacteria (either containing a plasmid or not containing a plasmid), bacteriophages, fungi and yeast)	10 frozen (0.5 ml each) or freeze-dried samples
Plasmids and Vectors not in host (e.g., purified DNA, libraries and associated rDNA material)	25 vials (min. 100 ng each)
Animal Viruses	25 frozen (1 ml each) or freeze-dried samples
Cell Lines and Hybridomas	25 frozen samples (2 – 6 million cells each)

(ii) Time Required for Viability Testing

The time required for testing the viability of the different types of deposits is indicated below. However, depositors should be aware that in certain cases viability testing may take longer.

Bacteria	3 – 7 days
Fungi and yeasts	7 – 10 days
Cell lines, hybridomas and bacteriophages	7 – 10 days
Plasmid, phages and other rDNA[1]	7 – 10 days
Animal viruses	30 or more days

(iii) Depositor Checks and Renewal of Stocks

It is the responsibility of the depositor to furnish a sufficient quantity of the material for the specified period of time. If a culture or other biological material should become non-viable or be destroyed during the effective term of the deposit, it is the responsibility of the depositor to replace it with viable material. The IDAC may consider, for a fee, to replenish the material on behalf of the depositor, however, it is the responsibility of the depositor to authenticate the material prepared and to inform the IDAC of the results. Whichever method is used for renewal of stocks the IDAC will maintain a portion of the material originally submitted for deposit.

[1] If applicable "viability" of the deposit is determined by the ability of the material to successfully transform, infect or otherwise alter a host cell.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of Canada and the IDAC are English and French. Communications in any other language are not accepted.

Contract. The IDAC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by completing the IDAC BP/1 deposit form, the depositor foregoes any right to withdraw his deposit during the required storage period and accepts that the material will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The IDAC is subject to Canadian and international regulations governing the importation, exportation and transportation of infectious substances. Information relating to the importation and safe handling of infectious substances affecting humans can be obtained through the Health Canada web site (http://www.hc-sc.gc.ca/hpb/lcdc/biosafty/index.html), or by contacting the Director, Office of Biosafety, Laboratory Centre for Disease Control, Ottawa, Ontario, K1A 0L2, tel: (613) 957-1779. Information regarding veterinary pathogens and permits may be obtained from Agriculture and Agri-Food Canada, 59 Camelot Drive, Nepean, Ontario K1A 0Y9, tel.: (613) 952-8000. Inquiries regarding the transportation of regulated material should be directed to the Director General of the Transport of Dangerous Goods Directorate of Transport Canada, Canada Building, 344 Slater Street, 14th Floor, Ottawa, Ontario K1A 0N5, tel.: (613) 998-0517. These agencies may also be able to assist with information relating to the relevant regulations in countries other than Canada however it is advised that the appropriate agencies for the country in question be contacted.

It is essential that the depositor contact the IDAC in advance of submitting a deposit which may be subject to these regulations to ensure that the appropriate documentation is obtained. This is particularly important for deposits made from outside of Canada. Failure to do so could result in the deposit being refused entry into the country.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The IDAC requires that depositors complete the Statement In The Case Of An Original Deposit (form BP/1) in order to meet the requirements of the Budapest Treaty. In the event of later amendments to the scientific description and/or proposed taxonomic designation the depositor must complete the IDAC form BP/7. In the case of a new deposit made under Article 4 of the Budapest Treaty the depositor must complete form BP/2.

Official Notifications to the Depositor. Notifications of receipt and viability are issued on the mandatory international forms (BP/4 and BP/9, respectively). Attestation of receipt of an amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/8. If requested, notification of furnishing of a sample to a third party is issued on form BP/14.

Unofficial Notifications to the Depositor. If requested, the IDAC will convey the date of deposit and accession number after the submission has been received but before the official receipt is issued. Notification of the result of the viability testing is only communicated through official correspondence.

Supply of Information to a Patent Agent. If requested, the IDAC will supply copies of the receipt and viability statement to the depositor's patent agent.

(iii) Converting a Previous Deposit

The IDAC does not permit the conversion of deposits not originally made for patent purposes for Budapest Treaty deposits. The procedures outlined above for making a deposit must be followed in all cases.

(iv) Making a New Deposit

In the advent that a new deposit is submitted the IDAC requires that the Statement In The Case Of A New Deposit (form BP/2) be completed. The deposit will retain its initial deposit number and date as long as the replacement deposit is viable, the deposit is made within three months of receiving notification from the IDAC and the IDAC receives a statement signed by the depositor alleging that the newly deposited material is the same as that originally deposited. Charges are for viability testing are required for new deposits.

2. Furnishing of Samples

(a) Requests for Samples

The IDAC makes available samples of deposited material only to parties who are so entitled under the terms of the Budapest Treaty and its Regulations. The IDAC will provide requesting parties with request forms (as appropriate) or assist with obtaining the necessary forms required for their request.

The IDAC accepts deposits of organisms which are potentially hazardous and may be subject to health and safety regulations. When such organisms are requested the IDAC will withhold issuing samples until it has confirmed that the requesting party can comply with such regulations. In certain cases, the IDAC may also require that the requesting party sign an assurance of acceptance of responsibility before agreeing to release a sample. In order to expedite the release of such samples it is therefore advisable that all requests be accompanied by documentation attesting to the fact that the requesting party has the facilities required for, and agrees to the regulations governing the handling of the requested material.

The IDAC attempts to ensure that the correct documentation is obtained prior to the shipping of the material requested. However, it is the responsibility of the requesting party to obtain all of the necessary permits which may be required.

(b) Notification of the Depositor

Unless the right to be so notified has been waived, the IDAC will notify the depositor on form BP/14 each time a sample of the deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

At this time the IDAC does not publish a catalog of its culture collection.

3. Schedule of Fees

		CAD
(a)	Issuance of a viability statement	200
(b)	Storage (30 years)	800
(c)	30 years of notification of requesting parties	500
(d)	Furnishing of a sample (plus expedition cost)	50
(e)	Attestation of receipt of revised scientific description	50
(f)	Communication of scientific description to 3rd party	50
(g)	Amount for additional five years of storage beyond 30 years	125

This list is of base prices. Deposits requiring special conditions or care are subject to surcharges. All charges are subject to the Canadian Goods and Services Tax at the current rate.

4. Guidance for Depositors

The IDAC is in the process of preparing a detailed information package for depositors. Until this is available all inquiries should be directed to the main office.

CL - CHILE

COLECCIÓN CHILENA DE RECURSOS GENÉTICOS MICROBIANOS (CChRGM)

Avenida Vicente Méndez 515,
Chillán, Region VIII

Telephone: (56-42) 209500
Fax: (56-42) 209599
E-mail: afrance@inia.cl
Internet: www.cchrgm.cl

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

CChRGM may receive for long-term deposit microorganisms for agricultural and forestry, environmental and industrial-process use and impact. More specifically, CChRGM will accept for deposit fungi (molds, filamentous fungi, yeasts, higher fungi), bacteria (including actinomycetes), microorganisms which contain plasmids; those which can be preserved, without any alteration to their properties, by means of sub-culture and storage in cryopreservation and lyophylization.

CChRGM will accept pathogenic microorganisms from plants, antagonists of phytopathogens, nematophogae, entomopathogens, mycorrhizal, plant endophytes, bioremediators and microorganisms from industrial processes.

Those animal and human pathogenic microorganisms and/or of unknown nature are excluded from being deposited as such. In the same way, mixtures of cultures, contaminated cultures, those without an adequate scientific description or cultures whose identity cannot be verified are excluded.

For the time being, algae, protozoa, human cell lines, animal viruses and hybridomas cannot be received.

As a general rule, within CChRGM only strains that may be cultivated and preserved under technically feasible conditions, within the sphere of the collections conserved, without inducing significant changes in their characteristics, can be accepted.

Preparations of nucleic acids and phages are not for the time being accepted, pending development of techniques and procedures inside the laboratory.

Through its curator, CChRGM reserves the right to accept or reject microorganisms which, by their nature, require special treatment or present a risk in their handling and preparation for storage. Exceptionally, microorganisms may be accepted for deposit, which require special treatment, although the costs and conditions of the deposit shall be established and negotiated case by case, as appropriate.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Organisms must be submitted for deposit as liquid cultures or in agar. Should samples be sent lyophilized, they will be accepted only after rehidratation and positive culturing. The minimum number of replicas that must be supplied for deposit is, in the case of fungi, of a pure culture in a known culture medium, free of contamination and other organisms (contaminated cultures will be rejected without being processed).

(ii) Time Required for Viability Testing

The average time required to carry out the viability analysis by CChRGM is 15 days, but depositors must take into account the fact that in some cases analysis may take up to 30 days. Any change will be notified to the depositor in advance.

(iii) Depositor Checks and Renewal of Stocks

CChRGM will prepare its own sub-cultures of organisms at the time of deposit. Cultures will be renewed in accordance with requests or the opinion of the laboratory already established for the different groups of microorganisms. Where the original material has been cryopreserved, the samples will be renewed through a subculture thereof or by requesting a new deposit from the depositor. Analysis of authenticity of the samples will be required from the first group of samples for deposit (not from the subsequent ones).

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of CChRGM are Spanish and English.

Contract. CChRGM will request the depositor to complete the application form, which serves as a contract whereby the depositor undertakes to:

- supply all the information requested by CChRGM;
- pay all the required fees;
- compensate CChRGM for any claim that may arise as a result of the dispatch of samples with information that has been altered, is misleading, amended or belongs to third parties;
- decline to withdraw his deposit during the period requested for its due storage;
- authorize CChRGM to supply the samples in accordance with Rule 11 of the Regulations under the Budapest Treaty.
-

Where an organism has been accepted for deposit, CChRGM shall notify the depositor and shall remind him that he is subject to the terms and conditions of the contract.

Import and/or Quarantine Regulations. The type of organisms accepted by CChRGM is subject to import and/or quarantine regulations as well as internationally recognized protocols on biosafety. For import and quarantine purposes, depositors must follow requirements and regulations

of the Livestock and Agriculture Service (Servicio Agricola Ganadero) and national customs services.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors must complete the application and deposit forms used by CChRGM for deposits according to the Budapest Treaty, equivalent to BP/1.

Official Notifications to the Depositor. The receipt and declaration of viability shall be issued on the compulsory international forms BP/4 and BP/9 respectively. The certificate for receipt of a subsequent indication or amendment of the scientific description and/or proposal of taxonomic designation shall be issued on form BP/8, the notification of supply of samples to third parties on form BP/14. For other official notifications, standard forms shall not be used.

Unofficial Notifications to the Depositor. If requested, CChRGM shall communicate by telephone, facsimile or email the date of deposit and the entry number after the organism has been received, but before the official receipt is issued. However, the depositor shall be informed that this information is provisional and that it depends on the result of the viability tests. CChRGM will also communicate the result of the viability analysis before the relevant certificate is issued.

Supply of Information to a Patent Agent. As a matter of course, CChRGM will ask the depositor to provide the name and address of his patent agent. If required, CChRGM will supply copies of the receipt and viability statement and any other information to the depositor and his patent agent.

(iii) Converting a Previous Deposit

CChRGM does not hold deposits made for patent purposes beyond what is stipulated by the Budapest Treaty.

(iv) Making a new Deposit

When the depositor makes a new deposit, he shall be asked to complete the model form BP/2 and to attach the documents required under Rule 6.2.

The receipt and viability certificate for a new deposit shall, as a matter of course, be issued using international forms BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

CChRGM will inform third parties of the procedures for the correct formulation of requests. In cases where requests require proof of authorization, CChRGM will supply the requesting parties with the request forms used by industrial property offices or copies of form BP/12.

Where requests from abroad are received, CChRGM assumes that the depositor knows the import requirements of his country.

All the samples sent by CChRGM come from groups of samples of specific preparations.

(b) Notification of the Depositor

The depositor will be informed, by letter and email, where samples of his organisms have been sent to third parties.

(c) Cataloguing of Budapest Treaty Deposits

CChRGM will publish the lists of deposits under the Budapest Treaty in its catalogues only with written authorization of the depositor.

3. Schedule of Fees

	Chilean pesos ($CL)
Storage of each strain	435,000 (30 years)
Issue of viability report	45,000
Supply of a sample	60,000
Communication of information	15,000

Note: The amounts do not take into account the dispatch costs and additional costs within Chile.

4. Guidance for Depositors

The CChRGM does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone, letter or email.

CN - CHINA

CHINA CENTER FOR TYPE CULTURE COLLECTION (CCTCC)

College of Life Sciences
Wuhan University
Wuhan 430072

Telephone: (86-27) 6875 2319, 6875 4712, 6875 4052, 6876 4001
Facsimile: (86-27) 6875 4833
E-mail: cctcc@whu.edu.cn
Internet: http://www.cctcc.org.cn

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal viruses, animal cell cultures, bacteria, bacteriophages, eukaryotic DNA, fungi, human cell cultures, stem cells, hybridomas, molds, mycoplasma, nematodes, oncogenes, plant cell cultures and plant seeds, plant viruses, plasmids, protozoa (non-parasitic) and yeasts are generally accepted by CCTCC for deposit. However, if the microorganism is a dangerous pathogen, the depositor should consult CCTCC in advance, which will decide whether or not the CCTCC can accept the biological material for deposit. The CCTCC does not accept for deposit pathogenic microorganisms of Risk Group 1 & 2 (Chinese classification).

In addition, the CCTCC does not accept for deposit biological material which is restricted from import according to Chinese law or whose conservation involves hazards deemed to be excessive. It also rejects applications which ask the CCTCC to supply biological material that is restricted from export according to Chinese law.

At present, the CCTCC does not accept for deposit embryos, parasitic and pathogenic protozoa and RNA preparations.

Notwithstanding the foregoing, the CCTCC reserves the right to reject depositing any material which, in the opinion of the Director, represents a risk that is either unacceptable or is too difficult to handle.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, molds, yeasts, algae and viruses must be submitted for deposit as lyophilized preparations. However, agar stab or slant cultures are also acceptable. Viruses that cannot be lyophilized should be frozen. Plasmids or other vectors in the form of an isolated DNA preparation must be furnished in freeze-dried form or precipitated in alcohol.

All kinds of viruses and plasmids need to be sent together with a suitable host if the host is not available in the public collection of the CCTCC. Plant cell cultures can only be

deposited in the form of callus or suspension cultures with non-differentiated growth. Animal cell cultures are accepted in the form of frozen cultures. The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the CCTCC, animal cell cultures must be examined to ensure that they are free from viruses.

All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

The minimum number of replicates that must be provided by the depositor when making his deposit is as follows:

Algae, bacteria, molds, plant viruses, yeasts	6 lyophilized or on culture media
Bacteriophages (at least 10^8 pfu/ml) 5 X 0,5 ml (free-cell lysate)	11
Animal cell lines, animal viruses, hybridomas, plasmids (DNA at least 20 meg/tube)	11
Seeds	2,500

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the CCTCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria	3 days (or up to 14 days)
Algae, molds, yeasts	5 days (or up to 20 days)
Animal cell lines, hybridomas, bacteriophages, plasmids	7 days (or up to 14 days)
Animal viruses, plant cell cultures, seeds	21 days (or up to 30 days)
Plant viruses	no period of time as yet

(iii) Depositor Checks and Renewal of Stocks

The CCTCC prepares its own depositing batches in lyophilized or frozen form from the original material supplied by the depositor. The deposits could also be made by subculturing the microorganisms from the original material at the request of the depositor. The CCTCC generally does not prepare its own batches of animal and plant viruses, plasmids, seeds, and some animal cell lines, hybridomas and plant tissue cultures. When stocks of material are depleted by the furnishing of samples, the CCTCC will ask the depositor to make a new deposit.

(c) Administrative Requirements and Procedures

(i) General

Language. The working languages of the CCTCC are Chinese and English.

Contract. The CCTCC does not enter into a written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by signing the CCTCC deposit forms and pay necessary fees, the depositor should supply all the necessary information requested by the CCTCC, surrender the right to withdraw his deposit during the required storage period and recognize that the deposits may be distributed according to the relevant regulation of the Budapest Treaty.

Import and/or Quarantine Regulations. Overseas depositors must contact the CCTCC in advance for advice about the shipping of their microorganisms. The microorganisms are all subject to the Chinese import and/or quarantine regulations. In such cases, the prospective depositor must supply the species name of the microorganisms, whereupon the CCTCC will apply the import license and/or quarantine to the concerned organizations in China. Obtaining such a permit usually takes one or two weeks. After obtaining it, the CCTCC will inform the depositor or depositor's patent agent when the import permit was obtained.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the application and accession form used by the CCTCC for deposits under the Budapest Treaty, which is model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the CCTCC has received such information, the depositor must complete the equivalent of model form BP/7.

Official Notifications to the Depositor. The receipt and viability statements 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 the equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Individual correspondence is used rather than standards forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CCTCC will telephone or telefax the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CCTCC will similarly communicate the result of the viability test before the viability statement is issued, but only after the viability test has been done and has given a positive result.

Supply of Information to a Patent Agent. The CCTCC routinely asks the depositor to give the name and address of his patent agent. If requested, the CCTCC will supply copies of the receipt, the viability statement and any other information to both the depositor and his 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 deposited for patent purposes. However, any deposits previously made free of charge are subject, on conversion, to storage fee normally levied for Budapest Treaty deposits. 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

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 of the Regulations under the Budapest Treaty. The receipt and viability statements for a new deposit are issued on mandatory "international forms" BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The CCTCC 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 CCTCC 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, the CCTCC will withhold samples of organisms that are subject to health and safety regulations until the requesting party has shown that he has a permit to work with such organisms. When responding to a request from overseas, the CCTCC must obtain an export permit from the concerned organizations in China, and assumes that the requesting party has met the import requirements of his own country.

Except for animal viruses, plasmids, seeds, and some animal cell lines, hybridomas and plant tissue cultures, the samples of microorganisms furnished by the CCTCC are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the CCTCC to make samples of a microorganism available to anyone, that organism is listed in the next published CCTCC catalog. All microorganisms that are the subject of granted and published Chinese patents are listed in the CCTCC catalog.

3. Schedule of Fees

		RMB
(a)	Storage	3.000
(b)	Issuance of a viability statement	500
(c)	Furnishing of a sample	500
(d)	Communication of information	200
(e)	Application for the import or export license	depends on individual situation

Other currencies will be converted into RMB (Chinese Yuan) according to the exchange rate of the Bank of China.

4. Guidance for Depositors

The CCTCC has published a leaflet describing its overall activities and it is available to possible depositors to provide detailed information by email, telephone, telefax, or letter.

CN – CHINA

CHINA GENERAL MICROBIOLOGICAL CULTURE COLLECTION CENTER (CGMCC)

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Facsimile: (86-10) 6480 7288
E-mail: cgmcc@im.ac.cn
Internet: http://www.cgmcc.net

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

With the exception of pathogenic microorganisms of Risk Group 1 (Chinese classification): bacteria (including actinomycetes), yeasts, filamentous fungi, anaerobic microorganisms, single cell algae, animal cell lines, plant cell lines, mycoplasma, viruses, bacteriophages, plasmids, plant seeds.

At present, the CGMCC does not accept temporarily the following biological material for deposit: protozoa.

As a general rule, the CGMCC will accept only strains that can be placed in a culture under conditions technically feasible for the collection concerned and conserved, other than in continuous vegetative activity, without inducing significant changes in the characteristics.

Exceptionally, the CGMCC may accept deposits that cannot be conserved other than by active culture, but acceptance of such a deposit will have to be decided, and the relevant fee determined, on a case-by-case basis, after prior negotiation with the potential depositor.

The CGMCC reserves the right to refuse a deposit of biological material under Article 5 of the Budapest Treaty:

- which is restricted from import according to Chinese law;

- whose conservation involves hazards deemed to be excessive.

The CGMCC also reserves the right to refuse an application which asks the CGMCC to supply biological material that is restricted from export according to Chinese law.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of microorganisms are accepted by the CGMCC in any form. The minimum number of replicates that must be provided by the depositor when making his deposit is as follows:

Bacteria, yeasts, filamentous fungi, phages, mycoplasma, single cell algae	5
Viruses, plasmids (not cloned into a host), animal cell lines, plant cell lines	15
Plant seeds	2,000

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the CGMCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria, yeasts	3 days (or up to 20 days)
Filamentous fungi, mycoplasma	6 days (or up to 30 days)
Phages, single cell algae, animal cell lines	7 days (or up to 14 days)
Plasmids[1]	8 days (or up to 14 days)
Animal viruses, plant cell lines, plant seeds	21 days (or up to 30 days)
Plant viruses	no date as yet

(iii) Depositor Checks and Renewal of Stocks

The CGMCC prepares its own lyophilized and/or frozen batches at the time of deposit of bacteria, actinomycetes, yeasts, filamentous fungi, phages, single cell algae and, in some cases, viruses, by subculture of, or directly from, active material supplied by the depositor. New batches are prepared as necessary for the renewal of diminishing stocks. The CGMCC stores and distributes lyophilized material supplied by the depositor, if this is his wish. The CGMCC generally does not prepare its own batches of animal viruses and plasmids. In such cases, when stocks of material are depleted by the furnishing of samples, the CGMCC will ask the depositor to make a new deposit.

[1] For plasmids, "viability" testing consists in inserting the plasmid into a host. If the host is transformed, the "viability test" is regarded as positive.

The CGMCC requires the depositor to check the authenticity of its lyophilized preparations. The viability statement issued by the CGMCC contains a section in which the depositor can record the result of this test. If the depositor does not inform the CGMCC of the results of this test within three months, the CGMCC assumes that its preparations are equivalent to the depositor's original deposit.

Whichever method is used for preparing batches of samples for distribution, the CGMCC stores a portion of the original prepared and deposited material.

(c) Administrative Requirements and Procedures

(i) General

Language. The working languages of CGMCC are Chinese and English.

Contract. The CGMCC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also,

- to supply all the necessary information requested by the CGMCC;

- to pay all the necessary fees;

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

- to authorize the CGMCC to supply samples in accordance with the requirements of the patent procedure applicable at the time.

Import and/or Quarantine Regulations. For the deposit from abroad, the CGMCC must obtain an import permit from the Chinese departments concerned for the import of microorganisms into China, which takes about seven days (or up to 14 days). The CGMCC will notify the depositor or depositor's patent agent when it gets the import permit. Depositors must pay for quarantine.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete CGMCC form BP/1 "Budapest Treaty Deposits" in all cases. The CGMCC 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 the CGMCC has received such information.

Official Notifications to the Depositor. The receipt and viability statements are issued on mandatory "international forms" BP/4 and BP/9, respectively. Notification of release of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CGMCC will telephone or telex the date of deposit and accession number after the microorganisms have been received, but before the official receipt is issued. A fee of $10 is charged for this service. The CGMCC similarly will telephone or telex the result of the viability test before the official viability statement is issued.

Supply of Information to a Patent Agent. If requested, the CGMCC will supply copies of the receipt and viability statements to the depositor's 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 deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fees normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit made under the Budapest Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

The CGMCC may accept a new deposit under Article 4 of the Budapest Treaty and Rule 6.2 of the Regulations under the Treaty. The CGMCC does not require the depositor to complete a standard form when making a new deposit, but he is asked to supply an acknowledgment that the new deposit is the same as the original deposit (Article 4), and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The CGMCC will furnish samples to interested industrial property offices, to the depositor or parties with the authorization of the depositor, to parties legally entitled under Rule 11.3 of the Regulations under the Budapest Treaty.

The CGMCC advises third parties of the correct procedures to be followed in making a valid request. In the case of requesters requiring proof of entitlement, the CGMCC provides them with copies of model request form BP/12.

The CGMCC will withhold samples of organisms that are subject to health and safety regulations until it has confirmed that the requesting party can comply with such regulations. Also, in some cases a permit from the Chinese departments concerned is required to work with certain organisms considered potentially very dangerous in China, and a requesting party in China must obtain such a permit before he can receive a sample.

When requests are received from abroad, the CGMCC presumes that the individual concerned is familiar with his country's import requirements.

Except for animal viruses and plasmids, the CGMCC furnishes samples of its own preparations of the deposited microorganism.

(b) Notification of the Depositor

Unless he has waived his right to be so notified, the CGMCC notifies the depositor on CGMCC form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the CGMCC to make samples of a microorganism available to anyone, that organism is listed in the next published CGMCC catalog. All microorganisms that are the subject of patents granted and published by the Patent Office of the People's Republic of China are listed in the CGMCC catalog.

3. Schedule of Fees

		USD
(a)	Storage	800
(b)	Issuance of a viability statement	100
(c)	Furnishing of a sample	100
(d)	Communication of information	50

Other currencies will be converted into US dollars according to the exchange rate of the Bank of China.

4. Guidance for Depositors

The CGMCC publishes a brochure giving details of its requirements and practices for the deposit of cultures for patent purposes.

CZ - CZECH REPUBLIC

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E-mail: ccm@sci.muni.cz
Internet: www.sci.muni.cz/ccm

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes), filamentous fungi, yeast-like microorganisms, yeasts accepted are those capable of long-term preservation without any substantial change of their initial properties, plasmids in a host.

The CCM accepts for deposit only those bacteria, filamentous fungi, yeast-like microorganisms and yeasts which, pursuant to *Laboratory Biosafety Manual* (World Health Organization, Geneva 1983), belong to hazard group I or II.

Microorganisms having special requirements for cultivation which the CCM is not technically capable of carrying out shall not be accepted.

Cultures without scientific description as well as cultures which cannot be identified shall not be accepted.

When depositing strains containing a plasmid, the CCM shall require information on the plasmid and its host strain in respect of their properties and classification (i.e., group P1, P2, P3 or P4). The CCM shall accept only plasmids belonging to group P1.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria and fungi, including those containing plasmids, are accepted by the CCM as lyophilized or actively growing cultures, except agar plate cultures (these are prone to become damaged in transport).

The depositor is required to provide two lyophilized or agar cultures when making his deposit.

(ii) Time Required for Viability Testing

The average time required for testing the viability of various microorganisms accepted by the CCM is five days, but the depositor should realize that in some cases, especially with slow growing microorganisms, viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The CCM prepares its own lyophilized and/or frozen batches of bacteria and fungi 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. The depositor is required to test for authenticity samples from all batches of his microorganisms prepared by the CCM.

Whichever method is used for preparing batches of samples for distribution, the CCM always keeps original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCM is Czech. Communications are also accepted in English.

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

Import and/or Quarantine Regulations. At present, there are no kinds of microorganisms in the CCM accepted under the Budapest Treaty which may be subject to import or quarantine regulations. But this may be changed in the future.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete form CCM-BP/1 (the equivalent of model form BP/1) which is the accession form used for Budapest Treaty deposits.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, both in Czech and English. Notification of furnishing of a sample to a third party is issued on model form BP/14. The CCM uses its own standard letters for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CCM will telephone or telefax the date of deposit and the accession number before the official receipt is issued, but only after a positive viability test has been obtained.

Supply of Information to a Patent Agent. The CCM does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the CCM will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty.

All conversions are subject to the storage fee normally levied for Budapest Treaty deposits.

(iv) Making a New Deposit

The depositor is required to complete the equivalent of 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) Request for Samples

The CCM 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 CCM 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).

When responding to requests from overseas, the CCM will ask the requesting party to provide an import permit if it knows that one is required for that particular country.

All samples furnished by the CCM are from batches of its own preparations.

(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 CCM does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

Patent Deposit of Cultures		CZK
(a)	Deposit and storage for 30 years	23,000
(b)	Issuance of a viability statement	700
(c)	Furnishing of a sample	1,000

Value added tax (21%) will be charged in addition, if applicable. Extra charge is payable for handling, postage and banking. A prepayment may be requested for orders coming from abroad.

4. Guidance for Depositors

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

FI - FINLAND

VTT Culture Collection (VTTCC)

VTT Technical Research Centre of Finland
Tietotie 2
Espoo

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02044 VTT

Telephone: (+358 20) 722 4526
Facsimile: (+358 20) 722 7071 (contact: Erna Storgårds)
E-mail: culture.collection@vtt.fi
Internet: http://culturecollection.vtt.fi/

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and fungi (including yeasts) which can be preserved at -150 °C or in freeze-dried state without significant damage to or loss of their properties or viability.

VTTCC accepts only organisms belonging to risk groups 1 or 2 according to Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, and genetically modified microorganisms belonging to class 1 according to Council Directive 98/81/EC on the contained use of genetically modified microorganisms.

Biological material cannot be accepted, if it is contaminated by foreign organisms. Mixtures or microbial cultures of more than two microorganisms will not be accepted. Mixtures of two microorganisms will be accepted in case these a) cannot be cultivated separately as pure cultures and b) can easily be distinguished macroscopically or microscopically.

VTTCC reserves the right to refuse to accept for deposit any material which in its view represents an unacceptable hazard or which it cannot process.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, yeasts and filamentous fungi submitted for deposit in VTTCC should be supplied as three active or freeze-dried cultures of the same batch. Cultures submitted for deposit should be free of foreign organisms. International regulations for packaging and shipping of microorganisms should be followed in the consignment.

(ii) Time Required for Viability Testing

The minimum time required for viability testing of the kinds of microorganisms accepted by VTTCC is 7 days. Depositors should consider that viability testing of slow growing organisms and organisms with special growth requirements may take longer.

(iii) Depositor Checks and Renewal of Stocks

VTTCC prepares frozen and/or freeze-dried batches of the deposited organism by subculturing the material supplied by the depositor. The depositor is requested to check the authenticity of a sample from each batch prepared from the material supplied. A portion of the original material is retained and stored by freezing or freeze-drying. New batches are prepared for renewal of stocks when necessary.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of VTT Culture Collection is English. Written statements and completed forms have to be in English, but communications are also accepted in Finnish and Swedish.

Contract. The form BP/1 for patent deposit in VTTCC is a contract between the depositor and VTTCC and it must be signed by the depositor. By signing the contract the depositor undertakes

- to supply VTTCC the sample and all the related necessary information requested by VTTCC;
- not to withdraw its deposit during the required storage period;
- to pay VTTCC all necessary fees related to the deposition under this contract;
- to authorize VTTCC to supply samples in accordance with the requirements and purposes of the patent procedure applicable;
- not to hold VTTCC liable for any damages related to deterioration of samples during storage when all precautions indicated by the depositor in respect of storage have been taken by VTTCC;
- to compensate VTTCC for any damage it may sustain as a consequence of dealing with the samples when all precautions indicated by the depositor in respect of dealing with the samples have been taken by VTTCC.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by VTTCC are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the form BP/1 for patent deposit in VTT Culture Collection, available at the internet site of the collection. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/8. Notification of the furnishing of samples to third parties is issued on form BP/14.

Unofficial Notifications to the Depositor. If requested, VTTCC communicates the date of deposit and the accession number before the official receipt is issued, but only after a positive viability test. Likewise VTTCC communicates the finding of the viability test before the official viability statement is issued.

Supply of Information to a Patent Agent. If requested, VTTCC will send copies of the receipt and viability statement to both the depositor and his/her patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty, whether or not they were originally made for patent purposes. Any earlier deposit is subject, on conversion, to the storage fee normally charged for deposits made under the Budapest Treaty. The administrative requirements for conversion are the same as those to be met for an original deposit made under the Treaty.

(iv) Making a New Deposit

The depositor is requested to complete the equivalent of 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

VTTCC advises third parties of the correct procedures to be followed to make a valid request. In case of requests requiring proof of entitlement, VTTCC will provide requesting parties with copies of model request form BP/12. Samples will only be furnished to recognized microbiological laboratories and not to private addresses. When requests are received from abroad, VTTCC assumes that the requesting party has met the import requirements of his/her country.

All samples of deposited microorganisms furnished by VTTCC are from batches prepared by VTTCC.

(b) Notification of the Depositor

Depositors are notified on form BP/14 when samples of his/her microorganisms have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

VTTCC does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

		EUR
1. (a)	Accession and deposit (including initial viability check, preservation and storage for 30 years)	900
(b)	Conversion of a deposit made outside of the Budapest Treaty into a deposit according to Budapest Treaty	900
(c)	Prolongation of the duration of storage, per year	50
2.	Issuance of viability statement	
(a)	Where a viability test is requested	120
(b)	On the basis of last viability test	50
3.	Furnishing of a sample	170
4.	Communication of information	50
5.	Issuance of an attestation	120

Fees do not include VAT, transport costs or bank fees.

4. Guidance for Depositors

VTTCC does not publish specific information for the guidance of depositors under the Budapest Treaty. Depositors are encouraged to contact VTTCC prior to making the deposit for further information on the procedure.

FR – FRANCE

COLLECTION NATIONALE DE CULTURES DE MICRO-ORGANISMES (CNCM)

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1. Requirements for Deposit

(a) Kinds of Microorganism that May Be Deposited

Animal cell cultures, including human cell lines, genetically modified cell lines and hybridomas, bacteria (including actinomycetes), bacteria containing plasmids, filamentous fungi and yeasts, and viruses, EXCEPT:

- plant cells;

- microorganisms whose manipulation calls for physical insulation standards of P3 or P4 according to the information provided by the National Institutes of Health *Guidelines for Research Involving Recombinant DNA Molecules* and *Laboratory Safety Monograph*;

- microorganisms liable to require viability testing that the CNCM is technically not able to carry out;

- mixtures of undefined and/or unidentifiable microorganisms.

The CNCM reserves the possibility of refusing any cell culture which, according to the curator, involves an unacceptable risk or is not suitable, for technical reasons, for handling and any microorganism for security reasons; specific risks to human beings, animals, plants and the environment.

In the eventuality of the deposit of cultures that are not or cannot be lyophilized, the CNCM must be consulted, prior to the transmittal of the microorganism, regarding the possibilities and conditions for acceptance of the samples; however, it is advisable to make this prior consultation in all cases.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The depositor must provide 12 replicates, either frozen or lyophilized, resulting from a single preparation and containing at least 10^6 viable units per ml. Lower concentrations may be allowed in exceptional cases.

The depositor should in addition supply any live material that is not available in a open collection at the CNCM but is necessary for checks on and /or the preservation of the microorganism to be deposited, and also any substance necessary for those purposes that is inaccessible or not readily accessible.

(ii) Time Required for Viability Testing

The average time required by the CNCM for testing the viability of the various kinds of microorganism is given below (but depositors should realize that the times given may be exceeded in the case of certain slow-developing microorganisms, or others whose viability checks call for particularly long preparatory phases):

Bacteria, bacteriophages	14 days
Filamentous fungi, yeasts	25 days
Animal or human cell cultures	40 days
Viruses (except bacteriophages)	60 days

(iii) Depositor Checks and Renewal of Stocks

The CNCM prepares its own batches, frozen in liquid nitrogen, at the time of deposit and whenever necessary thereafter by subculturing material supplied by the depositor. These stocks are intended to fulfill requests for samples. The depositor is required to test all batches of his microorganism prepared by the CNCM for continued presence of all its known specific properties.

In all cases the CNCM stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CNCM is French. Communications in English are also accepted. All forms to be completed are available in English as well as French. Letters and notifications are written in either French or English.

Contract. The CNCM enters into a contract with the depositor. By signing the contract the depositor acknowledges that he has noted the conditions governing the deposit of a microorganism under the Budapest Treaty, the procedural requirements to be observed in the relevant dealings with the CNCM and also the relative liability in the event of an incident.

Import and/or Quarantine Regulations. For infectious material from abroad the CNCM provides the depositor with a label to be attached to his package. It ensures the free entry of the microorganism into French territory, subject to the package conforming to international regulations of the transport of hazardous substances, and to compliance with all the necessary formalities for the export of the microorganism.

Very few microorganisms require special authorization to be handled and stored on the territory of France. Should it be necessary, the applicant would have to supply all the particulars required by the competent authorities, to which the CNCM would then immediately submit the necessary request for authorization.

There are no quarantine regulations applicable to microorganisms at present.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor has to complete and sign the deposit and contract forms (see under 1(c)(i) above). CNCM uses different deposit forms, depending on whether bacteria, bacteria cultivated on cell systems, bacteriophages, filamentous fungi and yeasts, viruses or cell cultures are being deposited. Every deposit form is completed with a statement by the depositor that he has made all the notifications required by national regulations in force in the country of origin with respect to the use and dissemination of the microorganism being deposited, and that he has received the necessary authorizations to that end.

The CNCM strongly advises the depositor to fax the deposit form back to it before the microorganism is sent, and to inform it without delay of the intended deposit date and the shipping method. The originals of the deposit documents should be sent before or with the microorganism itself.

In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor is required to complete a BP/7 form which may be requested from the CNCM by mail or fax.

Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9 respectively. Individual letters are used for all other official notifications.

Unofficial Notifications to the Depositor. On receiving the microorganism in a condition that does not preclude its acceptance for obvious reasons, the CNCM will fax the date and number of the deposit to the depositor. If the deposit is accepted later, the accession number will be the same as the registration number.

Supply of Information to a Patent Agent. The CNCM does not ask the depositor to give the name and address of a patent agent; it will however, at his request, provide his patent agent with copies or the originals, as specified in the request, of the receipt and viability statement.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor into deposits under the Budapest Treaty if they were originally made for the purposes of a patent procedure or for security purposes of confidential character. Any request for conversion of a deposit made outside the Treaty must bear the signature of the original depositor and give the date on which the original deposit was received, the accession number assigned to it by the CNCM, the name and address of the depositor, the mention that the conversion is requested under the Budapest Treaty and an undertaking not to withdraw the deposit during the period specified in Rule 9.1. The CNCM enters into a contract with the depositor (see under 1(c)(i) above). All conversions are subject to payment of the storage fee normally levied for Budapest Treaty deposits.

(iv) Making a New Deposit

When making a new deposit the depositor has to complete model form BP/2, which is already partly completed and is supplied to him by the CNCM, and to send copies of the documents mentioned in Rule 6.2. The CNCM enters into a contract with the depositor (see under 1(c)(i) above). For the sending of the microorganism the depositor has to conform to the same requirements as at the time of the original deposit (see under 1(b)(i) and 1(c)(i) above). The receipt and the viability statement of a new deposit are issued on mandatory "international forms" BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The CNCM 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 CNCM supplies requesting parties with copies of model request form BP/12, but does not supply the request forms used by individual industrial property offices.

Notwithstanding any entitlement to receive samples under patent regulations, the CNCM stores samples of potentially hazardous microorganisms until such time as the requesting party signs a declaration stating that he has made all the notifications in his country that are required by the regulations in force concerning it, and that he has received all the necessary authorizations to that end. When responding to requests from overseas, the CNCM will also request the requesting party to provide it with adequate import authorization or a declaration stating that no such authorization is necessary for the proper shipping of the microorganism.

(b) Notification of the Depositor

When the CNCM receives a request for a sample or sends samples of deposited microorganisms to third parties, it shall immediately inform the depositors concerned of the fact.

(c) Cataloguing of Budapest Treaty Deposits

The CNCM does not list deposits made under the Budapest Treaty in any catalogue.

3. Schedule of Fees

		EUR
(a)	Storage:	
	- bacteria, filamentous fungi, yeasts, phages	
	- freeze-dried	609.80
	- frozen at –80°C	701.27
	- frozen in liquid nitrogen	1 448.27
	- cell cultures	
	- animal viruses	
	- propagated on embryonated eggs	788.92
	- propagated on cultured cells	1 086.96
(b)	Issuance of a viability statement:	
	- requiring a new viability test	106.71
	- in other cases	18.29
(c)	Furnishing of a sample (plus shipping costs)	106.71
(d)	Communication of information or issuance of an attestation	38.11

Fees are subject to Value-Added Tax (VAT) according to current French regulations.

4. Guidance for Depositors

Details of the deposit procedure may be requested by mail or fax from the CNCM, which moreover is always available to provide additional information and guidance by telephone within the limits of its competence.

DE - GERMANY

LEIBNIZ-INSTITUT DSMZ - DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH (DSMZ)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including mycoplasma) and archaea (both including those containing plasmids), fungi (including yeasts), bacteriophages, plasmid DNAs, plant viruses, plant cell cultures (undifferentiated plant cell cultures, embryogenic plant cell cultures and tissues, *in-vitro* shoot cultures), human and animal cell cultures (including hybridomas).

The DSMZ accepts for deposit only those microorganisms which, pursuant to the Directive 2000/541EC on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work (OJ No. L262, pp. 21-45 of September 18, 2000) or the respective German Law (*Biostoffverordnung* (BGBI. 1pp. 2514 as of July 15, 2014)) belong to risk group 1 or 2.

Genetically manipulated organisms and isolated DNA must be processable in accordance with Class 1 or 2 of Directive 98/8 1/EC on the contained use of genetically modified microorganisms (OJ No. L330, pp. 13-31 of December 5, 1998) or safety level S1 or S2 of the German Law Regulating Genetic Engineering (BGBI. 1, pp. 2066-2083 of December 21, 1993, last changed by Art. 2 abs. 27 and Art. 4 Abs 14 G of August 7, 2013, I 3154).

The biological material indicated above cannot be accepted if it is contaminated by foreign organisms.

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 and b) can easily be distinguished macroscopically and/or microscopically.

Plant viruses which cannot be multiplied through mechanical infection of plants cannot be accepted for deposit.

The DSMZ 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.

In all instances, it must be possible to preserve the deposited material by lyophilization or storage in liquid nitrogen or by some other method of long-term preservation without significant change.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The DSMZ has the following special requirements for the form in which the microorganisms should be submitted for deposit.

- Bacteria, archaea and fungi should, where possible, be deposited in the form of two actively growing cultures. Lyophilized cultures are also accepted.

- Bacteriophages should be deposited in minimum quantities of 2 x 5 ml having a minimum titre of 1×10^9 pfu pro ml.

- Plasmids as isolated DNA preparations should be in a minimum quantity of 2 x 20 [micro] g.

- Bacteriophages and plasmids need to be sent together with a suitable host, if such a host is not available in the public collection of the DSMZ.

- Plant viruses should be deposited in the form of dried or frozen material along with the host's seeds, unless the host is generally available. 100 [micro] l of serum suitable for immunoelectron microscopy should also be deposited for the purity and identity test.

- Plant material can be deposited in the form of undifferentiated plant cell cultures, embryogenic plant cell cultures and tissues, and as *in-vitro* shoot cultures. For deposit 25 frozen ampoules are required. In the case of cryopreserved shoot tips or meristems these ampoules should contain a total of at least 100 surviving apices resp. meristems. If the cryopreservation procedure should be carried out at the DSMZ (on the depositor's expenses), actively growing plant material in the form of undifferentiated cell cultures or tissues (five Petri dishes) or suspension cultures (three culture vessels) or actively growing *in-vitro* plantlets (shoots or shooty structures, at least 10) have to be provided.

- Animal and human cell cultures should be deposited as frozen cultures in 12 ampoules (all prepared at the same time), each containing at least 5×10^6 cells per ampoule (cells growing in suspension) or 2×10^6 cells per ampoule (adherent cells).

The material for deposit must be free from contamination by foreign organisms. Before being dispatched to the DSMZ, animal and human cell cultures must be examined to ensure they are free from viruses. Cultures should be sent in appropriate containers.

(ii) Time Required for Viability Testing

The average time required for testing the viability of the various kinds of microorganisms accepted by the DSMZ is given below, but depositors should realize that in some cases, especially with slow growing microorganisms, viability testing may take longer, as indicated by the figures in brackets:

Bacteria, archaea, yeasts, bacteriophages and plasmids	2 days (or up to 3 weeks)
Fungi	3 days (or up to 3 weeks)
Plant viruses	2 weeks
Plant cell cultures	3 to 4 weeks (or up to 6 months)
Human and animal cell cultures (including test for contamination with mycoplasma)	2 weeks

(iii) Depositor Checks and Renewal of Stocks

The DSMZ prepares its own lyophilized and/or frozen batches of bacteria, archae, fungi and yeasts at the time of deposit by subculturing material supplied by the depositor (but not from plasmids, bacteriophages, plant cell cultures, plant viruses or animal and human cell cultures). New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the DSMZ.

Despite the methods used for preparing batches of samples for distribution, the DSMZ nevertheless stores a portion of the original material supplied by the depositor, if the culture supplied allows this.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the DSMZ is German. Communications are also accepted in English. Correspondence in French is accepted, except in the case of forms.

Contract. The DSMZ does not enter into a written contract with the depositor defining the liabilities of either party but, by signing the DSMZ deposit form, the depositor accepts the General Terms and Conditions of the DSMZ and surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. In very few cases import regulations apply to the kinds of microorganisms accepted by the DSMZ. In such cases, the depositor must supply the species name of the microorganism, whereupon the DSMZ will apply to obtain the necessary permit. The kinds of microorganisms accepted by the DSMZ are not subject to quarantine regulations. Further information about import requirements may be obtained from: Bundesminister für Ernährung, Landwirtschaft und Verbraucherschutz, Wilhelmstr. 64, 10117 Berlin, Germany.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete form DSMZ-BP/1 (the equivalent of model form BP/1) which is the deposition form used for Budapest Treaty deposits. The DSMZ uses separate forms for the deposit of bacteria, archaea or fungi, bacteriophages, plasmids, plant viruses, plant cell cultures and animal and human cell cultures. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the DSMZ has received such information, the depositor must complete 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 German and English. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The DSMZ will communicate by e-mail the date of deposit and deposition number before the official statements of receipt and viability are issued, but only after the viability and purity test has been done and has given a positive result.

Supply of Information to a Patent Agent. The DSMZ does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the DSMZ will send copies of the receipt and viability statement to both the depositor and his 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 the DSMZ, the depositor is requested to authorize the DSMZ to continue to make them so available and to waive his right to be notified of the release of samples. If the depositor is unwilling to accede to this request, he 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 requested to complete the equivalent of 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

The DSMZ 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 DSMZ 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).

Model request form BP/13 is used in connection with requests for deposited microorganisms where the responsible patent office has communicated lists of the accession numbers given by the IDA to deposits of microorganisms referred to in the said patents.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the DSMZ will withhold samples of potentially hazardous microorganisms until the requesting party has provided evidence that he is allowed to work with such organism. When responding to requests from overseas, the DSMZ will ask the requesting party to provide an import permit if it knows that one is required for that particular country.

All samples of bacteria, archaea and fungi furnished by the DSMZ are from batches of its own preparations of the microorganism.

(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

In accordance with Rule 9.2 of the Treaty, the DSMZ does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

		EUR
I.1		
(a)	Storage according to Rule 12.1 *(a)*(i) of the Regulations under the Budapest Treaty (comprising the initial viability check, the preservation and the storage of the biological material)	
	- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses	800
	- plant cell cultures, human and animal cell cultures	1.400
(b)	Conversion of a deposit made outside the Budapest Treaty into a deposit according to the Budapest Treaty	
	- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses	800
	- plant cell cultures, human and animal cell cultures	1.400
(c)	Prolongation of the duration of the storage over the one provided by Rule 9 of the Regulations under the Budapest Treaty, per year	
	- archaea, bacteria, fungi, plasmids, bacteriophages and plant viruses	30
	- plant cell cultures, human and animal cell cultures	50
I.2	Issuance of a viability statement according to Rule 12.1*(a)*(iii) of the Regulations under the Budapest Treaty	
(a)	where a viability test is requested	120
(b)	on the basis of the most recent viability test	50
I.3	Furnishing of a sample according to Rule 12.1*(a)*(iv) of the Regulations under the Budapest Treaty (plus current freight costs)	120
I.4	Communication of information under Rule 7.6 of the Regulations under the Budapest Treaty	50
I.5	Attestation referred to in Rule 8.2 of the Regulations under the Budapest Treaty	50

For the customers within Germany the fees are subject to VAT, currently at the rate of 7 %. Turnover tax, again currently at the rate of 7 %, must be charged on EU orders not quoting a VAT registration number.

A processing fee of 5-30 Euros to cover handling and bank charges is payable on all invoices

4. Guidance for Depositors

The DSMZ provides specific written notes for the guidance of prospective depositors on its home page (www.dsmz.de). In addition, it is always ready to give advice by telephone or by e-mail.

HU – HUNGARY

NATIONAL COLLECTION OF AGRICULTURAL AND INDUSTRIAL MICROORGANISMS (NCAIM)

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E-mail: judit.tornai@uni-corvinus.hu
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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including *Streptomyces*) except obligate human pathogenic species (e.g., *Corynebacterium diphtheriae*, *Mycobacterium leprae*, *Yersinia pestis*, etc.).

Fungi, including yeasts and molds, except some pathogens (*Blastomyces*, *Coccidioides*, *Histoplasma*, etc.), as well as certain basidiomycetous and plant pathogenic fungi which cannot be preserved reliably.

The following may not, at present, be accepted for deposit:

- viruses, phages, rickettsiae,
- algae, protozoa,
- cell lines, hybridomas.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The NCAIM accepts microorganisms for deposit as either lyophilized preparations or active cultures. The minimum number of replicates that the depositor must supply when making his deposit is 25 for lyophilized preparations or three for active cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of microorganisms accepted by the NCAIM is seven days, but depositors should realize that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

Where the microorganism is deposited in active culture, the NCAIM prepares its own batches by subculturing the material supplied by the depositor. The depositor is required to check for authenticity samples of all such batches. The NCAIM does not prepare its own batches of microorganisms that have been supplied as lyophilized preparations by the depositor.

In all cases, the NCAIM renews diminishing stocks of deposited microorganisms by asking the depositor to make a new deposit.

Whichever method is used for preparing batches of samples for distribution, the NCAIM nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NCAIM is Hungarian. Communications are also accepted in English, French, German and Russian.

Contract. The NCAIM does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the NCAIM deposit form the depositor surrenders any right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the NCAIM are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete model form BP/1, which is used by the NCAIM as its accession form for Budapest Treaty deposits. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the NCAIM has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third party is issued on form BP/14. The NCAIM uses its own standard letters for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NCAIM will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The NCAIM will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NCAIM does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the NCAIM will send copies of the receipt and viability statement to both the depositor and his 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 deposited for patent purposes. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fee had previously been paid in respect of those deposits.

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 NCAIM 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 NCAIM 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 to receive samples under patent regulations, a requesting party must show, by a business letterhead or requisition form or in some other way, that he is trained in microbiology and has access to a properly equipped laboratory. When responding to requests from overseas, the NCAIM assumes the requesting party has met the import requirements of his own country.

Samples furnished by the NCAIM may be from preparations supplied by the depositor, or from its own preparations, depending on the form in which the microorganism was deposited.

(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 NCAIM does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

		HUF
(a)	Storage	150,000
(b)	Issuance of an attestation pursuant to Rule 8.2 of the Regulations under the Treaty and communication under Rule 7.6 of the Regulations under the Treaty	10,000
(c)	Issuance of a viability statement with the exception provided for in the first sentence of Rule 10.2(e) of the Regulations of the Treaty	25,000
(d)	Furnishing of a sample with the exception provided for in the first sentence of Rule 11.4(h) of the Regulations under the Treaty	30,000

4. Guidance for Depositors

The NCAIM does not at present produce a standard letter or guidance notes for prospective depositors.

IN - INDIA

Microbial Culture Collection (MCC)
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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The MCC will at present accept bacteria, fungi, yeasts and plasmids in a host and/or as isolated DNA preparations belonging to Hazards Group 1 and 2 as per classification of the Indian Authority.

Genetically manipulated microorganisms and isolated DNA will be accepted if they can be processed in BSL-1 or BSL-2 facility or conform to Group 1 or 2 organisms.

The MCC reserves the right to refuse to accept a deposit if, in its view, the deposit may be an unacceptable hazard or the MCC may not be in a position to process it. Deposit of bacteria and fungi pathogenic to plants and animals will be accepted from other countries only if cleared by the appropriate authority in India.

The deposited material will generally be preserved by freeze-drying or storage in liquid nitrogen or by other method(s) of long-term preservation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Materials for deposit should be pure (uncontaminated) and should be sent in the following form:

Bacteria and fungi (including yeasts): two active cultures on slants
Plasmids 5 x 20 micrograms of isolated and purified DNA preparations.

Suitable host of the plasmid and host harbouring the plasmid also need to be deposited in active form (2 slants each). The deposit should be accompanied by appropriate forms duly

completed by the depositor. These forms can be obtained from the MCC. Separate forms need to be used for bacteria, fungi (including yeasts) and plasmids. A fee for storage (Rule 12.1(a) (i) of the Regulations under the Budapest Treaty) must be paid for each deposit.

(ii) Time Required for Viability Testing

The MCC will test viability as quickly as possible. Since growth rate of microorganisms vary the time required for viability testing for different microorganisms may accordingly vary. The average time that will be required for viability testing is indicated below:

Bacteria, yeast and plasmids	4 days to 3 weeks
Actinomycetes, fungi	7 days to 4 weeks

(iii) Depositor Checks and Renewal of Stocks

The MCC may prepare, as and when it finds necessary, new batch(es) of glycerol stocks, lyophilized and frozen (in liquid nitrogen) culture by subculturing available materials. The MCC will send samples of the new batch and the depositor is required to check the authenticity of such microorganisms.

(c) Administrative Requirements and Procedures

(i) General

Language. The language of communication of the MCC and of the forms will be English. Communication in Hindi is also acceptable. However, in case of any dispute, the English version will prevail.

Contract.

The MCC does not enter into any written contract with the depositor defining the liabilities of either party, but by signing the MCC deposit form the depositor accepts general terms and conditions and surrenders any right to withdraw his deposit during the required storage period. He also accepts that the organism will be distributed according to the relevant patent requirement.

Import and/or Quarantine Regulations. Cultures of microorganisms from outside India may require import clearance and/or be subjected to quarantine regulations. The depositor from outside India should communicate with the MCC regarding such deposits before dispatching cultures.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. A depositor will be required to send a complete BP/1 form which is the accession for a deposit under the Budapest Treaty. For amendments to the scientific description or taxonomic designation a depositor will be required to send a completed BP/7 form.

Official Notifications to the Depositor. The receipt and viability statement will be issued in English on the mandatory "international forms" BP/4 and BP/9, respectively. The attestation of receipt of an amendment to the scientific description or taxonomic designation will be issued on BP/8 form. The notification of furnishing a sample to third parties will be issued on BP/14 form.

Unofficial Notifications to the Depositor. If requested, the MCC may communicate the date of deposit and accession number before the official receipt is issued only after the viability test is completed and a positive result is obtained.

Supply of Information to a Patent Agent. If required by the depositor, the MCC will send copies of the receipt and viability statement to both the depositor and his/her patent agent.

(iii) Converting a Previous Deposit

In case of a deposit made in the MCC earlier, outside the provisions of the Budapest Treaty, the original depositor may convert the same to a Budapest Treaty deposit. However, if the original deposit was in the general category and is listed in the MCC catalogue (printed or electronic) and had no restriction for distribution by the MCC, the depositor will be requested to authorize the MCC not to restrict distribution of such a deposit and waive his/her right to notification of release of the sample. If this condition is not acceptable then a fresh deposit of the material under the Budapest Treaty will be required. Deposit previously made with MCC for patent procedure or for safekeeping also can be converted to deposits under the Budapest Treaty.

Administrative requirements and fees for conversion will be the same as for the original deposit under the Budapest Treaty.

(iv) Making a new Deposit

For making a new deposit the completed BP/2 form will be required along with the relevant documents as required under rule 6.2. A receipt and viability statement for such a deposit will be issued on BP/5 and BP/9 forms respectively.

2. Furnishing of Samples

(a) Requests for Samples

The MCC will follow procedure as provisions of the Budapest Treaty for furnishing samples to third parties. For proof of entitlement BP/12 form and for request BP/13 form will be used in furnishing samples. For hazardous microorganisms the requesting party has to provide evidence that proper facility for handling such microorganisms is available and he/she has the requisite permission to work on such organisms.

A requesting party from outside India also has to provide an import permit if it is required for that country.

The MCC will furnish samples prepared by it from the deposited sample(s).

(b) Notification of the Depositor

A depositor will be notified on BP/14 form when samples of their deposit have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

Materials deposited under the Budapest Treaty will not be published in the MCC catalogue (printed or electronic) or displayed on the internet.

3. Schedule of Fees

Bacteria, fungi, yeast and plasmids	Indian Rupees
(a) Storage under rule 12.1 (a)(i)	20,000
(b) Conversion of deposit	20,000
(c) Extension of duration storage beyond that provided by Rule 9 (per year)	2,000
(d) Issue of viability statement on the basis of test	3,000
(e) Issue of viability statement on the basis of last viability test	1,000
(f) Furnishing of samples	3,000
(g) Communication of information under Rule 7.6	1,000
(h) Attestation referred to in Rule 8.2	1,000

4. Guidance for Depositors

The MCC will be happy to provide written notes or advice to prospective depositors.

IN - INDIA

MICROBIAL TYPE CULTURE COLLECTION AND GENE BANK (MTCC)

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Council of Scientific and Industrial Research (CSIR)
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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The MTCC will accept bacteria, fungi, yeasts, bacteriophages, plasmids in a host and/or as isolated DNA preparations belonging to Hazard Groups 1 and 2 as per classification of the Indian authority.

Genetically manipulated microorganisms and isolated DNA will be accepted if they can be processed in the S1 or S2 facility or conform to Group 1 or 2 organisms.

The MTCC reserves the right to refuse to accept a deposit if, in its view, the deposit may be an unacceptable hazard or the MTCC may not be in a position to process it. Deposit of bacteria and fungi from other countries pathogenic to plants and animals, which can be processed in the Sl or S2 facility, will be accepted only if cleared by the appropriate authority in India.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Materials for deposit should be pure (uncontaminated) and should be sent in the following form:

Bacteria and fungi (including yeasts)	10 freeze-dried ampoules and 2 active cultures (on slants). If freeze-dried cultures cannot be submitted the MTCC may do the freeze-drying on payment by the depositor
Bacteriophages	5 x 2 ml quantity with a minimum titre of l x 10^9 pfu per ml. Suitable host of the bacteriophage also needs to be deposited in active form (2 slants)
Plasmids	5 x 20 micrograms of isolated and purified DNA preparations. Suitable host of the plasmid also needs to be deposited in active form (2 slants)

The deposit should be accompanied by appropriate forms duly completed by the depositor. These forms can be obtained from the MTCC. Separate forms need to be used for bacteria, fungi (including yeasts), bacteriophages and plasmids. A fee for storage (Rule 12.1(a)(i) of the Regulations under the Budapest Treaty) must be paid for each deposit.

(ii) Time Required for Viability Testing

The MTCC will test viability as quickly as possible. Since microorganisms may grow quite slowly, the time required for viability testing for different microorganisms varies. The average time that will be required for viability testing is indicated below:

Bacteria, yeast, bacteriophages and plasmids	4 days to 3 weeks
Fungi	7 days to 4 weeks

(iii) Depositor Checks and Renewal of Stocks

The MTCC may prepare, as and when it finds necessary, new batch(es) of lyophilized and frozen (in liquid nitrogen) cultures by subculturing materials supplied by the depositor. The MTCC will send samples of the new batch and the depositor is required to check the authenticity of such microorganisms.

(c) Administrative Requirements and Procedures

(i) General

Language. The language of communication of the MTCC and of the forms will be English. Communication in Hindi is also acceptable. However, in case of any dispute, the English version will prevail.

Import and/or Quarantine Regulations. Cultures of microorganisms from outside India may require import clearance and/or be subjected to quarantine regulations. The depositor from outside India should communicate with the MTCC regarding such deposits before dispatching cultures.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. A depositor will be required to send a completed BP/1 Form which is the accession form for a deposit under the Budapest Treaty. For amendments to the scientific description or taxonomic designation a depositor will be required to send a completed BP/7 Form.

Official Notification to the Depositor. The receipt and viability statement will be issued in English on the mandatory "international forms" BP/4 and BP/9, respectively. The attestation of receipt of an amendment of scientific description or taxonomic designation will be issued on BP/8 Form. The notification of furnishing a sample to third parties will be issued on BP/14 Form.

Unofficial Notification to the Depositor. If requested, the MTCC may communicate the date of deposit and accession number before the official receipt is issued only after the viability test is completed and a positive result is obtained.

Supply of Information to a Patent Agent. If requested by the depositor, the MTCC will send copies of the receipt and viability statement to both the depositor and his/her patent agent.

(iii) Converting a Previous Deposit

In case of a deposit made in the MTCC earlier, outside the provisions of the Budapest Treaty, the original depositor may convert the same to a Budapest Treaty deposit. However, if the original deposit was in the general category and is listed in the MTCC catalogue (printed or electronic) and had no restriction for distribution by the MTCC, the depositor will be requested to authorize the MTCC not to restrict distribution of such a deposit and waive his/her right to notification of release of the sample. If this condition is not acceptable then a fresh deposit of the material under the Budapest Treaty will be required. Deposits previously made with the MTCC for patent procedure or for safekeeping also can be converted to deposits under the Budapest Treaty.

Administrative requirements and fees for conversion will be the same as for the original deposit under the Budapest Treaty.

(iv) Making a New Deposit

For making a new deposit the completed BP/2 Form will be required along with relevant documents as required under Rule 6.2. A receipt and viability statement for such a deposit will be issued on BP/5 and BP/9 Forms respectively.

2. Furnishing of Samples

(a) Request for Samples

The MTCC will follow procedures as provided under the provisions of the Budapest Treaty for furnishing samples to third parties. For proof of entitlement BP/12 Form and for request BP/13 Form will be used in furnishing samples. For hazardous microorganisms the requesting party has to provide evidence that the proper facility is available and he/she has the requisite permission to work on such organisms.

A requesting party from outside India also has to provide an import permit if it is required for that country.

The MTCC will furnish samples prepared by it from the deposited sample(s).

(b) Notification of the Depositor

A depositor will be notified on BP/14 Form when samples of their deposit have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

Materials deposited under the Budapest Treaty will not be published in the MTCC catalogue (printed or electronic) or displayed on the Internet.

3. Schedule of Fees

		INR
(a)	Storage	15,000
(b)	Conversion of a deposit	15,000
(c)	Extension of duration storage (per year)	2,000
(d)	Issuance of a viability statement on the basis of test	3,000
(e)	Issuance of a viability statement on the basis of last viability test	1,000
(f)	Furnishing of a sample	3,000
(g)	Communication of information	1,000
(h)	Issuance of an attestation	1,000

4. Guidance for Depositors

The MTCC will be happy to provide written notes or advice to prospective depositors.

IT – ITALY

ADVANCED BIOTECHNOLOGY CENTER (ABC)

Interlab Cell Line Collection (ICLC)
S.S. Banca Biologica e Cell Factory
Largo Rosanna Benzi, 10
16132 Genova

Telephone: (39-010) 5558 474/289
Facsimile: (39-010) 5558 293
E-mail: iclc@istge.it
Internet: http://www.iclc.it/iclceng.html

1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

Human and animal cell lines and hybridomas, provided that they can be stored in liquid nitrogen vapors, without any significant loss of viability. The genetically modified cell lines are also accepted if they belong to category 1 of genetically modified microorganisms, and if they have been registered by the depositor. No deposits are accepted of cell lines and hybridomas beyond category of containment 2.

The ICLC reserves the right to refuse any material whose manipulation represents an unacceptable risk or technical difficulty. The ICLC requests that a form on the cell line/hybridoma characteristics be filled in on deposit.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cell lines and hybridomas. At least 12 frozen ampoules must be provided for each cell line deposited, containing not less than 2 x 106 cells per ampoule. The ampoules must be sent with a quantity of dry ice sufficient to remain frozen during the transport. If the package is found inadequate, the culture will not be accepted.

(ii) Time Required for Viability Testing

The average delay needed for the control of viability of the cell lines and hybridomas is of 10-14 days (the depositors should be aware that in some cases the control may take longer).

(iii) Depositor Checks and Renewal of Stocks

In general, the ABC does not prepare its stocks of cell lines/hybridomas, and when the stocks are exhausted because of the delivery of samples, it requests the depositor to make a new deposit. In some special cases, by an agreement with the depositor, the ABC can prepare its stocks of the material, asking the depositor to verify the authenticity and quality of the material.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the ABC is Italian. Deposits are also accepted in English and French.

Contract. The depositor must fill in a form in which he declares his agreement on the following:

- to deposit the material only in the required form and quantity;

- to indicate the characteristics of the cell line/hybridoma relating to danger and pathogenicity;

- to pay all required fees, including the postal expenses for the shipment(s) of the cell line/hybridoma to the ABC;

- to comply with the requirements of the Budapest Treaty;

- to comply with the requirements of the ABC concerning the deposit of microorganisms.

Import and/or Quarantine Regulations. The kind of material accepted for deposit by ABC is not required to follow any particular rule.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. The depositor is required to fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma.

Forty eight hours before shipping the material, the depositor must inform the ABC about the number of samples sent for deposit, the means of transport chosen and the expected time of arrival. If the material is sent by air, the ABC must be informed of the flight number, destination, number of bill and carrier.

Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9.

Unofficial Notifications to the Depositor. If requested, the ABC will communicate by telephone the date of deposit and the accession number of the cell line/hybridoma, before the official receipt is issued.

Supply of Information to a Patent Agent. If requested, the ABC will send a copy of the viability statement to the patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the Budapest Treaty can be converted by the original depositor to deposits under the Budapest Treaty. In this case, the fees normally payable under the Budapest Treaty are due. The other requirements are the same as for an original deposit.

(iv) Making a New Deposit

When making a new deposit, the depositor must fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma, and the depositor must send a copy of the documents and of the declaration indicated in Rule 6.2. As to the shipment, the depositor must follow the technical requirements and procedures described in point 1(b) above.

2. Furnishing of Samples

(a) Requests for Samples

The ABC does not inform the requesting parties about the procedure to be followed for the request, and does not provide the forms of request which can be obtained from the relevant Patent Offices.

The ABC assumes that the requesting parties have satisfied all the national requirements concerning importation.

(b) Notification to the Depositor

When ABC delivers samples of the deposited microorganisms to third parties, it notifies the depositor by letter.

(c) Cataloguing of Budapest Treaty Deposits

The ABC does not include the deposits made under the Budapest Treaty in its catalogs.

3. Schedule of Fees

		EUR
Cell lines and hybridomas		
(a)	Storage	1,350
(b)	Issuance of a viability statement	100
(c)	Furnishing of a sample	150
(d)	Communication and request of authorizations to the competent authorities	130

The fees, with the addition of the Value Added Tax where relevant, are payable to the *Centro di Biotecnologie Avanzate* (*Cassa di Risparmio di Genova e Imperia*, n. 49, c/c 21624/20, cod. ABI 6175, cab 1594).

4. Guidance for Depositors

The forms of the ABC for the deposit contain the recommendations for the depositors.

IT – ITALY

COLLECTION OF INDUSTRIAL YEASTS DBVPG

Department of Agricultural, Food and Environmental Science
Borgo XX Giugno, 74
06121 Perugia

Telephone: (39-075) 585 64 87, 585 64 55
Facsimile: (39-075) 585 64 70
E-mail: benedetta.turchetti@unipg.it; pietro.buzzini@unipg.it
Internet: http://www.dbvpg.unipg.it

1. Requirements for Deposit

(a) Kinds of Microorganisms that may be Deposited

Yeast and yeast-like fungi, with the exception of those having properties that may be dangerous to human health.

(b) Technical Requirements and Procedures

(i) Form and quantity

Samples must be sent in test tubes in liquid or gel form or in freeze-dried ampoules in rigid-sided containers. Frozen or deep frozen cultures must be shipped in containers of expanded polystyrene containing a quantity of dry ice sufficient to guarantee 48 hours autonomy at room temperature. The cells of the strain dispatched must be in pure culture and provide a high level of viability. In the presence of contamination by bacteria, molds, other yeasts and acarina, the dispatched culture is immediately sterilized.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of deposited cultures is 20 days.

(iii) Depositor Checks and Renewal of Stocks

The DBVPG prepares its own batches of the microorganism at the time of deposit by subculturing the material supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The DBVPG always stores a portion of the original material supplied by the depositor.

(c) Administrative Requirement and Procedures

(i) General

Language. The official language of the DBVPG is Italian. Deposits are also accepted in English and French.

Contract. The depositor must fill in a form in which he/she declares his agreement on the following:

- to deposit the material only in the required form and quantity;

- to indicate the characteristics of the yeast culture related to danger or pathogenicity;

- to pay all the required fees;

- to comply with the requirements of the Budapest Treaty;

- to comply with the requirements of the DBVPG concerning the deposit of yeasts.

Import and/or Quarantine Regulations. The material accepted for deposit by DBVPG is not required to follow any particular rule.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. The depositor is required to fill in a deposit form which includes a declaration on the pathogenicity of the yeast culture. Forty-eight hours before shipping the material, the depositor must inform the DBVPG about the number of samples sent for deposit, the means of transportation and the expected time of arrival; in case of air shipment, the DBVPG must be informed of the flight number, destination, number of bill and carrier.

Official Notification to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9.

Unofficial Notification to the Depositor. If requested, the DBVPG will communicate by telephone the date of deposit and the accession number of the yeast culture, before the official receipt is issued.

Supply of Information to a Patent Agent. If requested, the DBVPG will send a copy of the viability statement to the patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the Budapest Treaty can be converted by the original depositor to deposits under the Budapest Treaty. In this case, the fees normally payable under the Budapest Treaty are due. The requirements are the same as for an original deposit.

(iv) Making a New Deposit

When making a new deposit, the depositor must fill in a deposit form which includes a declaration on the pathogenicity of the yeast culture, and the depositor must send a copy of the documents of the declaration indicated in Rule 6.2. As to the shipment, the depositor must follow the technical requirements and procedures described in point 1(b).

2. Furnishing of Samples

(a) Requests for Samples

The DBVPG does not inform the requesting parties about the procedure to be followed for the request, and does not provide the forms of request which can be obtained from the relevant Patent Office.

The DBVPG assumes that the requesting parties have satisfied all the national requirements concerning importation.

(b) Notification to the Depositor

When the DBVPG delivers samples of the deposited microorganism to third parties, it notifies the depositor by letter.

(c) Cataloguing of Budapest Treaty Deposits

The DBVPG does not include the deposits made under the Budapest Treaty in its catalogs.

3. Schedule of Fees

		EUR
(a)	Storage for 30 years	650
(b)	Issuance of a viability statement	50
(c)	Furnishing of a sample:	
	- agar slants	40
	- freeze-dried samples	15
(d)	Communication of information	25

4. Guidance for the Depositors

The forms of the DBVPG for the deposit contain the recommendations for the depositor.

IT - ITALY

ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLA LOMBARDIA
E DELL'EMILIA ROMAGNA "BRUNO UBERTINI" (IZSLER)

Via Bianchi, 9
25124 Brescia

Telephone: (39-030) 22901
Facsimile: (39-030) 2425251
E-mail: info@izsler.it
Internet: http://www.izsler.it

Entity in charge of handling Deposits under the Budapest Treaty

IZSLER Biobank of Veterinary Resource (IZSLER BVR)
Via Bianchi, 9
25124 Brescia
Italy

Telephone: (39-030) 2290 248 / 536
Facsimile: (39-030) 2290 392 / 386
E-mail: substr@izsler.it
Internet: www.ibvr.org

1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

- Animal bacteria isolated from tissues and organs and from food;
- Human and Animal viruses.

IZSLER accepts for deposit microorganisms according to Directive 2000/54/EC, on the Protection of Workers from Risks related to Exposure to Biological Agents at work of 18 September 2000 (OJ L262 page 21-45). At IZSLER, animal pathogens of level risk 1 and 2 will be accepted. Those listed in article 265 and 265 bis of "*Testo Unico delle Leggi Sanitarie*", respectively will not be accepted for deposit.

Viruses of humans of level risk 1 and 2 will be accepted at IZSLER.

No mixed microbiological cultures will be accepted. They will be accepted if sent separately.

IZSLER reserves the right to refuse any biological resources that represent a high hazard or that, for technical reasons, cannot be processed.

Biological resources can be sent frozen or freeze-dried and their storage will be made at -20°C, and -80°C according to the method that allows a long-term preservation of vitality and maintenance of the characteristic of the material.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IZSLER BVR needs the following requirements for the form of the microorganisms that are submitted for deposit :

- Bacteria and viruses should be sent frozen or freeze-dried cultures. Twelve vials must be provided from a single preparation and at a concentration of no less than 10^5 viable units /vial.
- The material for deposit must be tested and free from contamination by foreign microorganisms by the Depositor

(ii) Time Required for Viability Testing

The time requested for testing the viability of the different kinds of microorganisms is below indicated. It must outlined that for slow growing microorganisms, tests for viability must be longer and they are indicated in the bracket

Bacteria	average time 14 days (up to 3 weeks)
Human and Animal Viruses	average time 20 days

(iii) Depositor Checks and Renewal of Stocks

In general, IZSLER does not prepare batches of bacteria and viruses and when the batches are exhausted it requests the depositor to make a new deposit. Only in particular case and following previous written consent of the depositor, IZSLER can prepare a new batch of the material. However, the depositor has to control the quality characteristics of the material.

A portion of each original material supplied by the depositor is stored as *master* deposit.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of IZSLER is Italian. Communications and correspondence are accepted in Italian and in English.

Contract. A contract between IZSLER and the depositor must be prepared. It has to be signed by both parties and the depositor acknowledges the conditions of the deposit under the Budapest Treaty, the rules and requirements to be observed and the relative liability in the event of an incident.

In particular, the depositor has to declare the following:

- quantity and form of the material to be deposited;
- characteristics and biological risk of the material;
- payment of the fees charged;

- to comply with the requirements of the Budapest Treaty and with those of IZSLER notified to WIPO.

Import and/or Quarantine Regulations. IZSLER requests an import authorization from Italian Ministry of Health.

No quarantine regulation must be followed for microorganisms that are accepted by IZSLER.

Transport of infectious material in Italy is subjected to the package conforming to international regulations of the transport of hazardous materials.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. Depositors have to complete and sign the contract and deposit forms for the Budapest Treaty deposits. Each form is specific for each type of Biological Resource.

In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor is required to complete a BP/7 form which may be requested from IZSLER by e-mail.

Sending of Biological Resource to be deposited must be previously agreed between two parties.

Original deposit documents have to be sent together with the biological resource; however, it is advised to send them before sending by e-mail.

Official Notifications to the Depositor. The receipt and the viability statement are communicated by transmission of "international forms" BP/4 and BP9, respectively. Other notifications are sent by individual letters.

Any attestation concerning a change of the technical description and/or the proposed taxonomic designation will be delivered on form BP/8.

Furthermore, any notification on the furnishing of samples to third parties will be sent to the Depositor on form BP/14.

Official forms will be sent to the depositor only after the results of viability testing and when deposit is accepted. Accession number will be the same of the registration number.

Unofficial Notifications to the Depositor. IZSLER will communicate by e-mail the date of deposit and number of deposit before the official statement of receipt and viability testing are made.

Supply of Information to a Patent Agent. IZSLER will provide, if requested, information to the patent agent.

(iii) Converting a Previous Deposit

Deposit of other types (open deposit, safe deposit) can be converted by the depositor into deposit under the Budapest Treaty. In this event the depositor has to indicate the date on which the original deposit was received, the accession number of the biological resource, the name and address of the depositor and the request of conversion of the deposit and to maintain deposit and distribution of the microorganism for research purposes during the period specified in rule 9.1. In this event the batch has to be moved from the previous to the new deposit. In alternative, the depositor prepares a new batch to be deposited under the Budapest Treaty. The new deposit is subjected to the rules and administrative requirements of the Budapest Treaty.

(iv) Making a New Deposit

The depositor has to complete the BP/2 model form in order to make a new deposit and to send copies of the documents mentioned in Rule 6.2.
Statements of the receipt and viability testing are sent on mandatory international forms BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

IZSLER notifies third parties of the correct procedures to order patent microorganisms. In the case of requests of proof of entitlement, IZSLER will send to requesting party copies of the model request form BP/12.

Third parties will receive a microorganism under patent regulations following providing evidence that they are allowed to work with such a microorganism.

Moreover, all documents, including permit importations, are requested by IZSLER to respond to requests from overseas, or a declaration stating that no authorization is necessary for the proper shipping of the microorganism.

(b) Notification to the Depositor

Depositors are informed by BP/14 form on the distribution of a patent microorganism to third parties.

(c) Cataloguing of Budapest Treaty Deposits

IZSLER does not publish list of deposits under the Budapest Treaty in any published catalogue.

3. Schedule of Fees

		EUR
Storage		
Bacteria		
	Freeze dried	608,80
	Frozen at -80°C	701,27
	Frozen liquid nitrogen	1.448,27
Animal viruses		
	From embryonated chicken embryos	788,92
	From cell cultures	1.086,96
Viability		
	Issuance of viability statement based on last test	60
	Viability statement (bacteria), if new test is carried out	100
	Viability statement (virus), if new test is carried out	150
Distribution		
	Furnishing of a sample (bacteria) (plus shipping costs)	105
	Furnishing of a sample (virus) (plus shipping costs)	400
Communication of information or issuance of an attestation		50

Value Added TAX (VAT) is added according to Italian regulations

4. Guidance for Depositors

IZSLER provides a written note for the request of deposit under the Budapest Treaty. It is at the home page of IZSLER (www.ibvr.org). Further information can be requested by e-mail.

JP – JAPAN

INTERNATIONAL PATENT ORGANISM DEPOSITARY (IPOD)

National Institute of Technology and Evaluation (NITE)
#120, 2-5-8 Kazusakamatari
Kisarazu-shi
Chiba 292-0818

Telephone: (81) 438 20 5910
Facsimile: (81) 438 20 5911
E-mail: ipod@nite.go.jp
Internet: http://www.nbrc.nite.go.jp/pod/

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Protozoa, plant cell cultures, seeds and algae, EXCEPT:

- microorganisms classified as biological safety level (BSL) 3 or 4 according to the Guidelines for the Handling of the Experiment of Microorganisms in NITE;
- microorganisms that require the containment measure levels P3 or P3P for experiments, as described in the Ministerial Ordinance stipulating Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (2004), which is based on the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (2003);
- mixtures of undefined and/or unidentifiable microorganisms.

IPOD reserves the right to refuse to accept deposit that is technically or legally too difficult to manage.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms should be submitted for deposit as frozen samples or as agar stab or slant cultures. The minimum number of replicates that must be supplied by the depositor when making his deposit, and the form in which they must be submitted, are as follows:

Plant cell cultures	5 slant cultures
Protozoa and algae	10 tubes or 5 agar stabs or 5 slant cultures
Seed	100 packs / 25 seeds per 1 pack

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the IPOD is 20 days, but depositors should realize that in some cases viability testing may take as long as 60 days.

(iii) Depositor Checks and Renewal of Stocks

The IPOD prepares its own batches of the microorganism 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. For seeds and samples supplied by depositor as frozen samples, the IPOD stores samples originally supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the IPOD is Japanese. However, the power of attorney and other attached documents can be in another language, but must be accompanied by a Japanese translation. Requests for samples may be in Japanese or English.

Contract. The IPOD does not enter into a written contract with the depositor defining the liabilities of either party but, by signing the IPOD deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. Certain plant and animal pathogens are subject to import and/or quarantine regulations. The IPOD advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits. On average, obtaining a permit takes about three weeks. Further information can be obtained from the Yokohama Plant Protection Station, Ministry of Agriculture, Forestry and Fisheries, 5-57 Kitanankadori, Naka-ku, Yokohama, Japan, and from the Animal Quarantine Service, Ministry of Agriculture, Forestry and Fisheries, 11-1 Hara-machi, Isogo-ku, Yokohama, Japan.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the IPOD as its accession form for Budapest Treaty deposits. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the IPOD has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of release of a sample to a third party is issued on form BP/14. The IPOD has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. The IPOD will inform the date of deposit and “provisional” accession number before the official receipt is issued, but the depositor must recognize that this information becomes official only on completion of the viability test and the payment.

Supply of Information to a Patent Agent. The IPOD does not routinely ask the depositor for the name and address of his patent agent. The IPOD will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt of the previous deposit. Conversions are subject to the normal storage fee levied for Budapest Treaty deposits in cases where any fee was previously charged in respect of their deposit for patent purposes outside the provisions of 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 IPOD 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 IPOD 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).

Requesting parties are required to complete the IPOD form BP/14 (Acknowledgement and Agreement for Furnishing and Use of Samples) to comply with health and safety requirements. When responding to requests from overseas, the IPOD assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the IPOD are from batches of its own preparations of the microorganism, with the exception of seeds and samples supplied by depositor as lyophilized or frozen samples.

(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 IPOD does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

		JPY
(a)	Storage (for 30 years) [*1]	
	- original deposit	175,000
	- new deposit	33,000
(b)	Issuance of an attestation under Rule 8.2	3,000
(c)	Issuance of a viability statement:	
	(i) if the viability test is to be carried out [*1]	29,000
	(ii) based on the last viability test	3,000
(d)	Furnishing of a sample [*1] [*2]	41,000
(e)	Issuance of communication under Rule 7.6	3,000

[*1] Japanese consumption tax will be charged for (a), (c) (i) and (d)
[*2] To ship abroad, handling and delivery cost will be charged separately

4. Guidance for Depositors

The IPOD produces notes for the guidance of prospective depositors.

JP - JAPAN

NATIONAL INSTITUTE OF TECHNOLOGY AND EVALUATION,
PATENT MICROORGANISMS DEPOSITARY (NPMD)

#122, 2-5-8 Kazusakamatari
Kisarazu-shi
Chiba 292-0818

Telephone: (81) 438 20 55 80
Facsimile: (81) 438 20 55 81
E-mail: npmd@nite.go.jp
Internet: http://www.nite.go.jp/en/nbrc/patent/npmd/index.html

1. Requirements for Deposit

(a) Kinds of Microorganisms that May be Deposited

Actinomycetes, animal cell cultures (including hybridomas and human cell cultures), archea, bacteria, bacteriophages, embryos, fungi, plasmids (in hosts or not in hosts) and yeasts, EXCEPT:

- microorganisms which belong to biosafety level 3 or level 4 according to the NITE (National Institute of Technology and Evaluation) Classification.

- microorganisms which call for containment measures level P3, P3A or P3P as described in the Ministerial Ordinance stipulating Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (2004), which is based on the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (2003).

- Mixtures of undefined and/or unidentifiable microorganisms.

NPMD reserves the right to refuse to accept deposit that is technically or legally too difficult to manage.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The NPMD accepts microorganisms for deposit any lyophilized or frozen samples. In case the microorganisms are difficult to be stored as lyophilized or frozen samples, agar stabs or slant cultures are also acceptable. The depositor should send the following to NPMD:

Actinomycetes, archea, bacteria, bacteriophages, fungi, plasmids (in hosts or not in hosts) and yeasts	10 ampoules, 10 tubes, 5 agar stabs or 5 slant cultures

Animal cell cultures (including hybridomas and human cell cultures) and embryos	12 tubes

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the microorganisms is as follows, but in some cases viability testing may take longer than the figures indicated below.

Plasmids	1 day
Bacteria	3 days
Yeasts	5 days
Actinomycetes, fungi and bacteriophages	7 days
Embryos	7 days
Animal cell cultures (including hybridomas and human cell cultures)	3 to 4 weeks

(iii) Depositor Checks and Renewal of Stocks

The NPMD stores samples originally supplied by the depositor, and doest not subculture material supplied by the depositor. The NPMD requires the depositor to supply the samples to replenish diminishing stocks. If requested, the NPMD makes its own preparations by subculture from material supplied by the depositor at an additional fee. In this case, the NPMD requires the depositor to test for authenticity of samples prepared by the NPMD and to inform the NPMD of the result.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NPMD is Japanese. Requests for the furnishing of samples may be in Japanese or English.

Contract. The NPMD enters into a written contact with the depositor by which the latter is bound.

- to provide the necessary information requested by the NPMD;

- to replenish the microorganism at his own expense if the NPMD is no longer able to furnish samples of it;

- not to withdraw the deposit during the required storage period.

Import and/or Quarantine Regulations. Certain plant and animal pathogens are subject to import and/or quarantine regulations. Further information can be obtained from Yokohama

Plant Protection Station or Animal Quarantine Station administrated by the Ministry of Agriculture, Forestry and Fisheries of Japan. http://www.maff.go.jp/eindex

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, in addition to the NPMD form 2 (Acknowledgement and Agreement for Original Deposit under the Budapest Treaty). In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the NPMD has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8.

Unofficial Notifications to the Depositor. The NPMD will inform the date of deposit and "provisional" accession number before the official receipt is issued, but the depositor must recognize that this information becomes official only on completion of the viability test and the payment.

Supply of Information to a Patent Agent. The NPMD does not ask the depositor for the name and address of his patent agent, if requested, the NPMD will supply the receipt and the viability statement through the depositor's 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 provided they were originally made for patent purposes. 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 the depositor is also required to supply a copy of the receipt of the previous deposit. The storage fee will be charged to the original depositor for conversion.

(iv) Making a New Deposit

The depositor will be required to complete model form BP/2 when making a new deposit, and to supply copies of the relevant documents specified in Rule 6.2. The receipt and the viability statement for a new deposit are issued on mandatory "international forms" BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The NPMD advises third parties of the correct procedures to follow in order to make a valid request and supplies the request forms used by Japan Patent Office. Request forms used by other individual industrial properties office must be obtained from the appropriate

industrial property offices. Requesting parties are required to complete the NPMD form 14 (Acknowledgement and Agreement for Furnishing and Use of Samples) to comply with health and safety requirements. When responding to requests from overseas, the NPMD assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the NPMD may be from preparations supplied by the depositor, with the exception of those not supplied by the depositor as lyophilized or frozen samples.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

The NPMD does not publish any catalogue.

3. Schedule of Fees

		JPY
(a)	Storage (for 30 years) *1	
	- original deposit	175,000
	- new deposit	33,000
(b)	Issuance of an attestation under Rule 8.2	3,000
(c)	Issuance of a viability statement:	
	(i) if the viability test is to be carried out *1	29,000
	(ii) based on the last viability test	3,000
(d)	Furnishing of a sample *1 *2	41,000
(e)	Issuance of communication under Rule 7.6	3,000

*1 Japanese consumption tax will be charged for (a), (c) (i) and (d)
*2 To ship abroad, handling and delivery cost will be charged separately

4. Guidance for Depositors

The NPMD provides pamphlets for the guidance of prospective depositors.

LV - LATVIA

MICROBIAL STRAIN COLLECTION OF LATVIA (MSCL)

Kronvalda Blvd. 4
Riga LV-1586

Telephone: (371) 6703 48 68
Facsimile: (371) 6703 48 68
E-mail: collect@lanet.lv
Internet: http://mikro.daba.lv

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, fungi (including yeasts), plasmids in a host with the exception of pathogenic microorganisms of hazard group 3 or 4. Microorganisms having special requirements for cultivation, which the MSCL is not technically capable of carrying out, shall not be accepted.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to MSCL for deposit must be in the form of agar stabs (slants) or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs (slants) or 25 lyophilized ampoules.

(ii) Time Required for Viability Testing

The average time required for testing the viability of various microorganisms accepted by MSCL is 7 days, but in some cases viability testing may take 20 days.

(iii) Depositor Checks and Renewal of Stocks

The MSCL prepares its own batches by subculturing material originally supplied by the depositor. New batches are prepared for renewal of diminishing stocks. MSCL routinely asks the depositor to check the authenticity of the preparations made by the MSCL at the time of deposit from material supplied by the depositor. The MSCL routinely checks newly received deposits for contamination and, if they are found contaminated, returns them to the depositor. The MSCL stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the MSCL is Latvian. Communications are accepted in English, German and Russian.

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

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by the MSCL are not subject to import or quarantine regulations. The MSCL does not advise the depositor of the procedures he must follow to obtain an import permit.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. Depositors are required to complete form MSCL–BP/1 (the equivalent of model form BP/1) which is the accession form used for Budapest Treaty deposits. They must complete the equivalent of model form BP/2 when making a new deposit and the equivalent of model form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Except the mandatory "international forms," official notifications are not issued on standard forms.

Unofficial Notifications to the Depositor. If requested, the MSCL will telephone or telefax the date of deposit and the accession number before the official receipt is issued, but only after a positive viability test has been obtained. The MSCL will similarly communicate the results of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The MSCL does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the MSCL will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty.

All conversions are subject to the storage fee normally levied for Budapest Treaty deposits.

(iv) Making a New Deposit

The depositor is required to complete the equivalent of 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

The MSCL 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 MSCL 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). All samples furnished by the MSCL are from batches of its own preparations.

(b) Notification of 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 MSCL does not list Budapest Treaty deposits in its published catalog.

3. Schedule of Fees

		Euros
(a)	Storage	426.86
(b)	Issuance of a viability statement	42.69
(c)	Furnishing of a sample (plus expedition cost)	42.69

The fees are subject to the Value Added Tax (VAT) at the rate of 21 %.

4. Guidance for Depositors

At present, the MSCL does not have specific written notes for the guidance of depositors, but is always ready to offer advice by telephone, telefax or e-mail.

NL – NETHERLANDS

CENTRAALBUREAU VOOR SCHIMMELCULTURES (CBS)

Uppsalalaan 8
3584 CT Utrecht

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

Telephone: (31-30) 212 26 00
Facsimile: (31-30) 251 20 97
Internet: http://www.cbs.knaw.nl

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

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).

The following bacteria of pathogenic group I (PG I: World Health Organization (WHO)) are accepted only when they can be maintained by the *Rijks Instituut voor Volksgezondheid en Milieuhygiene* (RIVM), *Centraal Diergeneeskundig Instituut* (CDI) or the Royal Institute for Tropical Research: *Bordetella* (all species), *Brucella* (all species), *Erysipelothrix* (all species), *Leptospira* (all species), *Listeria* (all species), *Mycobacterium paratuberculosis*, *Pasteurella* (all species), *Treponema* (all species).

The following bacteria of pathogenic group II (PG II (WHO)) are accepted only when they can be maintained by RIVM or CDI: *Bartonella* (all species), *Francisella* (all species), *Mycobacterium bovis*, *Mycobacterium tuberculosis*, *Pseudomonas mallei*, *Pseudomonas pseudomallei*.

The following bacteria are not accepted: *Bacillus anthracis* and *Yersinia pestis*.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The CBS prefers to receive microorganisms submitted for deposit as lyophilized preparations. Where it is undesirable or impossible to supply lyophilized preparations, active cultures growing in or on a suitable nutrient medium are acceptable. The minimum number of replicates that must be supplied by the depositor when making his deposit is as follows:

Fungi	12 lyophilized cultures; or 2 agar cultures;
Yeasts	12 lyophilized plus 1 agar culture; or 2 agar cultures;
Bacteria	12 lyophilized plus 1 agar culture; or 3 agar cultures;
Plasmids (in hosts)	12 lyophilized plus 1 agar culture; or 3 agar cultures;
Plasmids (purified DNA)	minimum quantity of 50 g;
Phages	10 ml with a titre of at least 109 pfu/ml.

In cases where the depositor is unable to supply lyophilized preparations, the CBS prepares lyophilized cultures at the time of deposit from the material supplied by the depositor at a fee of Euro 125 for a batch of 10 ampoules freeze-dried material. When the material can not be freeze-dried, CBS prepares a batch of 10 frozen straws at a fee of Euro 175. The preparation of a phage lysate with a sufficiently high titre can be done at a fee of Euro 500. Plasmid stocks are not prepared by the CBS.

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

(ii) Time Required for Viability Testing

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 if unusual antibiotics or other additives are necessary in the medium.

Fungi, bacteria, plasmids in hosts or purified DNA,[1] phages	2 weeks
Yeasts	1 week

[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.

(iii) Depositor Checks and Renewal of Stocks

The CBS routinely asks the depositor to check the authenticity of the deposited preparations after transfers. New batches of cultures are prepared whenever it is necessary to renew diminishing stocks.

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

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CBS is English. Communications are also accepted in Dutch, German and French. The preferred language for correspondence is English.

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 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: Plantenziektenkundige Dienst (PD), Geertjesweg 15, Postbus 9102, 6700 NC Wageningen, Netherlands.

The CBS should be contacted in advance if deposit of any of the following plant pathogenic bacteria is intended:

Agrobacterium rhizogenes, Corynebacterium flaccumfaciens, C. insidiosum, C. michiganense, C. sepedonicum, Erwinia amylovora, E. stewartii, E. tracheiphila, Pseudomonas caryophylli, P. solanacearum, P. syringae, pv glycinae, pv persicae, pv pisi, P. woodsii, Xanthomonas ampelina, X. campestris, pv citri, pv corylina, pv oryzae, pv oryzicola, pv phaseoli, pv pruni, pv vesicatoria, X. fragariae, X. populi.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the CBS accession form for patent deposits and model form BP/1. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. 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. If requested, the CBS will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CBS similarly will telephone or telex the result of the viability test before the official viability statement is issued.

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) 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 deposited for patent purposes. All converted deposits 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 model form BP/2 and to send copies of the relevant documents (Rule 6.2); otherwise the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

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 confirm that the requesting party is competent to handle them. Samples are not released to private persons not engaged in a relevant profession. When responding to requests from overseas, the CBS assumes that the requesting party has met the import requirements of his own country.

Samples of 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

Unless he has waived his right to be so notified, the CBS notifies the depositor by letter when samples of his microorganisms have been furnished to third parties. The CBS offers a reduced fee for storage to depositors who waive their right to be notified of the release of samples.

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

		EUR
(a)	Storage (30 years)	650
(b)	Conversion of a deposit	650
(c)	Preservation of stock material for the deposition of 30 years:	
	- set of 10 ampoules of freeze-dried material	125
	- set of 10 frozen straws	175
(d)	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	80
	- based on the last viability test	25
(e)	Communication of information	25
(f)	Issuance of an attestation	25
(g)	Furnishing of a sample:	
	- in accordance with Rule 11.2(ii), 11.3*(a)* and 11.3*(b)* of the Regulations of the Budapest Treaty	100
	- in accordance with Rule 11.2(i) of the Regulations of the Budapest Treaty:	
	- agar slant	40
	- freeze-dried ampoule	15
(h)	Surcharge to cover bank and administrative costs	10

4. Guidance for Depositors

The CBS does not produce a standard letter or guidance notes for prospective depositors, but from time to time guidance is provided in the CBS Newsletter.

PL – POLAND

IAFB COLLECTION OF INDUSTRIAL MICROORGANISMS

Institute of Agricultural and Food Biotechnology (IAFB)
Ul. Rakowiecka 36
02-532 Warsaw

Telephone: (48-22) 606 36 91, 606 36 00
Facsimile: (48-22) 849 04 28
E-mail: kolekcja@ibprs.pl
misiewicz@ibprs.pl

1. Requirements for Deposit

(a) Kinds of Microorganism that May Be Deposited

Bacteria, yeasts and filamentous fungi are accepted which are capable of long-term preservation without any substantial change in their initial properties.

Note:

- dangerous pathogens and species that can be hazardous to man and animals will not be accepted;

- microorganisms with special requirements for cultivation that the IAFB Collection of Industrial Microorganisms is not capable of carrying out technically will not be accepted;

- mixtures and cultures without scientific description and cultures that cannot be identified will not be accepted;

- when strains containing a plasmid are deposited, the IAFB Collection of Industrial Microorganisms will require information on the properties and classification of the plasmid and its host strain (i.e., group P1, P2, P3 or P4). The Collection will accept only plasmids and host strains belonging to group P1.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The Collection of Industrial Microorganisms prefers to receive microorganisms submitted for deposit as lyophilized preparations. When it is undesirable or impossible to supply lyophilized preparations, active cultures growing in or on a suitable nutrient medium are acceptable.

The minimum number of replicates that the depositor must supply when making his deposit is 20 for lyophilized preparations or three active cultures (agar slants).

(ii) Time Required for Viability Testing

The average length of time for testing viability is 7 to 14 days, but occasionally viability testing may take longer, particularly if unusual antibiotics or other additives are necessary in the medium.

(iii) Depositor Checks and Renewal of Stocks

Where the microorganism is deposited as an active culture, the Collection of Industrial Microorganisms prepares its own batches by subculturing the material supplied by the depositor. The Collection of Industrial Microorganisms routinely asks the depositor to check the authenticity of the deposited preparations after subculturing.

New batches of cultures are prepared whenever it is necessary to renew diminishing stocks. Whatever method is used for preparing batches of samples of distribution, the Collection of Industrial Microorganisms always keeps a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the IAFB Collection is Polish. Communications in English or Russian are also accepted.

Contract. The IAFB Collection does not enter into a written contract with the depositor defining the liabilities of the two parties. However, by signing the IAFB Collection deposit form, the depositor surrenders any right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. The kinds of microorganism accepted by the Collection of Industrial Microorganisms are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete model form BP/1. In the event of later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third party is issued on model form BP/14. The IAFB Collection uses its own standard letters for other official notifications.

Unofficial Notifications to the Depositor. If requested, the IAFB Collection will give the date of deposit and accession number by telephone, fax or e-mail when a microorganism has been received and before the official receipt is issued. The IAFB Collection will also give the result of the viability test by telephone, fax or e-mail before the official viability statement is issued.

Supply of Information to a Patent Agent. The IAFB Collection does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the Collection of Industrial Microorganisms will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The administrative requirements for conversion are the same as those to be met for an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to send copies of the relevant documents (Rule 6.2); otherwise the procedure is similar to that for making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

The IAFB Collection 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 Collection of Industrial Microorganisms will provide the requesting parties with copies of model request form BP/12 and/or request forms used by individual industrial property offices.

(b) Notification of the Depositor

Unless the right to be so notified has been waived, the IAFB Collection notifies the depositor by letter when samples of its microorganisms have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The IAFB Collection does not list Budapest Treaty deposits in its List of Cultures.

3. Schedule of Fees

		PLN
(a)	Storage	3,400
(b)	Issuance of a viability statement	350
(c)	Furnishing of a sample	400

4. Guidance for Depositors

The IAFB Collection does not produce a standard letter or guidelines for prospective depositors, but can of course be contacted for specific information. All inquiries should be addressed to the Collection of Industrial Microorganisms.

PL – POLAND

POLISH COLLECTION OF MICROORGANISMS (PCM)

Institute of Immunology and Experimental Therapy
Polish Academy of Sciences
Ul. Weigla 12
53-114 Wroclaw

Telephone: (48-71) 337 11 72
Facsimile: (48-71) 337 13 82
E-mail: gamian@immuno.iitd.pan.wroc.pl
Internet: http://immuno.iitd.pan.wroc.pl

1. Requirements for Deposit

(a) Kinds of Microorganism that May Be Deposited

Bacteria (including actinomycetes) and bacteriophages that are capable of long-term preservation without any substantial change in their initial properties are accepted.

Note:

- dangerous pathogens and species that may be hazardous to man and animals will be conditionally accepted;

- microorganisms with special requirements for cultivation that the PCM is not capable of carrying out technically will not be accepted;

- mixtures and cultures with no scientific description and cultures which cannot be identified will not be accepted;

- when strains containing a plasmid are deposited, the PCM will require information on the properties and classification of the plasmid and its host strain (i.e., group P1, P2, or P4). The PCM will accept only plasmids and host strains belonging to group P1.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria (including those containing plasmids) must be submitted for deposit as lyophilized preparations or on culture transport media, except agar plate cultures (these are too easily damaged in transport). Bacteriophages have to be sent together with a suitable host. The material for deposit must be free of contamination by foreign organisms. All replicates of the microorganism to be deposited should be from the same batch. The deposit must be accompanied by the appropriate form, duly completed. Forms are obtainable from the PCM.

The minimum number of replicates that must be provided by the depositor when making his deposit and the form in which they must be submitted are as follows:

Bacteria	10 lyophilized or on media or frozen (0,5ml each)
Bacteriophages	sufficient quantity and titre for preservation (at least 10^8 pfu/ml, 10 x 10ml or 2 x 5ml cell-free lysate)

The depositor is required to check the authenticity of a sample from the batch prepared by the PCM, and to inform the PCM of the result.

(ii) Time Required for Viability Testing

The average time required for testing the viability of microorganisms accepted by the PCM is given below, but depositors should understand that in some cases viability testing may take longer, as indicated by the bracketed figures:

Bacteria	3 days (or up to 14 days)
Actinomycetes and other slow-growing organisms	5 days (or up to 20 days)
Bacteriophages	7 days (or up to 14 days)

(iii) Depositor Checks and Renewal of Stocks

The PCM has prepared its own batch of microorganisms by subculturing material supplied by depositors. The depositor is asked to check the authenticity of batches prepared by the PCM from material supplied by him at the time of deposit. The PCM stores the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the PCM is Polish. Communications in English are accepted.

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

Import and/or Quarantine Regulations. At present, the kinds of microorganism accepted by the PCM for deposit under the Budapest Treaty are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the application and accession form for deposit under the Budapest Treaty, which is equivalent to model form BP/1. The PCM uses separate forms for bacteria and for bacteriophages. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and viability statements are issued on mandatory international forms BP/4 and BP/9 respectively. Notification of release of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the PCM will give the date of deposit and accession number by telephone, e-mail or fax after the microorganism has been received and before the official receipt is issued. However, the depositor is informed that the information is provisional and subject to the outcome of the viability test. Similarly, the PCM will communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The PCM does not routinely ask the depositor for the name and address of his patent agent. It will send copies of the receipt and viability statement to the patent agent if requested to do so.

(iii) Converting a Previous Deposit

Deposits not made under the Budapest Treaty may be converted into deposits under the Budapest Treaty, regardless of whether or not they were originally deposited for patent purposes. The administrative requirements for conversion are the same as those to be met for an original deposit under the Budapest Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to supply copies of the documents specified in Rule 6.2. The receipt and viability statements for a new deposit are issued on mandatory international forms BP/5 and BP/9 respectively.

2. Furnishing of Samples

(a) Requests for Samples

The PCM advises third parties of the procedure to be followed in order to make a proper request. For requests that require proof of the right to receive samples, PCM will supply the requesting parties with copies of the standard request form BP/12 and/or forms used by individual industrial property offices (where it has been supplied with such forms).

Notwithstanding any entitlement of a third party to receive samples under patent regulations, the PCM will withhold samples of potentially dangerous microorganisms until it has satisfied itself that the requesting party is competent to handle such organisms. When responding to requests from overseas, the PCM assumes that the requesting party has met the import requirements of his own country.

Samples of bacteria furnished by PCM are usually from batches prepared by itself; samples of bacteriophages may be from batches of its own or from material supplied by the depositor.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

The PCM does not list Budapest Treaty deposits in his published catalogue.

3. Schedule of Fees

		PLN
(a)	Storage	1,200
(b)	Issuance of a viability statement	40
(c)	Furnishing of a sample	100

4. Guidance for Depositors

At present, the PCM does not produce a standard letter or guidelines for prospective depositors, but offers advice by telephone, fax or e-mail.

KR – REPUBLIC OF KOREA

KOREAN AGRICULTURAL CULTURE COLLECTION (KACC)

Agricultural Microbiology Division
National Academy of Agricultural Science
Rural Development Administration
166, Nongsaengmyeong-ro, Iseo-myeon
Wanju-gun
Jeollabuk-do 55365

Telephone: (+82) 63 238 3024
Facsimile: (+82) 63 238 3845
E-mail: kacc@korea.kr
Internet: http://www.genebank.go.kr

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The KACC will accept bacteria (non-pathogenic including actinomycetes), fungi (non-pathogenic), yeasts (non-pathogenic), mushroom, plasmids in hosts, plant viruses, bacteriophages and plant seeds.

KACC accepts only those organisms belonging to risk groups 1 or 2, in accordance with Directive 2000/54/EC on the protection of workers from job risks related to exposure to biological agents.

KACC reserves the right to refuse the deposit of any material which in its view represents an unacceptable hazard or which it cannot process.

KACC must be consulted in advance about the conditions for acceptance.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The KACC accepts microorganisms submitted for deposit as lyophilized or frozen. All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations. The minimum number of replicates that must be provided by the depositor is as follows:

- Bacteria, fungi, yeasts, mushroom, bacteria containing plasmid	10
- Bacteriophages (at least 10^9 pfu/ml)	10 ml

Viruses should be deposited in the form of lyophilized or dried material along with the host. The minimum of number of replicates that must be provided by the depositor is as follows:

- Plant viruses	10 g

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 seeds 1000

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of biological material accepted by KACC is given below; however depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

- Bacteria, fungi, yeasts, mushroom, bacteria containing plasmid, plant viruses, bacteriophages 14 days (or up to 30 days)
- Plant seeds Depends entirely on the kind of seed

(iii) Depositor Checks and Renewal of Stocks

The KACC prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The KACC generally does not prepare its own batches of viruses, bacteriophages and seeds. In such cases, the depositor is responsible for replenishing the stock to ensure that there is sufficient stock to make the deposit available to the general public for the required period of deposit.

Whichever method is used for preparing batches of samples for distribution, the KACC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of the KACC are Korean and English. Communications in any other language are not accepted.

Contract. The KACC does not enter into any written contract with the depositor defining the liabilities of either party. Also, by completing the KACC BP/1 deposit form, the depositor foregoes any right to withdraw his deposit during the required storage period and accepts that the material will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. It is essential that the depositor contact the KACC in advance of submitting a deposit which may be subject to these regulations to ensure that the appropriate documentation is obtained. This is particularly important for deposits made from outside of Korea. Failure to do so could result in the deposit being refused entry into the country.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the KACC as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the KACC has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of furnishing of a sample to a third party is issued on form BP/14. The KACC has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KACC will write an e-mail the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KACC will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KACC does not routinely ask the depositor for the name and address of his patent agent. The KACC will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(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, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The KACC advises third parties about the correct procedures to follow in order to make a valid request. In the case of requests requiring proof of entitlement, the KACC 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). The KACC furnished samples on the basis that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KACC assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the KACC are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

	Services	KRW
1)	Deposit (including initial viability check, preservation and storage for 30 years):	
	- original deposit	800,000
	- new deposit	70,000
2)	Furnishing of a sample	100,000
3)	Issuance of a viability statement:	
	- where a viability test is requested	70,000
	- on the basis of the most recent viability test	10,000
4)	Issuance of an attestation under Rule 8.2	10,000
5)	Communication of information under Rule 7.6	10,000

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

At Present, the KACC does not produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.

KR - REPUBLIC OF KOREA

KOREAN CELL LINE RESEARCH FOUNDATION (KCLRF)

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College of Medicine
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Seoul 110-799

Telephone: (82-2) 3668 7915
Facsimile: (82-2) 742 0021
Internet: http://cellbank.snu.ac.kr

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Cell lines (human, animal, plant and hybridomas), eukaryotic DNA, plasmids (either in hosts or not in hosts), EXCEPT:

- cell lines having properties which are or may be hazardous to human health and/or the environment;
- cell lines which have special requirements for experimentation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cell lines submitted to KCLRF for deposit should be in the form of frozen and viable culture. All cell lines submitted to KCLRF for deposit should be free of contaminants.

The minimum number of replicates that must be provided by the depositor is as follows:

Cell lines in frozen form: 7

(ii) Time Required for Viability Testing

The average time required for testing the viability of cell lines accepted by KCLRF is as follows:

Cell lines (animal, plant and hybridomas) 14 days (or up to 28 days)

In some cases, the test may take longer.

(iii) Depositor Checks and Renewal of Stocks

KCLRF prepares its own batches in frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter. The depositor is required to check for authenticity samples of all batches prepared by KCLRF. Regardless of the methods for preparing the batches of samples for distribution, KCLRF stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. Korean is the official language of KCLRF, but correspondence may be carried out also in English.

Contract. KCLRF does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCLRF deposit form, the depositor surrenders the right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact KCLRF in advance for advice about the shipping of their cell lines. Certain pathogens are subject to import and/or quarantine regulations. KCLRF advises prospective depositors concerning the procedures which must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by KCLRF as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on model form BP/8. Notification of furnishing of a sample to a third party is issued on model form BP/14. KCLRF has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, KCLRF will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. KCLRF will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. KCLRF does not routinely ask the depositor for the name and address of his patent agent. KCLRF will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for the conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is required to supply also a copy of the receipt for the previous deposit. All conversions are subject to payment of the normal storage fee levied on Budapest Treaty deposits, regardless of whether any fee had been paid previously in respect of those deposits.

(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, respectively.

2. Furnishing of Samples

(a) Requests for Samples

KCLRF 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, KCLRF will provide the requesting parties with copies of a model request form BP/12 and/or request forms used by individual industrial property offices (where they have been supplied with such forms).

KCLRF furnishes samples on the basis that it is the responsibility of the requesting party to ensure that it complies with any relevant health and safety requirements. When responding to requests from overseas, KCLRF assumes that the requesting party has met the import requirements of its own country.

All samples of cell lines furnished by KCLRF are from batches of its own preparation.

(b) Notification of the Depositor

Depositors are notified in model form BP/14 when samples of their cell lines have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

KCLRF does not list Budapest Treaty deposits in the catalog of its publications.

3. Schedule of Fees

Services	KRW
1. Deposit (including initial viability check, preservation and storage for 30 years)	
- Original deposit (eukaryotic DNA, plasmids)	800.000
- Original deposit (human, animal and plant cell cultures, hybridomas)	900.000
- New deposit	70.000
2. Furnishing of a sample	
- Eukaryotic DNA, plasmids	100.000
- Human, animal and plant cell cultures, hybridomas	150.000
3. Issuance of a viability statement	
- Where a viability test is requested	70.000
- On the basis of the most recent viability test	10.000
4. Issuance of an attestation under Rule 8.2	10.000
5. Communication of information under Rule 7.6	10.000

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

KCLRF does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.

KR - REPUBLIC OF KOREA

KOREAN COLLECTION FOR TYPE CULTURES (KCTC)

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E-mail: patent@kribb.re.kr
Internet: http://kctc.kribb.re.kr/

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal embryos, bacteria (including actinomycetes), bacteria containing plasmids (either in hosts or not in hosts), bacteriophages, RNA, cell cultures (including hybridoma lines), eukaryotic DNA, fungi (including yeasts), human cell cultures, molds, murine embryos, plant cell cultures, plant seeds, protozoa (non-parasitic), and animal and plant viruses, EXCEPT:

- microorganisms having properties which are or may be dangerous to human health and/or the environment;

- microorganisms which require special containment for experimentation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cultures submitted to the KCTC for deposit should be lyophilized. Viruses that cannot be lyophilized and bacteriophages should be frozen. All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

The minimum number of replicates that must be submitted by the depositor is as follows:

Actinomycetes, bacteria, fungi, yeasts, bacteria containing plasmid	10
Plasmids, algae, protozoa, animal and plant cell lines, hybridomas, viruses, bacteriophages	25

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the microorganisms accepted by the KCTC is given below, but depositors should realize that in some cases it may take longer:

Bacteria	7 days (or up to 14 days)
Fungi, yeasts, actinomycetes, algae, protozoa	10 days (or up to 20 days)
Plasmids, bacteria containing plasmids viruses, bacteriophages, animal and plant cell lines, hybridomas	14 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

The KCTC prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples of all batches of his microorganisms prepared by the KCTC.

Whichever method is used for preparing batches of samples for distribution, the KCTC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. Korean is the official language of the KCTC. However, correspondence may also be carried out in English.

Contract. The KCTC does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCTC deposit form the depositor surrenders any right to withdraw his deposit during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact the KCTC in advance for advice about the shipping of their microorganisms. Certain pathogens are subject to import and/or quarantine regulations. The KCTC advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the KCTC as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the KCTC has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of furnishing of a sample to a third party is issued on form BP/14. The KCTC has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KCTC will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KCTC will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KCTC does not routinely ask the depositor for the name and address of his patent agent. The KCTC will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(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, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The KCTC 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 KCTC 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).

The KCTC furnishes samples on the basis that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KCTC assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the KCTC are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

Services	KRW
1. Deposit (including initial viability check, preservation and storage for 30 years)	
- Original deposit (bacteria, fungi, yeasts, bacteriophages, molds, animal and plant viruses, eukaryotic DNA, RNA, plasmids, seeds)	800.000
- Original deposit (human, animal and plant cell cultures, embryos, murine embryos, hybridomas, algae, non-parasitic protozoa)	900.000
- New deposit	70.000
2. Furnishing of a sample	
- Bacteria, fungi, yeasts, bacteriophages, molds, animal and plant viruses, eukaryotic DNA, RNA, plasmids, seeds	100.000
- Human, animal and plant cell cultures, embryos, murine embryos, hybridomas, algae, non-parasitic protozoa	150.000
3. Issuance of a viability statement	
- Where a viability test is requested	70.000
- On the basis of the most recent viability test	10.000
4. Issuance of an attestation under Rule 8.2	10.000
5. Communication of information under Rule 7.6	10.000

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

The KCTC does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.

KR - REPUBLIC OF KOREA

KOREAN CULTURE CENTER OF MICROORGANISMS (KCCM)

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Seoul, 120-091

Telephone: (82-42) 392 09 50
Facsimile: (82-42) 392 28 59
Internet: http://www.kccm.or.kr/

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, actinomycetes, fungi, yeasts, plasmids, bacteria containing plasmids, viruses, bacteriophages, EXCEPT:

- hybridomas, plant tissue cultures, rickettsiae;

- microorganisms liable to require viability testing that the KCCM is technically not able to carry out;

- mixtures of undefined and/or unidentifiable microorganisms.

The KCCM reserves the right to refuse any microorganism for security reasons: specific risks to human beings, animals, plants and the environment. In cases where a microorganism cannot be lyophilized, the KCCM must be consulted in advance about the conditions for acceptance.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Whenever possible, cultures submitted to the KCCM for deposit should be lyophilized. Viruses that cannot be lyophilized and bacteriophages should be frozen. All replicates of the microorganisms to be deposited should be from the same batch of lyophilized or frozen preparations.

Bacteriophage suspensions must contain at least 10^7 plaque forming units per ml.

The minimum number of replicates that must be submitted by the depositor is as follows:

Bacteria, fungi, yeasts, actinomycetes	8
Plasmids, bacteria containing plasmids, viruses, bacteriophages	25

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the microorganisms accepted by the KCCM is given below, but depositors should realize that in some cases it may take longer.

Bacteria	7 days (or up to 14 days)
Fungi, yeasts, actinomycetes	10 days (or up to 20 days)
Plasmids, bacteria containing plasmids, viruses, bacteriophages	14 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

The KCCM prepares its own batches in lyophilized or frozen form at the time of deposit by subculturing the microorganism supplied by the depositor. New batches are prepared from these as necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples of all batches of his microorganisms prepared by the KCCM.

Whichever method is used for preparing batches of samples for distribution, the KCCM nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the KCCM is Korean. However, communications in English are also accepted.

Contract. The KCCM does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the KCCM deposit form, the depositor surrenders any right to withdraw his microorganism during the required storage period.

Import and/or Quarantine Regulations. Overseas depositors must contact the KCCM in advance for advice about the shipping of their microorganisms. Certain pathogens are subject to import and/or quarantine regulations. The KCCM advises prospective depositors of such microorganisms of the procedures that must be followed to obtain the necessary permits.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the equivalent of model form BP/1, which is used by the KCCM as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the KCCM has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of furnishing of a sample to a third party is issued on form BP/14. The KCCM has its own standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the KCCM will telephone the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The KCCM will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The KCCM does not routinely ask the depositor for the name and address of his patent agent. The KCCM will send copies of the receipt and viability statement either to the depositor or to his agent if requested, but not to both.

(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 only if they were originally made for patent purposes. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty, except that the depositor is also required to supply a copy of the receipt for the previous deposit. All conversions are subject to the normal storage fee levied for Budapest Treaty deposits, regardless of whether any fees have been paid previously in respect of those deposits.

(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, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The KCCM 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 KCCM 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).

The KCCM furnishes samples in the belief that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the KCCM assumes that the requesting party has met the import requirements of his own country.

All samples of microorganisms furnished by the KCCM are from batches of its own preparations of the microorganisms.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

Services	KRW
1. Deposit (including initial viability check, preservation and storage for 30 years)	
- Original deposit	800.000
- New deposit	70.000
2. Furnishing of a sample	100.000
3. Issuance of a viability statement	
- Where a viability test is requested	70.000
- On the basis of the most recent viability test	10.000
4. Issuance of an attestation under Rule 8.2	10.000
5. Communication of information under Rule 7.6	10.000

Fees do not include transport costs or bank fees.

4. Guidance for Depositors

The KCCM does not at present produce specific written notes for the guidance of prospective depositors, but is always ready to give advice by telephone or letter.

RU – RUSSIAN FEDERATION

RUSSIAN COLLECTION OF MICROORGANISMS (VKM)

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Internet: http://www.vkm.ru

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts), also if they are carriers of recombinant DNA, are accepted for deposit, to the exclusion of microorganisms that are covered by hazard categories in relation to man, animal or plant health and appear on the lists published by national regulatory authorities.

VKM does not accept for deposit:

- microorganisms whose manipulation needs physical containment levels P2, P3 or P4, as described in “Laboratory Safety Monographs”;

- microorganisms liable to require viability testing that VKM is technically not able to carry out and mixtures of undefined and/or unidentifiable microorganisms.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to VKM for deposit must be in the form of agar stabs or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs or 50 ampoules.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the different kinds of microorganisms accepted for deposit by VKM is given below; however, depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria	7 days (or up to 30 days)
Fungi	7 days (or up to 25 days)
Yeasts	7 days (or up to 14 days)

(iii) Depositor Checks and Renewal of Stocks

VKM prepares its own batches by subculturing material originally supplied by the depositor. As a rule, new batches are prepared from these and by subculturing VKM's own preparations as necessary thereafter for the renewal of diminishing stocks. VKM routinely asks the depositor to check the authenticity of the preparations made by VKM at the time of deposit from material supplied by the depositor. VKM routinely checks newly received deposits for contamination and, if they are found contaminated, it returns them to the depositor.

VKM stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of VKM is Russian. Communications may also be exchanged in English.

Contract. VKM does not enter into a contract with the depositor. Completion by the depositor of form BP/1 is considered sufficient.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by VKM are not subject to import or quarantine regulations. VKM does not advise the depositor on the procedures he must follow to obtain an import permit. To this effect, the depositor must check the applicable national regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor must complete form BP/1 when making the original deposit and when converting a deposit made outside the Budapest Treaty. He must complete form BP/2 when making a new deposit and form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Other than the mandatory "international forms", official notifications are not issued on standard forms.

Unofficial Notifications to the Depositor. VKM does not notify unofficially to the depositor the date of deposit and the accession number nor the result of the viability test before the relevant receipt and viability statement are issued.

Supply of Information to a Patent Agent. VKM does not ask the depositor to supply the name and address of his patent attorney. However, if requested, it will supply copies of the official receipt and viability statement to both the depositor or his attorney.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty, whether or not they were originally deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion of a deposit not previously made for patent purposes are the same as those to be met in respect of an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is not required to meet any requirement additional to those provided for in connection with the original deposit.

2. Furnishing of Samples

(a) Requests for Samples

VKM advises third parties of the correct procedure to follow in order to make a valid request and will supply such parties with copies of model request form BP/12 or request forms used by individual industrial property offices.

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

(b) Notification of the Depositor

VKM does not notify depositors when samples of their microorganism are furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

VKM does not list deposits made under the Budapest Treaty in its published catalog.

3. Schedule of Fees

		USD
(a)	Storage	650
(b)	Issuance of a viability statement	100
(c)	Furnishing of a sample	130

4. Guidance for Depositors

VKM does not at present produce a standard letter or guidance notes for prospective depositors, but would be willing to answer inquiries or questions, preferably by e-mail.

RU – RUSSIAN FEDERATION

NATIONAL RESEARCH CENTER OF ANTIBIOTICS (NRCA)

Nagatinskaya St. 3-a
Moscow 113105

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Facsimile: (7-499) 611 42 38
E-mail: fgup_gnca@mail.ru

l. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts) for essentially medical purposes are accepted for deposit, to the exclusion of microorganisms that cause disease in man and animals and microorganisms that are toxicogenic for plants or require them to be quarantined.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures submitted to NRCA for deposit must be in the form of agar stabs or lyophilized. The minimum number of replicates that must be provided by the depositor is five stabs or 50 ampoules.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the different kinds of microorganisms accepted for deposit by NRCA is given below; however, depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria	15 days (or up to 30 days)
Fungi	10 days (or up to 30 days)
Yeasts	5 days (or up to 30 days)

(iii) Depositor Checks and Renewal of Stocks

NRCA prepares its own batches by subculturing material originally supplied by the depositor. As a rule, new batches are prepared from these and by subculturing NRCA's own preparations as necessary thereafter for the renewal of diminishing stocks. NRCA routinely asks the depositor to check the authenticity of the preparations made by NRCA at the time of deposit from material supplied by the depositor. NRCA routinely checks newly received deposits for contamination and, if they are found contaminated, it returns them to the depositor.

NRCA stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of NRCA is Russian. Communications may also be exchanged in English.

Contract. NRCA does not enter into a contract with the depositor.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted for deposit by NRCA are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor must complete form BP/1 when making the original deposit and when converting a deposit made outside the Budapest Treaty. He must complete form BP/2 when making a new deposit and form BP/7 when communicating a later designation or amendment of a scientific description and/or taxonomic designation.

Official Notifications to the Depositor. Official notifications are not issued on standard forms other than the mandatory "international forms" used for the receipt and viability statement.

Unofficial Notifications to the Depositor. NRCA does not notify unofficially to the depositor the date of deposit and the accession number nor the result of the viability test before the relevant receipt and viability statement are issued.

Supply of Information to a Patent Agent. NRCA does not ask the depositor to supply the name and address of his patent attorney. However, if requested, it will supply copies of the official receipt and viability statement to both the depositor and his attorney.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty when they were originally deposited for patent purposes. 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

When making a new deposit, the depositor is not required to meet any requirement additional to those provided for in connection with the original deposit.

2. Furnishing of Samples

(a) Requests for Samples

NRCA advises third parties of the correct procedure to follow in order to make a valid request.

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

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

NRCA does not list deposits made under the Budapest Treaty in its published catalog.

3. Schedule of Fees

		USD
(a)	Storage for the deposit of a microorganism for 30 years	250
(b)	Issuance of a viability statement	70
(c)	Furnishing of a sample	70
(d)	Communication of information or issuance of an attestation	25
(e)	Other fees (communication, carriage)	according to effective cost

The above amounts do not include mailing charges, which are invoiced separately at cost.

4. Guidance for Depositors

NRCA does not at present produce a standard letter or guidance notes for prospective depositors.

RU – RUSSIAN FEDERATION

RUSSIAN NATIONAL COLLECTION OF INDUSTRIAL MICROORGANISMS (VKPM)

FGUP GosNII Genetika
1 Dorozhny proezd, 1
Moscow 117545

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Facsimile: (7-495) 315 12 10, 315 05 01
E-mail: vkpm@genetika.ru

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria (including actinomycetes) and microscopic fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA), plant cell cultures, animal and human cell cultures (including hybridoma lines), EXCEPT:

- microorganisms having properties which are or may be dangerous to health or the environment;

- microorganisms which need the special containment required for experiments.

Deposits containing recombinant DNA molecules must not require physical containment higher than level P2 as described in the National Institute of Health “Guidelines for Research Involving Recombinant DNA Molecules” (USA).

(b) Technical Requirements and Procedures

(i) Form and Quantity

The VKPM prefers to receive microorganisms submitted for deposit as lyophilized preparations. Where it is undesirable or impossible to supply lyophilized preparations, active culture growing in or on a suitable nutrient medium are acceptable. The minimum number of replicates that must be supplied by the depositor is as follows:

Fungi, yeasts, bacteria, plasmids (in host)	20 lyophilized cultures or 5 agar cultures
Plasmids (purified DNA)	25 vials (100ng each)
Cell lines and hybridomas	25 frozen samples
Bacteriophages	5x0.5ml (free cell lysate) (at least 10^8 pfu/ml)

Bacteriophages and plasmids need to be sent with a suitable host, if such a host is not available in the public collection of the VKPM.

(ii) Time Required for Viability Testing

The average length of time requested for testing the viability of the kinds of microorganisms accepted by the VKPM is given below:

Bacteria, plasmids in hosts	10 days
Fungi, yeasts, bacteriophages, cell lines, hybridomas	20 days

(iii) Depositor Checks and Renewal of Stocks

In case of necessity, the VKPM prepares the additional samples of bacteria, fungi, yeast by subculturing material supplied by the depositor. The depositor is entitled to test for authenticity samples from all batches prepared by the VKPM.

Despite the method used for preparing batches of samples for distribution, the VKPM nevertheless stores a portion of the original material supplied by the depositor, if the culture supplied allows this.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the VKPM is Russian. Communications may also be exchanged in English.

Contract. The VKPM does not enter into any written contract with the depositor defining the liabilities of either party, except the VKPM-BP/1 application form, which depositor is required to complete.

Import and/or Quarantine Regulations. Certain microorganisms accepted for deposit by the VKPM are subject to import regulations. The VKPM may obtain on behalf of the depositor the necessary import permits; however, the depositor must supply information on the non-pathogenicity of the microorganisms.

Microorganisms accepted for deposit by the VKPM must not be subject to quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the VKPM-BP/1 accession form for patent deposits (the equivalent of model form BP/1). In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, the depositor must complete model form BP/7.

Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively. Notification of the furnishing of samples to third parties is issued on model form BP/14. The VKPM uses the standard form in preference for the other official notifications.

Unofficial Notifications to the Depositor. If requested, the VKPM will telephone or telefax 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. The VKPM will similarly communicate the results of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. If requested, the VKPM supplies copies of the receipt and viability statement to the depositor's patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provision of the Budapest Treaty may be converted to Budapest Treaty deposits, provided that they were originally made for patent purposes, or they were confidential for safe-keeping. All converted deposits are subject to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion of a deposit are the same as those to be met by an original deposit made under the Treaty.

(iv) Making a New Deposit

When making a new deposit, the depositor is required to complete model form BP/2 and to send copies of the relevant documents specified in Rule 6.2; otherwise the procedure is similar to that when making an original deposit.

2. Furnishing of Samples

(a) Requests for Samples

The VKPM advises third parties of the correct procedure to follow in order to make a valid request and will supply such parties with copies of model request form BP/12.

(b) Notification of the Depositor

The VKPM notifies the depositor on form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

At the request of the depositor, the VKPM lists Budapest Treaty deposits in its published catalog. All microorganisms that are the subject of granted and published patents of the Russian Federation are listed in the catalog.

3. Schedule of Fees

		EUR
(a)	Storage (30 years):	
	- bacteria (including actinomicetes), fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA)	500
	- cell lines, hybridomas	800
(b)	Issuance of a viability statement:	
	- bacteria (including actinomicetes), fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA)	100
	- cell lines, hybridomas	150
(c)	Furnishing of a sample:	
	- bacteria (including actinomicetes), fungi (including yeasts), bacteriophages, plasmids (in host or as an isolated DNA)	100
	- cell lines, hybridomas	150
(d)	Communication of information under Rule 7.6 or issuance of an attestation under Rule 8.2	30
(e)	Other fees (communication, carriage)	according to real cost

4. Guidance for Depositors

The VKPM produces notes for the guidance of potential depositors.

SK – SLOVAKIA

CULTURE COLLECTION OF YEASTS (CCY)

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Facsimile: (421-2) 59 41 02 22
E-mail: yeasts@ccy.sk
Internet: http://www.ccy.sk/

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Yeasts which can be stored in liquid nitrogen or as active cultures without any substantial change in their properties.

Yeasts whose storage can be accomplished by standard laboratory techniques without appreciable adapting during storage in liquid nitrogen or during storage on agar slant.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The CCY accepts microorganisms for deposit as either lyophilized preparations or active cultures. The minimum number of replicates that must be provided by the depositor when making his deposit is four for lyophilized preparations and two for agar slope cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of yeasts cultures by the CCY is six days, but in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The CCY prepares its own batches of yeasts by subculturing the material supplied by the depositor. New batches are prepared from the depositor's original material for the renewal of stocks. The CCY routinely asks the depositor to check the authenticity of the preparations made by the CCY at the time of deposit from material supplied by the depositor.

The CCY stores original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the CCY is Slovak. Communications are also accepted in English.

Contract. The CCY does not enter into a written contract with the depositor defining the liabilities of either party. However, by signing the CCY deposit form, the depositor surrenders any right to withdraw his microorganisms during the required storage period.

Import and/or Quarantine Regulations. Import and/or quarantine regulations do not apply to the kinds of microorganisms accepted by the CCY for deposit.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The depositor is required to complete the equivalent of model form BP/1, which is used by the CCY as its accession form for Budapest Treaty deposits. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the CCY has received such information, the depositor must complete 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. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on the equivalent of model form BP/8. Notification of the furnishing of samples to third parties is issued on model form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The CCY does not telephone or telex the date of deposit, accession number or results of the viability test in advance of the relevant official notifications.

Supply of Information to a Patent Agent. The CCY does not routinely ask the depositor for the name and address of his patent agent. However, if requested, the CCY will send copies of the receipt and viability statement to both the depositor and his 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 deposited for patent purposes. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fee had previously been paid in respect of those deposits.

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 CCY 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 CCY 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).

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

All samples furnished by the CCY are from batches of its own preparations.

(b) Notification of the Depositor

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

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

		EUR
(a)	Storage	664
(b)	Issuance of a viability statement	33
(c)	Furnishing of a sample	40

4. Guidance for Depositors

The CCY does not produce a standard letter or guidance notes for prospective depositors.

ES - SPAIN

BANCO ESPAÑOL DE ALGAS (BEA)

Marine Biotechnology Center
University of Las Palmas, Gran Canaria
Muelle de Taliarte s/n
35214 Telde
Las Palmas

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Facsimile: (34-928) 13 28 30
E-mail: info@marinebiotechnology.org
Internet: http://bea.marinebiotechnology.org

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Freshwater, marine, hypersaline and soil microalgae and cyanobacteria and marine macroalgae which can be preserved by means of subcultures without change of their properties.

BEA will shortly accept microalgae, cyanobacteria and macroalgae (tissue or spores) which can be preserved by means of cryopreservation.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Organisms must be submitted for deposit as liquid cultures or in agar. The minimum number of identical copies that must be supplied for deposit is five. The cultures of microalgae and cyanobacteria shall contain a minimum of 10^2 to 10^4 cells per millilitre, depending on the species and three plants in the case of macroalgae.

(ii) Time Required for Viability Testing

The average time required for analyzing viability of microalgae, cynobacteria and macroalgae accepted by the BEA is seven days, but depositors must take into account that in some cases analysis can take up to 35 days.

(iii) Depositor Checks and Renewal of Stocks

The BEA will prepare its own lots of organisms at the time of deposit, and will make a subculture of the material supplied by the depositor. The new lots are prepared according to the needs for renewal of lots which have been exhausted. Where the original material has been cryopreserved, the lots will be renewed by means of a subculture thereof or by requesting a new deposit from the depositor. The depositor will be required to analyze the authenticity of the samples of the first lot (not of subsequent lots) of the organisms prepared by the BEA. Except for the cryopreserved material, the BEA shall not store the material supplied by the depositor.

(c) Administrative Requirements and Procedure

(i) General

Language. The official languages of the BEA are Spanish and English.

Contract. The depositor will be required to complete the BEA application form, which constitutes a contract by means of which the depositor agrees to:

- supply all the information requested by the BEA;

- pay all the requisite fees;

- compensate the BEA for any claim that may arise as a result of the dispatch of samples, unless such claims are due to negligence on the part of the BEA;

- not withdraw his deposit during the period required for its due storage;

- authorize the BEA to supply samples, in accordance with the patent procedure requirements in force at that time.

Where an organism has been accepted for deposit, the BEA will notify the depositor accordingly and will remind him that he is subject to the terms and conditions of the contract.

Import and/or Quarantine Regulations. The type of organisms accepted by the BEA is not subject to import and/or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors must complete the application and access forms used by the BEA for deposits, according to the Budapest Treaty, equivalent to model BP/1.

Official Notifications to the Depositor. Receipt and declaration of viability are published in the compulsory *international models* BP/4 and BP/9 respectively. The certificate of receipt of information or a subsequent amendment of the scientific description and/or proposal for taxonomic designation is published in model BP/8. Notification of submission of samples to third parties is published in model BP/14. For other official notifications standard models will not be used.

Unofficial Notifications to the Depositor. If requested, the BEA will communicate by telephone, fax or electronic mail the date of deposit and entry number after the organism has been received, but before the official receipt is published. However, the depositor will be informed that the information is provisional and that it depends on the result of the viability tests. The BEA will also communicate the result of the viability analysis before the certificate therefor is published.

Supply of Information to a Patent Agent. As a matter of course, the BEA will ask the depositor for the name and address of his patent agent. If required, the BEA will supply copies of the receipt of the samples, the state of viability and any other information to the depositor and to his patent agent.

(iii) Converting a Previous Deposit

The BEA does not hold deposits made for patent purposes beyond what is stipulated in the Budapest Treaty.

(iv) Making a New Deposit

When the depositor makes a new deposit, he will be asked to complete the model form BP/2 and to attach the most relevant documents required by Rule 6.2. The receipt and certificate of viability for a new deposit will be published as a matter of course in the international models BP/5 and BP/9.

2. Furnishing of Samples

(a) Requests for Samples

The BEA will inform third parties of the procedures for the correct filing of applications. In the case of requests where supporting authorization is required, the BEA will provide the requesting parties with the application forms used by industrial property offices.

Where requests are received from abroad, the BEA assumes that the depositor is familiar with the requirements for import from his country.

All the samples sent by the BEA come from lots containing its own preparations.

(b) Notification of the Depositor

The depositor will be informed, by letter and electronic mail, when samples of his organisms have been sent to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The BEA will publish the lists of deposits under the Budapest Treaty in its catalogues only with the written authorization of the depositor.

3. Schedule of Fees

		Euros
(a)	Storage:	
	- Cryopreserved strains	950
	- Other methods	3.000
(b)	Publication of viability status	100
(c)	Supply of samples	60 (plus dispatch cost)
(d)	Communication of information	50

4. Guidance for Depositors

No provision.

ES - SPAIN

COLECCIÓN ESPAÑOLA DE CULTIVOS TIPO (CECT)

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Facsimile: (34-963) 54 31 87
E-mail: patents@cect.org
Internet: http://www.cect.org

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria, archaea, filamentous fungi, yeast and plasmids, which may be preserved, without any significant alteration of their properties, by freezing or freeze-drying, and which belong to a risk group up to 3(*) according to the Spanish legislation (*Guía Técnica para la Evaluación y Prevención de Riesgos relacionados con la Exposición a Agentes Biológicos del Instituto Nacional de Seguridad e Higiene en el Trabajo, RD 664/1997 de 12 Mayo*). Microorganisms belonging to risk group 3(*) (equivalent to risk group 3(**) in Directive 2000/54/EC), are those that may present a limited risk of infection for workers because they are not normally infectious by the airborne route.

The CECT does not accept the following biological material for deposit: algae and cyanobacteria, embryos, protozoa, animal cell lines, plant cell lines, mycoplasms, plant seeds, viruses and bacteriophages.

Notwithstanding the foregoing, the CECT reserves the rights to reject or accept for deposit any material that, in the opinion of the Director, represents a risk that is either unacceptable or too difficult to handle.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria and fungi (including those containing plasmids) are accepted in freeze-dried form in ampoules or in the form of active cultures in agar solution. The depositor should send the CECT five ampoules or agar samples of each strain.

(ii) Time Required for Viability Testing

On average, the time required for testing the viability of bacterial samples is three days (or up to 14 days), and for fungus strains six days (or up to 30 days). The depositor has to take into account that, in certain cases, viability testing can take a great deal of time, as indicated by the bracketed figures.

(iii) Depositor Checks and Renewal of Stocks

The CECT prepares its frozen or freeze-dried batches by subculturing the materials supplied by the depositor. While the batches are being completed, further batches are prepared on the basis of frozen or freeze-dried samples from the first batch prepared. Whatever the method used for the preparation of batches or samples for distribution, the CECT freeze-dries, freezes and retains a portion of the original material supplied by the depositor. The depositor is requested to prove the authenticity of all the freeze-dried and frozen samples prepared by the CECT.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of the CECT are Spanish and English.

Contract. The application to the CECT that the depositor has to complete is a contract under which the depositor undertakes:

- to supply all the necessary information requested by the CECT;

- to pay all the necessary fees;

- to indemnify the CECT against any claim that may be made on it as a result of the sending of samples, except where the claims are due to negligence on the part of the CECT;

- not to withdraw the deposit during the time required for its period of storage;

- to authorize the CECT to supply samples in accordance with the requirements of the patent procedure applicable at the time.

Import and/or Quarantine Regulations. The packaging and dispatch of CECT cultures is done in accordance with the laws of the Convention of the Universal Postal Union. Depositors from abroad apply to the CECT in advance for information on the correct procedure for the dispatch of samples. Spain does not allow infectious substances to be sent by air mail, with the exception of samples originating in the United Kingdom and sent direct to the CECT. The samples may be sent direct to the CECT from other countries as freight in accordance with IATA rules.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors have to complete the application and accession forms used by the CECT for deposits under the Budapest Treaty, which are equivalent to model form BP/1.

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 form BP/8. Notification of the furnishing of samples to third parties is

issued on model form BP/14. Individual correspondence is used rather than standard forms for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CECT communicates the date of deposit and the accession number by telephone after the microorganism has been received but before the official receipt is issued. In that case however the depositor is informed that the information is provisional and subject to the outcome of the viability tests. The CECT likewise communicates the finding of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The CECT routinely asks the depositor for the name and address of his patent agent and, if so requested, supplies copies of the receipt, the viability statement and any other information to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to deposits under the Budapest Treaty, whether or not they were originally made for patent purposes. Any deposit previously made free of charge is subject, on conversion, to the payment of the storage fee specified in this technical memorandum, and also to whatever fees may be payable for successive updating. With the above exceptions, the administrative requirements for conversion are the same as those to be met for an original deposit effected under the Treaty. The date of deposit for such samples will then be that of the conversion.

(iv) Making a New Deposit

The depositor will be 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 the 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

The CECT advises third parties of the correct procedures to be followed in making a valid request. In the case of requests requiring proof of entitlement, the CECT provides requesters with copies of model request form BP/12. When requests are received from abroad, the CECT presumes that the individual concerned is familiar with his country’s import requirements.

All samples of bacteria and fungi furnished by the CECT are taken from batches prepared by itself.

(b) Notification of the Depositor

The depositor is informed on model form BP/14 when samples of his microorganisms have been sent to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The CECT issues lists of deposits under the Budapest Treaty in its catalogs only with the express written consent of the depositor.

3. Schedule of Fees

		EUR
Storage of:		
(a)	Original deposits	600
(b)	New deposits	80
(c)	Extension of the duration of the storage beyond the period provided for in Rule 9 of the Regulations under the Budapest Treaty, per year	30
Issuance of a viability statement:		
(a)	Where a viability test is requested	110
(b)	On the basis of the most recent viability test	45
Furnishing of samples		110
Communication of information		110

4. Guidance for Depositors

For the moment, the CECT does not publish specific information for the guidance of prospective depositors, but is always willing to provide information by telephone or correspondence.

GB – UNITED KINGDOM

CABI BIOSCIENCE, UK CENTRE (IMI)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Nematodes, fungal isolates (including yeasts) and bacteria (including actinomycetes), other than known human and animal pathogens that can be preserved without significant change to their properties by methods of preservation in use. Organisms up to and including ACDP Category 2 deposits are accepted by the Collection.

Notwithstanding the foregoing, IMI reserves the right to refuse to accept any material for deposit which in the opinion of the Curator presents an unacceptable risk or is technically unsuitable to handle. IMI will accept organisms which do not significantly change after long-term nitrogen freezing or freeze-drying. A statement regarding potential pathogenicity and storage conditions is required when a deposit is made.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IMI prefers fungi to be submitted as healthy, clean, sporing cultures on agar slants suitable for preparing suspensions for freeze-drying and liquid nitrogen storage. The minimum number of replicates to be supplied by the depositor when making his deposit should be six.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of fungi accepted by the IMI is 14 days, but depositors should be aware that in some cases viability testing may take as long as 21 days.

(iii) Depositor Checks and Renewal of Stocks

Depending on the number and conditions of the cultures sent for deposit, the IMI either prepares frozen and lyophilized batches direct from the depositor's material or from subcultures derived from it. New batches are prepared as necessary for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the IMI.

Whichever method is used for preparing batches of samples for distribution, the IMI nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The IMI application form (CC PF1), which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the IMI;

- to replace the microorganism at his expense if the IMI is no longer able to furnish samples of it;

- to pay all necessary fees;

- to indemnify the IMI 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 the IMI;

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

- to authorize the IMI to furnish samples according to the appropriate patent requirements.

After the deposit and acceptance procedure is complete, the depositor is sent a standard letter (form CC PF3) reminding him of his contractual obligations.

Import and/or Quarantine Regulations. Plant pathogenic fungi not indigenous to the United Kingdom are subject to import regulations. The IMI holds a permit for the import of such organisms and will advise the depositor of any necessary procedures.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the IMI application form CC PF1 referred to in (i), above, depositors are required to complete the IMI accession form (CC PF2) for Budapest Treaty deposits. The IMI 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 the IMI has received such information.

Official Notifications to the Depositor. The receipt is issued on form CC PF3, which is the IMI version of the mandatory "international form" BP/4. The viability statement is issued on form CC PF5, which is the IMI version of the mandatory "international form" BP/9. A standard form (CC PF4) is used for notifying the depositor of refusal to accept a microorganism for deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. The IMI acknowledges delivery of cultures, but this does not constitute acceptance. The IMI does not assign an accession number to the microorganism until it has been shown to be viable. After a positive result of the viability test has been obtained, the IMI will, if requested, telephone or telex this information along with the accession number before the issue of the official documentation.

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

(iii) Converting a Previous Deposit

The IMI does not permit the conversion of deposits not originally made for patent purposes to Budapest Treaty deposits. Deposits previously made for patent purposes outside the provisions of the Treaty may be converted provided that the depositor supplies the IMI with a new sample of the deposited microorganism and checks the authenticity of all batches prepared from it. The administrative requirements for conversion are similar to those to be met in respect of an original deposit made under the Treaty. All conversions are subject to the storage fee normally levied for Budapest Treaty deposits, regardless of whether any fees had been paid previously in respect of those deposits.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit and to send with it copies of the relevant documents required by Rule 6.2. The receipt and viability statement for a new deposit are issued on forms CC PF3 and CC PF5, which are the IMI versions of mandatory "international forms" BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The IMI advises third parties of the correct procedures to follow in order to make a valid request. However, in the case of requests requiring proof of entitlement, the IMI does not supply copies of request forms; these must be obtained from the relevant industrial property office.

Notwithstanding any entitlement to receive samples under patent regulations, the IMI will furnish samples of plant pathogens that require a permit to be worked with in the United Kingdom only to third parties in the United Kingdom who have such a permit. The IMI will supply requesting parties who do not hold a permit with the necessary application form and will furnish samples when the requesting party confirms that he has obtained a permit. When responding to requests from overseas (other than from the United States of America), the IMI assumes that the requesting party has met the import requirements of his own country. In the case of requests from the United States of America, samples of plant pathogens are sent via the United States Department of Agriculture quarantine authority.

All samples furnished by the IMI are from batches of its own preparations which, whenever possible, have been made direct (i.e., without subculture) from material supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

		GBP
(a)	Storage of each strain	600
(b)	Issuance of a viability statement	80
(c)	Furnishing of a sample	55
(d)	Issuance of an attestation	25
(e)	Communication of information	25

The fees paid in the United Kingdom are subject to Value Added Tax at the current rate.

4. Guidance for Depositors

The IMI makes available detailed notes for the guidance of depositors.

GB – UNITED KINGDOM

CULTURE COLLECTION OF ALGAE AND PROTOZOA (CCAP)

SAMS Research Services Ltd.
Scottish Marine Institute
Oban, Argyll PA37 1QA
Scotland

Telephone: (44-1631) 559 000 or 1631 559 268 (direct line)
Facsimile: (44-1631) 559 001
E-mail: ccap@sams.ac.uk
Internet: www.ccap.ac.uk

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

- Freshwater and terrestrial algae and free living protozoa (Institute of Freshwater Ecology), and

- Marine algae, other than large seaweeds (Dunstaffnage Marine Laboratory).

(b) Technical Requirements and Procedures

(i) Form and Quantity

Microorganisms should be submitted for deposit as liquid or agar slope cultures. The minimum number of replicates that must be provided by the depositor when making his deposit is six. Algal cultures must contain a minimum of 10^2 to 10^4 cell/ml, depending on the species, and three plants in the case of seaweeds. The minimum number of cells in cultures of protozoa must be decided by negotiation.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of algae and protozoa accepted by the CCAP is seven days, but depositors should realize that in some cases viability testing may take as long as 35 days.

(iii) Depositor Checks and Renewal of Stocks

Except where the depositor's original material is preserved by freezing, as is the case with some algae, the CCAP prepares its own batches of the microorganism 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. In cases where original material has been cryopreserved, stocks are renewed by subculturing these or by asking the depositor for a new deposit. The depositor is required to test for authenticity samples from the first (but not any subsequent) batch of his microorganism prepared by the CCAP.

Except for cryopreserved strains, the CCAP does not store original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The CCAP application form, which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the CCAP;

- to replace the microorganism at his expense if the CCAP is no longer able to furnish samples of it;

- to pay all necessary fees;

- to indemnify the CCAP 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 the CCAP;

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

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

When a microorganism has been accepted for deposit, the CCAP notifies the depositor and reminds him that he is bound by the terms and conditions of its contract.

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the CCAP are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the CCAP application form referred to in (i), above, depositors are required to complete the CCAP accession form for patent deposits. The CCAP 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 the CCAP has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively. The CCAP has its own standard forms notifying the depositor of acceptance of a microorganism (see (i), above) or of refusal to accept a microorganism, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the CCAP will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The CCAP will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The CCAP routinely asks the depositor for the name and address of his patent agent. If requested, the CCAP will supply copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The CCAP does not have any deposits made for patent purposes outside the provisions of the Budapest Treaty and does not consider Rule 6.4(d) applicable in other cases.

(iv) Making a New Deposit

The CCAP does not require the depositor to complete a standard form when making a new deposit, but he must supply copies of the relevant documents and declarations 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, respectively.

2. Furnishing of Samples

(a) Requests for Samples

The CCAP 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 CCAP 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).

The CCAP furnishes samples in the belief that it is the responsibility of the requesting party to ensure that he complies with any relevant health and safety requirements. When responding to requests from overseas, the CCAP assumes that the requesting party has met the import requirements of his own country.

Except where material originally supplied by the depositor has been cryopreserved, as is the case with some algae, samples of microorganisms furnished by the CCAP are from batches of its own preparations of the microorganism.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

		GBP
(a)	Storage:	
	- cryopreserved strains	600
	- other methods of maintenance fee	case-by-case basis
(b)	Issuance of a viability statement	50
(c)	Furnishing of a sample (plus expedition cost)	40
(d)	Issuance of an attestation	20

The fees are subject to Value Added Tax where applicable.

4. Guidance for Depositors

The CCAP does not yet have notes available for the guidance of prospective depositors.

GB – UNITED KINGDOM

EUROPEAN COLLECTION OF CELL CULTURES (ECACC)

Culture Collections
Public Health England
Porton Down
Salisbury, Wiltshire SP4 0JG

Telephone: (44-1980) 61 25 12
Facsimile: (44-1980) 61 13 15
E-mail: culturecollections@phe.gov.uk
Internet: http://www.phe-culturecollections.org.uk

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Animal cell lines, human cell lines, genetically modified cell lines, and hybridomas that can be preserved without significant change to or loss of their properties by freezing and long-term storage. Viruses capable of assay in cell culture, eukaryotic and viral recombinant DNA as naked DNA or cloned in a host organism.

Organisms up to and including Advisory Committee on Dangerous Pathogens (ACDP) Category 4 and Advisory Committee on Genetic Modification (ACGM) Activity Class 4 are accepted for deposit.

Note that:

- No patent deposit should be sent to ECACC without a Biohazard Risk Assessment having been first received and reviewed by ECACC. Following favorable review of a Risk Assessment the customer will be invited to ship the material for deposit. Risk Assessment forms can be accessed from the ECACC website.

- Processing of material that requires handling at Containment Level 4 may require a longer period to completion depending on the availability of high containment facilities. The price charged for such high containment processing is necessarily higher to reflect the increased cost to ECACC.

- Genetically modified organisms evaluated as Activity Class 2 to 4 cannot be accepted until ECACC has obtained authorization from the UK Health and Safety Executive (HSE). ECACC has to pay a fee for this authorization and this will be charged to the customer (see below). A time of several weeks should be allowed for this approval process.

- ECACC reserves the right to refuse to accept any material for deposit that, in the opinion of the curator, presents an unacceptable risk or is technically unsuitable to handle.

ECACC will only accept organisms that do not significantly change after long-term storage at the appropriate temperature.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Animal Cell Cultures. Material submitted to the ECACC for deposit must be in the form of frozen cultures. The ECACC may refuse deposits which have not been packed in sufficient dry ice to keep them frozen during transit. The minimum number of replicates that must be provided by the depositor when making his deposit is 12. All animal cell cultures must contain at least 4×10^6 cells/ampoule. Any requests to deposit human embryo stem cell lines will be subject to current UK regulations and guidelines.

Recombinant DNA. Deposits are accepted in the form of frozen ampoules of a host organism containing plasmid or phage or naked plasmid or phage DNA. Plasmids and bacteriophage are accepted on condition that they can be preserved without significant change or loss of properties by freezing and long term storage. The minimum number of ampoules (all prepared at the same time) that must be provided by the depositor is 12, containing a culturable quantity of organisms which must be replaced, if required. Naked DNA should be deposited frozen in an appropriate solution e.g. 10mM, 1mM EDTA (pH7.5) in quantities suitable for electrophoretic analysis.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the ECACC is given below, but depositors should realize that, in some cases, viability testing may take longer. Customers will be advised of this prior to deposit being accepted.

Viruses	21 days (or up to 28 days)
Animal cell cultures	14 days (or up to 21 days)
Recombinant DNA	14 days

(iii) Depositor Checks and Renewal of Stocks

The ECACC generally does not prepare its own batches of the deposited organisms, and when stocks are depleted by the furnishing of samples, the depositor will be asked to make a new deposit. The depositor is asked to check for authenticity samples of batches prepared by the ECACC.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The ECACC application form, which the depositor is required to complete, binds the depositor:

- to provide material only in the required form and quantity;

- to provide a biohazard statement;

- to pay all necessary fees including all charges for the transportation of deposits to the ECACC;

- to observe the terms and conditions of the Budapest Treaty;

- to accept the terms and conditions of deposit in the ECACC.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. The customer will be advised to obtain the regulatory documentation once ECACC has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the ECACC application form referred to in (i), above, the depositor must complete an ECACC deposit form and biohazard statement. Different sets of forms are used for different kinds of microorganisms and the depositor should ask the ECACC for the set of forms appropriate to the microorganism he wishes to deposit.

At least 48 hours before the microorganism is dispatched the ECACC must be informed of the number of ampoules being sent, the method of transportation and the estimated time of arrival. If dispatch is by air, the ECACC must be told the flight number and destination, waybill number and handling agent for delivery.

The ECACC 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 the ECACC has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the ECACC will telephone or fax the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. The ECACC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and his 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 deposited for patent purposes. However, any deposits previously made free of charge are subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit, except that requirements relating to shipping procedures do not, of course, apply.

(iv) Making a New Deposit

The depositor is required to complete the ECACC deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform with the procedures mentioned previously in respect of shipping requirements.

2. Furnishing of Samples

(a) Requests for Samples

The ECACC does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the ECACC will withhold samples of potentially hazardous microorganisms until it has confirmed that the requesting party has the appropriate containment facilities to handle such organisms. When responding to requests from overseas, the ECACC assumes that the requesting party has met the import requirements of his own country, and the customer is responsible for provision of the relevant documentation to do so.

Samples furnished by the ECACC are usually from preparations supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

		GBP
1.	Cell lines	
(a)	Deposit and storage, including certification and viability statement	950
(b)	Issuance of a (new or updated) viability statement	80
2.	Viruses	
(a)	Deposit and storage, including certification and viability statement	1,100
(b)	Issuance of a (new or updated) viability statement	150
3.	Eukaryotic and viral recombinant DNA either as naked DNA or cloned into a host organism	
(a)	Deposit and storage, including certification and viability statement	600
(b)	Issuance of a new (or updated) viability statement	80
4.	General	
(a)	Organisms requiring Level 4 containment	Price on application
(b)	ACGM 2 to 4 assessment and HSE registration charge	Price on application
(c)	Furnishing of a sample (excluding carriage costs)	100
(d)	Issuance of (new or amended) certification	50
(e)	Administration fee for amendments	50

Fees plus VAT, where applicable, are payable to the Health Protection Agency – Porton Down.

4. Guidance for Depositors

Guidance for depositors is provided on the ECACC application form.

GB - UNITED KINGDOM

NATIONAL COLLECTION OF TYPE CULTURES (NCTC)

Culture Collections
Public Health England
Porton Down
Salisbury, Wiltshire SP4 0JG

Telephone: (44-1980) 61 25 12
Facsimile: (44-1980) 61 13 15
E-mail: culturecollections@phe.gov.uk
Internet: http://www.phe-culturecollections.org.uk

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Bacteria that can be preserved without significant change to their properties by freeze-drying and which are pathogenic to man and/or animals.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of bacteria are accepted by the NCTC either lyophilized or in agar slabs. The depositor is required to provide only one culture when making his deposit.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of bacteria accepted by the NCTC is four days, but depositors should realize that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The NCTC prepares its own lyophilized batches of bacteria 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. The depositor is required to test for authenticity samples of the first batch of his microorganism (but not subsequent batches) prepared by the NCTC.

The NCTC does not store material originally supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The NCTC application form, which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the NCTC;

- to replace the microorganism at his expense if the NCTC is no longer able to furnish samples of it;

- to pay all necessary fees;

- to indemnify the Health Protection Agency or the NCTC against any claims which may be brought against them as a consequence of the release of samples, unless such claims result from negligence on the part of the NCTC;

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

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

A supplement to the NCTC application form requires the depositor to state whether he is acting on his own behalf or on behalf of the Organisation employing him.

Import and/or Quarantine Regulations. Animal pathogenic bacteria being sent from overseas are subject to import regulations (Importation of Animal Pathogens Order 1980; Statutory Instrument 1980 No. 1212). The HPA Centre for Infections, of which the NCTC is part, has a general license to cover the import of animal pathogens, but the depositor is required to give the NCTC his name and address and the scientific name of the organism to be deposited. Further information about the import of animal pathogens may be obtained from The Pathogens Licensing Team, DEFRA, Area 607, 1A Page Street, London SW1P 4PQ, United Kingdom.

The kinds of microorganisms accepted for deposit by the NCTC are not subject to quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NCTC application form referred to in (i), above, depositors are required to complete the NCTC accession form for Budapest Treaty deposits. The NCTC 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 the NCTC has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively. Letters, rather than standard forms, are used for all other official notifications.

Unofficial Notifications to the Depositor. The NCTC does not telephone or fax the date of deposit, accession number or result of the viability test in advance of the relevant official notifications.

Supply of Information to a Patent Agent. The NCTC does not routinely ask the depositor for the name and address of his patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and his patent agent.

(iii) Converting a Previous Deposit

The NCTC does not accept deposits for patent purposes outside the provisions of the Budapest Treaty, nor does it permit the conversion of deposits previously made for scientific purposes to Budapest Treaty deposits. In the latter case, the NCTC requires the same organism to be redeposited under the terms of the Treaty. Thus Rule 6.4(d) does not apply.

(iv) Making a New Deposit

The depositor is required to complete model form BP/2 when making a new deposit, and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The NCTC 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 NCTC 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 to receive samples under patent regulations, in the case of potentially dangerous microorganisms of ACDP Hazard Group 3, the requesting party must previously have been authorized by his head of department as being competent to request such organisms. This authorization, which must be made out on a special NCTC form, is required only once in respect of any one individual. When responding to requests from overseas, the NCTC assumes that the requesting party has met the import requirements of his own country.

The NCTC reserves the right to withhold the supply of samples to parties having outstanding debts in respect of any previous transactions with the NCTC until such debts have been settled.

All samples furnished by the NCTC are from batches of its own preparations.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCTC does not list deposits made under the Budapest Treaty in its published catalog.

3. Schedule of Fees

		GBP
(a)	Storage	450
(b)	Issuance of a viability statement	60
(c)	Furnishing of a sample (plus expedition cost)	45
(d)	30-year declaration for already deposited collection strains	50

Item (a) refers to Hazard Group 2 (fees for Hazard Group 3 increase by 50%). For items (c) and (d) the fees are subject to Value Added Tax at the current rate where appropriate.

4. Guidance for Depositors

The NCTC makes available to prospective depositors copies of *Industrial Property*, 1982, pp. 219 and 220, which contains information furnished by the United Kingdom Government in respect of the NCTC immediately prior to its acquisition of IDA status.

GB – UNITED KINGDOM

NATIONAL COLLECTION OF YEAST CULTURES (NCYC)

Institute of Food Research
Norwich Research Park
Colney
Norwich NR4 7UA

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Facsimile: (44 (0) 1603) 458 414
E-mail: ncyc@ncyc.co.uk
Internet: http://www.ncyc.co.uk

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Yeasts, other than known pathogens, that can be preserved without significant change to their properties by freeze drying or storage in liquid nitrogen.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of yeasts are accepted by the NCYC either lyophilized or on agar slopes. The minimum number of replicates that must be provided by the depositor when making his deposit is two for lyophilized preparations and two for agar slope cultures.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of yeasts accepted by the NCYC is five days, but depositors should be aware that in some cases viability testing may take as long as 14 days.

(iii) Depositor Checks and Renewal of Stocks

The NCYC prepares its own lyophilized batches of the microorganism at the time of deposit, by subculturing material supplied by the depositor. New batches are prepared from these whenever necessary thereafter for the renewal of diminishing stocks. The depositor is required to test for authenticity samples from all batches of his microorganism prepared by the NCYC.

The NCYC stores material originally supplied by the depositor only until its own procedures have been completed.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The NCYC application form, which the depositor is required to complete, constitutes a contract by which he is bound:

- to provide all necessary information requested by the NCYC;

- to replace the microorganism at his expense if the NCYC is no longer able to furnish samples of it;

- to pay all necessary fees;

- to indemnify the NCYC 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 the NCYC;

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

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

Import and/or Quarantine Regulations. The kinds of microorganisms accepted by the NCYC are not subject to import or quarantine regulations.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NCYC application form referred to in (i), above, depositors are required to complete the NCYC accession form for patent deposits. The NCYC 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 the NCYC has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively. A standard form is used for notifying the depositor of refusal to accept a microorganism for deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NCYC will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The NCYC will similarly communicate the result of the viability test before the viability statement is issued.

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

(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 deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fees normally levied for Budapest Treaty deposits. 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 NCYC does not require the depositor to complete a standard form when making a new deposit, but he must supply copies of the relevant documents and declarations 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, respectively.

2. Furnishing of Samples

(a) Requests for Samples

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

All samples furnished by the NCYC are from batches of its own preparations.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

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

3. Schedule of Fees

		GBP
(a)	Storage	440
(b)	Issuance of a viability statement, where a fee may be charged	100
(c)	Furnishing of a sample (plus expedition and packaging costs for destinations outside the United Kingdom)	82

Fees paid within the United Kingdom are subject to Value Added Tax at the current rate.

4. Guidance for Depositors

The NCYC does not produce a standard letter or guidance notes for prospective depositors.

GB - UNITED KINGDOM

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

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

NCIMB accepts bacteria (including actinomycetes), yeasts 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.

A 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 - 20^{o} 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

Bacteria and yeasts (including those containing plasmids) are accepted in any form; agar plate cultures should be avoided where possible, as these are too easily damaged in transit. Bacteriophages should be supplied as cell-free lysates along with a suitable host. NCIMB prefers to receive sufficient lysate for direct freezing and distribution but, where this is not possible, smaller volumes from which NCIMB may produce its own lysates are acceptable (see below).

Naked plasmids should be submitted as DNA solutions.

Seeds may be deposited either:

- 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

- 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 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.

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

Bacteria and yeasts	2
Bacteriophages (at least 10^8 pfu/ml)	2 x 0.5 ml or 1 x 10 ml of cell-free lysate
Plasmids (DNA at least 20 mcg/ml)	1 x 10 ml
Seeds	250 seeds are required. It is in the depositor's responsibility to ensure that there are enough seeds to make the deposit available throughout the life of the deposit. The IBPGR recommends a minimum of 4,000 for long-term storage and the United States Patent and Trademark Office requires a minimum of 2,500.
Plant cell tissue cultures	
- Frozen	25 ampoules of appropriate cultures. NB: frozen shoot tips should, preferably, have 100 surviving apeces
- Active	3 cultures of suspension cultures or 5 cultures of undifferentiated cell or tissue cultures or 10 in vitro plantlets or shoots etc (eg. Shooty structures)

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of biological material accepted by NCIMB is given below; however depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria and yeasts	3 days (or up to 14 days)
Bacteriophages	3 days (or up to 5 days)
Plasmids[1]	5 days (longer in slow growing hosts)
Seeds[2]	depends entirely on the kind of seed
Plant cell tissue cultures	depends entire on type or culture/material deposited

[1] For plasmids, 'viability' testing consists of inserting the plasmid into a host. If the host is transformed, the 'viability test' is regarded as positive.

[2] For seeds, 'viability' testing means testing for germination.

(iii) Depositor Checks and Renewal of Stocks

NCIMB prepares its own 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 its own 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 dried batches of seeds direct 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 he is 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 his 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 and reminds him that he is 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 license to be worked with in Scotland, and 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 by NCIMB of the material submitted. Further information may be obtained from the Department of Agriculture and Fisheries for Scotland, Agricultural Scientific Services, East Craigs, Edinburgh EH12 8NJ, Scotland, United Kingdom.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as NCIMB application form referred to in (i), above, depositors are required to complete the NCIMB accession form for patent deposits. 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.

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 (see (i), above) or of refusal to accept a microorganism, and for notifying the depositor of the inability of NCIMB to furnish samples. Individual letters, rather than standard forms, are used for other official notifications.

Unofficial Notifications to the Depositor. If requested, NCIMB will telephone, fax or email the date of deposit and the accession number after the microorganism has been received, but before the official receipt is issued. However, the depositor is informed that such information 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 his patent agent and, if requested, will supply copies of the receipt, viability statement and any other information to both the depositor and his 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 his right to be notified of the release of samples. If the depositor is unwilling to accede to this request, he 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. Also, 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 his own country.

All samples of bacteria furnished by NCIMB are from batches of its own preparations; samples of bacteriophages may be from its own preparations or from material supplied by the depositor; samples of plasmids and seeds are from material 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

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

3. Schedule of Fees

	GBP
Storage of bacteria, actinomycetes, yeasts, bacteriophages, plasmids and seeds	675
Storage of plant cell tissue culture i) frozen	1.000
ii) active	1.500

Furnishing of a sample in accordance with Rule 11.2 (i)	95 (plus carriage)
Furnishing of a sample in accordance with Rule 11.2 (ii) and 11.3	150 (plus carriage)
Issuance of a viability statement	100

Fees are payable to NCIMB Ltd. (where applicable all fees are subject to Value Added Tax at the current rate).

Where statutory provisions require NCIMB to obtain a license or certificate prior to accepting a deposit of seeds, the actual cost of obtaining any such license or certificate will be charged to the depositor.

4. Guidance for Depositors

NCIMB publishes a leaflet containing guidance notes for prospective depositors.

GB – UNITED KINGDOM

NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL (NIBSC)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Animal cell lines, human cell lines and genetically modified cell lines that can be preserved without significant change to or loss of their properties from freezing and/or long-term storage.

Note that:

- No patent deposit should be sent to NIBSC without a Biohazard Risk Assessment having been first received and reviewed by NIBSC. For genetically modified cell lines this will include a formal review by the NIBSC Biological Safety Committee. Following a favourable review of the Risk Assessment the customer will be invited to ship the material for deposit. Risk Assessment forms can be accessed from the NIBSC website.

- Processing of material that requires handling at Containment Levels higher than Level 2 may require a longer period to completion depending on the availability of high containment facilities. The price charged for such high containment processing is necessarily higher to reflect the increased cost to NIBSC.

- NIBSC reserves the right to refuse to accept any material for deposit that, in its opinion, presents an unacceptable risk or is technically unsuitable to handle. NIBSC will only accept organisms that do not significantly change after long-term storage at the appropriate storage temperature.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Human Cell Cultures. Human material submitted to NIBSC for deposit must be in the form of cryopreserved cultures. NIBSC may refuse deposits which have not been packed in a manner capable of maintaining the material in its original cryopreserved state during transit. The minimum number of replicates that must be provided by the depositor for deposit is 12. Deposits of human cell lines cultured as monolayers or suspension cultures must contain at least 1 $x10^6$ cells/ampoule (of viable cells as determined prior to cryopreservation). Deposits of human cell lines, if cultured as colonies from colony fragments, must contain at least 4 colony fragments per ampoule or straw. Where the cell line requires a feeder cell layer to support its growth in culture, a sample of this material must also be provided in a quantity sufficient to support the necessary testing. Any requests to deposit human embryonic stem cell lines will be subject to current UK regulations and guidelines. Any request to deposit human cell lines other than embryonic stem cell lines must conform to EU regulations and guidelines.

Animal Cell Cultures. Material of animal origin submitted to NIBSC for deposit must be in the form of cryopreserved cultures. Cells whose distribution is prohibited under the CITES convention will not be accepted by NIBSC. NIBSC may refuse deposits which have not been packed in sufficient dry ice to keep them frozen during transit. The minimum number of replicates that must be provided by the depositor for deposit is 12. Deposits of animal cell lines must contain at least 1 $x10^6$ cells/ampoule (of viable cells as determined prior to cryopreservation).

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by NIBSC is given below. Depositors should realize that viability testing may, under some circumstances, take significantly longer especially in the case of human embryonic stem cells. Depositors will be advised of this prior to the deposit being accepted.

Human embryonic stem cells	28 days
Human and animal cell cultures	14 days

(iii) Depositor Checks and Renewal of Stocks

NIBSC does not prepare its own batch of the deposited microorganisms. When the stock, originally provided by the depositor, has been depleted through furnishing samples, the depositor will be asked to provide a new deposit. In the case of human stem cell lines deposited in the UK Stem Cell Bank at NIBSC, it may be possible to transfer some of the stock held by the UKSCB to NIBSC patent deposit to provide a new stock of microorganisms. In this case, the depositor will be asked to check samples prepared by the UKSCB for authenticity.

(c) Technical Requirements and Procedures

(i) General

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

Contract. The NIBSC deposit form, which the depositor is required to complete, binds the depositor to:

- provide all necessary information requested by NIBSC;
- provide a biohazard statement;
- provide material only in the form and quantity required by NIBSC;
- pay all necessary fees, including all charges for the transportation of deposits to NIBSC;
- observe the terms and conditions of the Budapest Treaty;
- accept the terms and conditions of deposit at NIBSC;
- indemnify NIBSC against any claim which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of NIBSC.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. In the case of human embryonic stem cell lines this may include application to the UK Steering Committee for the UK Stem Cell Bank and the Use of Human Stem Cell Lines. The depositor will be advised to obtain the regulatory documentation once NIBSC has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NIBSC deposit form referred to in (i) above, the depositor must complete a NIBSC biohazard statement. In the case of human embryonic stem cell lines the depositor may also be required to complete the applicable form for the UK Steering Committee. The depositor should request information from NIBSC or the UK Stem Cell Bank concerning the appropriate forms.

At least 48 hours before the microorganism is dispatched the depositor must inform NIBSC of the number of ampoules being sent, the method of transportation and the estimated time of arrival. Dispatch must only be handled by couriers approved by NIBSC. If dispatch is by air, NIBSC must be told the flight number and destination, waybill number and handling agent for delivery together with their contact telephone number.

In the event of a later indication or amendment of the scientific description, and/or proposed taxonomic designation or other information supplied to NIBSC, the depositor must complete a revision form indicating the revised information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. NIBSC will notify the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. NIBSC does not routinely ask the depositor for the name and address of their patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and their patent agent for which a charge will be made.

(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 deposited for patent purposes providing an accession number was supplied at the time the original deposit was made. However, any deposits previously made free of charge are subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit, except that requirements relating to shipping procedures do not apply.

(iv) Making a New Deposit

The depositor is required to complete the NIBSC deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform to the procedures mentioned previously in respect of shipping requirements. The receipt and viability statements for any new deposit will also be issued on the “international“ forms BP/4 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

NIBSC does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, NIBSC will withhold samples of potentially hazardous microorganisms until it has confirmed that the requesting party has the appropriate containment facilities to handle such organisms. When responding to requests from overseas, NIBSC assumes that the requesting party has met the import requirements of his own country, and the customer is responsible for provision of the relevant documentation to do so.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

NIBSC does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

		GBP
Cell Lines		
(a)	Deposits and storage including provision of certification and viability statements	1,000
(b)	Issuance of a new (or updated) viability statement	100
(c)	Furnishing of a sample (excluding carriage costs)	100
(d)	Issuance of (new or updated) certification	50
(e)	Administration fee for amendments	50

Fees plus VAT, where applicable are payable to NIBSC.

4. Guidance for Depositors

Guidance for depositors is provided on the NIBSC deposit form.

US – UNITED STATES OF AMERICA

AGRICULTURAL RESEARCH SERVICE CULTURE COLLECTION (NRRL)

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Internet: http://nrrl.ncaur.usda.gov

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

1. All strains of agriculturally and industrially important bacteria, yeasts, molds and *Actinomycetales*, EXCEPT:

(a) *Actinobacillus* (all species); *Actinomyces* (anaerobic/microaerophilic, all species); *Afrizona* (all species); *Bacillus anthracis*; *Bartonella* (all species); *Bordetella* (all species); *Borrelia* (all species); *Brucella* (all species); *Clostridium botulinum*; *Clostridium chauvoei; Clostridium haemolyticum; Clostridium histolyticum; Clostridium novyi; Clostridium septicum; Clostridium tetani; Corynebacterium diphtheriae; Corynebacterium equi; Corynebacterium haemolyticum; Corynebacterium pseudotuberculosis; Corynebacterium pyogenes; Corynebacterium renale; Diplococcus* (all species); *Erysipelothrix* (all species); *Escherichia coli* (all enteropathogenic types); *Francisella* (all species); *Haemophilus* (all species); *Herellea* (all species); *Klebsiella* (all species); *Leptospira* (all species); *Listeria* (all species); *Mima* (all species); *Moraxella* (all species); *Mycobacterium avium*; *Mycobacterium bovis*; *Mycobacterium tuberculosis*; *Mycoplasma* (all species); *Neisseria* (all species); *Pasteurella* (all species); *Pseudomonas pseudomallei*; *Salmonella* (all species); *Shigella* (all species); *Sphaerophorus* (all species); *Streptobacillus* (all species); *Streptococcus* (all pathogenic species); *Treponema* (all species); *Vibrio* (all species); *Yersinia* (all species);

(b) *Blastomyces* (all species); *Coccidioides* (all species); *Cryptococcus neoformans; Cryptococcus uniguttulatus; Histoplasma* (all species); *Paracoccidioides* (all species);

(c) All viral, Rickettsial, and Chlamydial agents;

(d) Agents which may introduce or disseminate any contagious or infectious disease of animals, humans or poultry and which require a permit for entry and/or distribution within the United States of America;

(e) Agents which are classified as plant pests and which require a permit for entry and/or distribution within the United States of America;

(f) Mixtures of microorganisms;

(g) Fastidious microorganisms which require (in the view of the Curator) more than reasonable attention in handling and preparation of lyophilized material;

(h) Phages not inserted in microorganisms;

(i) Monoclonal antibodies;

(j) All cell lines;

(k) Plasmids not inserted in microorganisms.

2. Recombinant strains of microorganisms, strains containing recombinant DNA molecules, strains containing their own naturally occurring plasmid(s), strains containing inserted naturally occurring plasmid(s) from another host, strains containing inserted constructed plasmid(s), and strains containing viruses of any kind, excluding those already listed as nonacceptable, only if the deposit document accompanying the microbial preparation(s) includes a clear statement that progeny of the strain(s) can be processed at a Physical Containment Level of P1 or less and Biological Containment requirements meet all other criteria specified by the U.S. Department of Health and Human Services, National Institutes of Health *Guidelines for Research Involving Recombinant DNA Molecules*, December 1978 (*Federal Register*, Vol. 43, No. 247-Friday, December 22, 1978) and any subsequent revisions.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, fungi and yeasts are accepted as slant, stab or broth cultures, or as lyophilized preparations. If the depositor wishes the NRRL to distribute his own lyophilized preparations, he must supply these preparations in tubes of overall dimensions no greater than 50mm in length and 6mm outside diameter. The minimum number of replicates that must be provided by the depositor when making his deposit is as follows: for bacteria, fungi and yeasts, the NRRL requires the deposit of one or more preparations (slants, stabs, or lyophilized preparations) if the NRRL is to distribute its own preparations. If the NRRL is to distribute depositor's preparations, 30 lyophilized preparations must be deposited.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the NRRL is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria	3 days (or up to 15 days)
Fungi	10 days (or up to 15 days)
Yeasts	10 days (or up to 20 days)

(iii) Depositor Checks and Renewal of Stocks

The NRRL stores and distributes lyophilized material supplied by the depositor, if this is his wish, or it makes its own lyophilized preparations by subculture of, or directly from, active material supplied by the depositor. New batches are prepared as necessary for the renewal of diminishing stocks. The NRRL requires the depositor to check the authenticity of its lyophilized preparations. The viability statement issued by the NRRL contains a section in which the depositor can record the result of this test. If the depositor does not inform the NRRL of the results of this test within three months, the NRRL assumes that its preparations are equivalent to the depositor's original deposit.

The NRRL does not accept plasmids, except when they are contained in a living host microorganism.

Whichever method is used for preparing batches of samples for distribution, the NRRL stores a portion of the original prepared and deposited material.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The NRRL does not enter into any written contract with the depositor defining the liabilities of either party. However, by completing the NRRL deposition form, the depositor surrenders any right to withdraw his deposit during the required storage procedure, accepts NRRL policy on the handling and distribution of patent deposits, and accepts responsibility for the authenticity of NRRL preparations of his microorganism.

Import and/or Quarantine Regulations. Import and/or quarantine regulations do not apply to the kinds of microorganisms accepted by the NRRL for deposit.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the NRRL Budapest Treaty Deposition Form. The NRRL 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 the NRRL has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively. (NRRL has modified the latter to include a section in which the depositor can record the result of his authenticity check of NRRL preparations of his deposit--see (iv), below.) Notification of furnishing of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NRRL will telephone or telex the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test is not so communicated.

Supply of Information to a Patent Agent. If requested, the NRRL will supply copies of the receipt and viability statement to the depositor's patent agent.

(iii) Converting a Previous Deposit

The NRRL does not permit the conversion of deposits not originally made for patent purposes to Budapest Treaty deposits. The administrative requirements for converting a deposit previously made for patent purposes are the same as those to be met with respect to an original deposit made under the Treaty, except that no fee is payable.

(iv) Making a New Deposit

The NRRL does not require the depositor to complete a standard form when making a new deposit, but he is asked to supply an acknowledgment that the new deposit is the same as the original deposit (Article 4), and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The NRRL does not advise third parties of the correct procedures to follow in order to make a valid request for samples. In the case of requests requiring proof of entitlement, third parties requesting a sample under European Patent Office regulations are supplied with the relevant EPO form, but otherwise the NRRL does not supply copies of model request form BP/12 or request forms used by other individual industrial property offices; these must be obtained from the appropriate industrial property office.

Although the NRRL does not knowingly maintain hazardous microorganisms or those requiring a permit to be worked with in the United States of America, the requesting party must be "skilled in the art" (of microbiological practice) before any microorganisms are shipped. If a microorganism being requested is a known producer of a restricted substance, e.g., a hallucinogen, the requesting party must furnish his drug registration number before he can be supplied with a sample. When responding to requests from overseas, the NRRL assumes that the requesting party has met the import requirements of his own country.

Samples of bacteria, fungi and yeasts furnished by the NRRL may be from batches of its own lyophilized preparations or from lyophilized preparations supplied by the depositor, depending on the wishes expressed by the latter at the time of deposit (see 1(b), above).

(b) Notification of the Depositor

Unless he has waived his right to be so notified, the NRRL notifies the depositor on form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

The NRRL does not publish any catalog.

3. Schedule of Fees

Applicable to patent cultures deposited after October 30, 1983. No fee charged for cultures on deposit or received before that date.

		USD
(a)	Deposit of each strain (payable at the time of deposit)	500
(b)	Furnishing of a sample	20

Checks, in US dollars, should be made payable to the Agricultural Research Service, United States Department of Agriculture.

United States Department of Agriculture laboratories and designated cooperators are exempt from payment of fees.

4. Guidance for Depositors

The NRRL makes available a detailed statement on policies and procedures and a standard letter of explanation.

US – UNITED STATES OF AMERICA

AMERICAN TYPE CULTURE COLLECTION (ATCC)

10801 University Boulevard
Manassas, Virginia 20110-2209

Telephone: (1-703) 365 27 00
Facsimile: (1-703) 334 29 32
E-mail: PatentDeposit@atcc.org
Internet: http://www.atcc.org

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal viruses, animal cell cultures, bacteria (pathogenic and nonpathogenic), bacteriophages, embryos[1], DNA, fungi (pathogenic and nonpathogenic), human cell cultures, hybridomas, oncogenes, plant cell cultures, plant viruses, plasmids (in host and not in host), protozoa (nonparasitic, parasitic and pathogenic), RNA, seeds and yeasts (pathogenic and nonpathogenic).

The highest acceptable containment level for deposits is biosafety level (BSL) 3 as described in the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*, 4th Edition, 1999, and the NIH publication *Guidelines for Research Involving Recombinant DNA Molecules*, 2002.

When materials to be deposited cannot be tested for viability *in vitro*, ATCC should be contacted for guidance on whether or not the material can be accepted. In addition, some microorganisms and viruses may require special permits for transport to ATCC, and ATCC should be contacted in advance for assistance.

CDC = U.S. Centers for Disease Control and Prevention
NIH = U.S. National Institutes of Health

[1] ATCC must be notified before sending.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cultures of microorganisms are accepted by the ATCC in any form. However, ATCC prefers frozen or freeze-dried material. The minimum number of replicates that must be provided by the depositor when making the deposit is as follows:

Microorganisms (either containing a plasmid or not containing a plasmid), including bacteriophages, fungi, algae, yeast and protozoa	6 frozen or freeze-dried samples (0.5 ml each)
Cell lines and hybridomas	25 frozen samples (2 – 6 million cells each)
Plasmids and vectors not in host (e.g., purified DNA, libraries associated rDNA material)	25 vials (100 ng each) and
Animal and plant viruses	25 frozen or freeze-dried samples (1 ml each)
Embryos	25 frozen samples(12 embryos constitute one sample)
Plant tissue cultures	25 frozen samples
Seeds	2500 seeds (100 labelled packets of 25 seeds each)

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the ATCC is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures:

Bacteria	3 - 7 days
Fungi, molds, yeasts	5 - 7 days
Algae	10 days
Cell lines, hybridomas, oncogenes, bacteriophages	7 - 10 days
Plasmids[1], phages and other rDNA	8 - 10 days
Protozoa	10 or more days

[1] For plasmids, “viability” testing consists of inserting the plasmid into a host. If the host is transformed, the “viability test” is regarded as positive.

Animal and plant viruses	30 or more days
Embryos	3 - 7 days
Plant tissue cultures, seeds	21 - 30 days

(iii) Depositor Checks and Renewal of Stocks

The ATCC prepares additional samples at the time of release of algae, bacteria, oncogenes, bacteriophages, yeasts, molds and, in rare cases, cell lines and hybridomas. Additional samples are prepared from the depositor's original material whenever necessary for the renewal of distribution stocks. The ATCC generally does not prepare its own batches of viruses, plasmids, seeds, plant tissue cultures, protozoa, cell lines and hybridomas. In such cases, the depositor is responsible for replenishing the stock to ensure that there is sufficient stock to make the deposit available to the general public for the required period of deposit.

The depositor is required to test for authenticity of samples of all batches of the microorganism prepared by the ATCC and to inform the ATCC of the result.

Whichever method is used for preparing batches of samples for distribution, the ATCC nevertheless stores a portion of the original material supplied by the depositor.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The ATCC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by completing the ATCC BP/1 deposit form, 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. The ATCC must obtain an import permit from either or both the US Department of Agriculture and the US Public Health Service for the import of cell lines and viruses into the United States. Cell lines and viruses must be safety tested by the USDA for specific diseases. Material from Japan, Australia and the United Kingdom is tested in vitro, which takes about eight weeks and costs about $500. Material from other countries must be tested in vivo, which takes about three months and costs about $3,000.

As of May 1995, the US Department of Agriculture has determined that the following materials and products of animal origin from Canada, a country not restricted by the USDA for specified diseases, may enter the United States without a Veterinary Services import permit:

Research materials - (examples: bacteria, viruses, cell lines, monoclonal and polyclonal antibodies, diagnostic test kits, and other kit components such as animal serum/blood).

These biologicals require a certificate on the depositor's letterhead stating that the material was manufactured in Canada and obtained from animals resident in Canada.

The ATCC requires the prospective depositor of a cell line or virus to complete a special form which asks for the information necessary to enable the ATCC to obtain an import permit. Obtaining such a permit usually takes four to six weeks. The ATCC will advise prospective depositors about import and quarantine regulations and the procedures that must be followed. Information may also be obtained from the Veterinary Services and/or the Plant Protection and Quarantine Biological Assessment Support Staff both at the US Department of Agriculture, Animal and Plant Health Inspection Service, Federal Center Building, Hyattsville, Maryland 20872, United States of America, and from the Department of Health and Human Services, Public Health Service, Office of Biosafety, Centers for Disease Control, Atlanta, Georgia 30333, United States of America.

Except in rare instances, the ATCC does not need to obtain import permits for microorganisms other than cell lines and viruses.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete ATCC form BP/1 "Budapest Treaty Deposits" in all cases. For animal cell lines, hybridomas and viruses, the form referred to in (i), above, must also be completed, so that the ATCC may apply for an import permit. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the ATCC has received such information, the depositor must complete ATCC form BP/7-8.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and 9 which are combined in form BP/4-9. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/7-8. Notification of release of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the ATCC will telephone or fax the date of deposit and accession number after a positive showing of viability, but before the official receipt is issued. A fee of $10 is charged for this service. The ATCC similarly will telephone or telex the result of the viability test before the official viability statement is issued.

Supply of Information to a Patent Agent. The ATCC asks that the depositor supply the name, address, phone and fax number of the patent attorney or agent. The ATCC sends copies of the certificates and notifications to the depositor's attorney or 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 deposited for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fees normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those required for 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

New Deposit

In the event that the ATCC determines that a biological material is no longer viable, although originally found viable upon initial deposit, the depositor may replace the nonviable deposit with a new deposit. The deposit will retain its initial deposit number and date as long as (1) the replacement deposit is viable, (2) the ATCC receives the replacement deposit within three months of receipt by the depositor of the notification of nonviability, and (3) the ATCC receives a statement signed by the depositor alleging that the newly deposited biological is the same as that originally deposited. The only charges are for viability testing.

Supplemental Deposits

In the event that the ATCC determines that the deposit, although still viable, no longer retains the characteristics as originally thought, the depositor will be asked to provide a Supplemental Deposit. This deposit will obtain a new date and a new accession number. All the normal forms for deposit must be filled out and the regular fees for an original deposit apply.

2. Furnishing of Samples

(a) Requests for Samples

Generally, availability of the biological material is required only after the issuance of a pertinent patent. Prior to that time, the deposit need only be made available to a requesting party if (1) the Commissioner of the United States Patent and Trademark Office, in accordance with 35 U.S.C. paragraph 122, issues a decision to release such deposit; (2) the patent office of another country signatory to the Budapest Treaty issues such a decision to release the deposit to a particular requesting party; or (3) the original depositor requests in writing that the deposit be released to a particular requesting party. The ATCC will provide requesting parties with form BP/12 or request forms used by an individual industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the ATCC will withhold samples of organisms that are subject to health and safety regulations until it has confirmed that the requesting party can comply with such regulations. For organisms considered potentially very dangerous, the requesting party must sign an assurance of acceptance of responsibility. Also, in some cases a permit is required to work with certain material in the United States of America, and a requesting party in the United States of America must obtain such a permit before he can receive a sample. If a valid request

is received from overseas for a sample of a microorganism that would require a permit to be worked with in the United States of America, the ATCC advises the requesting party to check the import requirements of his own country. If the ATCC knows that a country requires an import permit for a microorganism (even if the United States of America does not), it will so advise a requesting party in that country.

(b) Notification of the Depositor

The ATCC offers a notification service in which a depositor is notified on form BP/14 each time a sample of the deposit is furnished to a third party. For the fee relating to this service, see below under 3 (Schedule of Fees).

(c) Cataloguing of Budapest Treaty Deposits

If the depositor or a competent patent office instructs the ATCC to make samples of a microorganism available to anyone, that organism is listed in the next published ATCC catalog.

3. Schedule of Fees

	USD
(a) Storage and issuance of a viability statement: - 30 years of storage and notification of request - Issuance of a viability statement	2,500
(b) Furnishing of a sample	
- All ATCC Cultures	per item
- US Non-Profit Institutions	86[1] to 281[1]
- Foreign Non-Profit Institutions	86[1] to 281[1]
- Other US and Foreign Institutions	107[1] to 330[1]
Biosafety Level 1	21 to 107
Biosafety Level 2	90 to 310
Biosafety Level 3	90 to 310

Because of the diversity of ATCC holdings, and the requirements for complicated and varied culture media and growth conditions, the fees for furnishing ATCC cultures vary. Therefore, the current fees have been listed as a range representing all currently available ATCC cultures.

4. Guidance for Depositors

The ATCC publishes a brochure giving details of its requirements and practices for the deposit of cultures for patent purposes.

[1] Additional handling and processing – dependent on destination and hazard level.

US – UNITED STATES OF AMERICA

Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA)

Bigelow Laboratory for Ocean Sciences
60 Bigelow Drive
East Boothbay, Maine 04544

Telephone: 1-207-315-2567, Ext. 1
Facsimile: 1-207-315-2320
E-mail: PatentDeposit@bigelow.org
Internet: https://ncma.bigelow.org

1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Any algae (including single-celled microalgae and multicellular algae), eukaryotic protists, bacteria, archaea or viruses from any aquatic environments (including freshwater, brackish, marine and hyper-saline).

(b) Technical Requirements and Procedures

(i) Form and Quantity

Deposited microorganisms are accepted by the NCMA in any form. However, the NCMA prefers viable frozen (2 mL) or lyophilized (freeze-dried) cultures. If the depositor is uncertain if the microorganism can be cryopreserved, then the NCMA can determine an appropriate cryopreservation protocol via a separate contractual negotiation. For example, since many marine algae species cannot be cryopreserved, they must be maintained in perpetual culture to remain viable. The depositor must provide a minimum of six replicates for deposit (frozen or lyophilized) or duplicate 15 mL cultures (for live perpetual culturing). Algal cultures must contain a minimum of $10^2 – 10^5$ cells mL^{-1} (depending on the species), a minimum of three plants are required for macroalgae (seaweeds), a minimum of $10^4 – 10^6$ cells mL^{-1} are required for marine bacteria and a minimum of $10^5 – 10^7$ particles mL^{-1} are required for marine viruses.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of algae accepted by the NCMA is 30 days, but depositors must realize that, in some cases, viability testing of certain marine algae can take as long as 90 days. Marine bacteria, archaea and viruses can take up to 30 days (viruses require a viable host on which to propagate). When the deposited organisms cannot be tested for viability *in vitro*, the NCMA should be contacted to determine if the organism can be accepted for deposit.

(iii) Depositor Checks and Renewal of Stocks

Except where the depositor's original deposit is preserved by freezing or lyophilization, the NCMA prepares its own batches of the deposited microorganism at the time of deposit by subculturing the microorganism supplied by the depositor. Additional samples are prepared from the original deposit whenever necessary for the renewal of distribution stocks. In cases where the original deposit has been cryopreserved by the depositor, stocks are renewed by requesting that the depositor provide a new deposit or are renewed by thawing and subculturing (via a separate contractual negotiation). Perpetually-cultured microorganisms are transferred into fresh growth medium on average once every 21-90 days depending on the individual species.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NCMA is English.

Contract. The NCMA will enter into a specific contractual arrangement with the depositor. Among other things, the contract will outline the terms of payment, deposition details, relevant patent requirements and any specific arrangements for the term of the deposit.

Import and/or Quarantine Regulations. The kinds of deposits accepted by the NCMA are typically not subject to import or quarantine regulations; however, if this situation should change, then the depositor will be responsible for adhering to the import and quarantine regulations that must be followed, as well as any additional financial requirements, prior to deposit. If any special permits are required for shipment to the NCMA, then the NCMA should be contacted in advance for guidance.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the NCMA online application form, depositors are required to complete the NCMA accession form for patent deposits. The NCMA 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 the NCMA has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" NCMA BP/4 and BP/9, respectively. The NCMA has its own standard forms notifying the depositor of acceptance of a deposit or refusal to accept a deposit, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, then the NCMA will telephone or e-inform the depositor of the date of deposit and accession number after the deposit has been received, but before the official receipt is issued. The NCMA will similarly communicate the result of the viability test before the viability statement is issued.

Supply of Information to a Patent Agent. The NCMA routinely asks the depositor for the name, mailing address, telephone number and e-mail address of their patent attorney or agent. If requested, then the NCMA will supply copies of the receipt and viability statement to both the depositor and the patent attorney or agent.

(iii) Converting a Previous Deposit

The NCMA does not have any deposits made for patent purposes outside the provisions of the Budapest Treaty and does not consider Rule 6.4(d) of the Budapest Treaty applicable in other cases.

(iv) Making a New Deposit

The NCMA requires the depositor to supply copies of the relevant documents and declarations required by Rule 6.2 of the Budapest Treaty. The receipt and viability statement for a new deposit are issued on mandatory "international forms" NCMA BP/5 and BP/9, respectively.

2. Furnishing of Samples

(a) Requests for Samples

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

The NCMA furnishes the samples in the belief that it is the responsibility of the requesting party to ensure it complies with any relevant health and safety requirements. When responding to requests from outside of the United States, the NCMA assumes that the requesting party has met the import requirements of their home country.

(b) Notification of the Depositor

Depositors will be notified by either letter or electronic communication when samples of their deposit have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

The NCMA usually does not list Budapest Treaty deposits in its published catalog; however, if the depositor or a competent patent office instructs the NCMA to make samples of a deposit available to the public, then that deposit will be listed in the then-current NCMA published catalog.

3. Schedule of Fees

	US$
Storage	
- Frozen or lyophilized for 30 years	3,000
- Perpetual culturing for 30 years	10,000
Viability Statement Fee	500
Furnishing of Microorganisms Sample Fee	200

4. Guidance for Depositors

Upon request, the NCMA will provide an e-brochure that describes the NCMA's requirements and practices for patent-related deposits.

Section E: Requirements of Industrial Property Offices of States Party to the Budapest Treaty and of Intergovernmental Industrial Property Organizations

Introduction

(i) General

This section describes the statutory requirements and the practices of the industrial property offices of the States party to the Budapest Treaty and of the African Regional Intellectual Property Organization (ARIPO), the European Patent Organisation (EPO) and the Eurasian Patent Organization (EAPO) as regards the deposit of microorganisms for the purposes of patent procedure.

(ii) Information on Industrial Property Offices

The industrial property offices are listed by country in accordance with the two-letter country code as per WIPO Standard ST.3, followed by the African Regional Intellectual Property Organization (ARIPO), the European Patent Organisation (EPO) and the Eurasian Patent Organization (EAPO), according to the following scheme: country, name of industrial property office, address, telephone, telefax and telex numbers and electronic and Internet addresses, if any.

1. Requirements for Deposit

Information is given on the question whether the deposit with an international depositary authority of a microorganism which is the subject of a patent application, is obligatory in order to describe the invention adequately.

2. Time of Deposit

The time limit is indicated for depositing with an international depositary authority a microorganism which is the subject of a patent application.

3. Duration of Storage

Information is given on the length of time during which a microorganism deposited with an international depositary authority must be stored by the said authority.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Information is given when samples of deposited microorganisms should be available to any requesting party.

(ii) Restrictions Concerning the Furnishing of Samples

Information is given with respect to restrictions on the availability of samples of deposited microorganisms.

AL - ALBANIA

General Directorate of Patents and Trademarks (Albania)
Bulevardi 'Gjergj Fishta'
Godina Nr. 10
Kati V
Tirana

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Telefax: (355-42) 234 412
E-mail: mailinf@dppm.gov.al
Internet : www.alpto.gov.al

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

AM - ARMENIA

Intellectual Property Agency of the Republic of Armenia
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Telefax: (374-10) 54 34 67, 56 11 26
E-mail: armpat@cornet.am, invention@cornet.am
Internet: http://aipa.am

1. Requirements for Deposit

The description of the processes of the strain, cell chain, consortium shall be brought in the examples of realization of inventions regarding the strain of the microorganism, plant or animal line, strain or cell consortiums.

If the description thereof is not sufficient for the realization of invention, data on the deposit of the microorganism shall be submitted (the name or abbreviation, address and the registration number of the depositary center).

2. Time of Deposit

The date of deposit shall precede the date of filing the application or where the priority is claimed, the date of priority of invention.

3. Duration of Storage

The deposit with the aim of patent procedures shall be deemed as realized if the strain, cells chain or consortium are stored in the international depositary authority under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms or in the National Collection authorized for the deposit of strain, cells chain, consortium, which guarantees the protection of the viability of strain, cells chain, consortium at least during the viability period of the patent.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Where a patent application relating to a deposited biological material has been refused or withdrawn, the deposited biological material shall only be available to third parties for 20 years from the date of filing of the application, if so requested by the applicant.

AU – AUSTRALIA

IP Australia
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Woden A.C.T. 2606

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E-mail: assist@ipaustralia.gov.au
Internet: http://www.ipaustralia.gov.au

1. Requirements for Deposit

The deposit of a culture of a microorganism is required if the invention involves the use, modification or cultivation of a microorganism which is not reasonably available to a person skilled in the art and if, without a sample of such microorganism, such person could not reasonably be expected to be able to perform the invention.

(Patents Act 1990, Sections 6, 41(1) and (2); Patents Regulations, Regulations 1.5(1) and ((2) - (4))

2. Time of Deposit

The microorganism deposit must be made on or before the filing date of the application. Where the application claims priority from an earlier application, the deposit must have been made on or before the filing date of the earlier application.

(Patents Act 1990, Section 6(a)); Patents Regulations, Regulations 3.13A, 3.13B, 3.13C and 3.13D)

3. Duration of Storage

A deposited microorganism shall be stored for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the international depositary authority and, in any case, for a period of at least 30 years after the date of the deposit.

(Patents Act 1990, Section 6(d); Budapest Treaty Rule 9.l)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Samples of deposited microorganisms may be made available to a requesting party

provided the specification lodged in respect of the patent application or patent is open to public inspection.

(Patents Regulations, Regulation 1.5(3) and 3.25(4)(a))

(ii) Restrictions Concerning the Furnishing of Samples

The requesting party must give an undertaking:

(a) not to make the microorganism, or any culture derived from the microorganism, available to any other person, and

(b) to use the microorganism only for experimental purposes, in relation to specified proceedings.

(Patents Regulations, Regulation 3.25(4)(c), Form P/00/031)

The specified proceedings are:

(a) opposition proceedings under Chapter 5 of the Patents Act in relation to the grant of a standard patent on the application; or

(b) opposition proceedings under section 101M of the Patents Act in relation to an innovation patent; or

(c) relevant proceedings in relation to the patent.

The Commissioner may also require, before granting the certification referred to in Rule 11.3(a) of the Budapest Treaty Regulations, that a requesting party comply with such conditions as are reasonable, including a condition that the requestor give security for damages for any breach of the undertaking.

(Patents Regulations, Regulation 3.25(2))

The applicant may, at any time before the specification relating to the application is open for public inspection, notify the Commissioner that a sample of the deposited microorganisms is only to be provided during the period;

(a) before the patent is granted on that application; or

(b) before the application has lapsed or been withdrawn or refused to a person who is:

(i) a skilled addressee without an interest in the invention; and

(ii) nominated by the person who made the request.

(Patent Regulations, Regulation 3.25(3) and (3A))

AT – AUSTRIA

Austrian Patent Office
Dresdner Strasse 87
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Telefax: (43-1) 53 424 - 535
E-mail: info@patentamt.at
Internet: http://www.patentamt.at

1. Requirements for Deposit

If an invention relates to a biological material that is not accessible to the public, nor can be described in the application in a manner that a person skilled in the art is able to carry out the invention accordance therewith, of if the invention contains the use of such a biological material, the invention shall be regarded as disclosed only if

1. the biological material has been deposited at a place of deposit under the Budapest Treaty not later than on the day of filing,

2. the application contains the pertinent information on the characteristic features of the deposited biological material, that is known to the applicant, and

3. the place of deposit and the file number of the deposit have been specified in the application.

The information mentioned in subparagraph 3 can be filed subsequently either

1. within 16 months after the application date or, if a priority has been claimed, after the priority date, or

2. up to date of the filing of a request for publication of the application ahead of schedule, or

3. within one month after the Patent Office has informed the applicant that a right of inspection under to Section 81, paragraph (3), exists,

wherein it is relevant which term expires first.

(Patent Act of 1970, as amended in 2005, Section 87a (2) and (3))

2. Time of Deposit

The biological material must be deposited not later than the filing date of the patent application.

(Patent Law, Section 87a (2)1)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

Section 81a (1) Before the date of publication of the application any person who has the right of inspection of files shall be entitled to get a sample of a biological material deposited under Section 87a, paragraph (2), subparagraph 1. From the date of publication of the application any person who makes a respective request has this right. The access is granted being subject to paragraphs (2) and (3) by handing out a sample of the deposited biological material to the requesting party or an independent expert.

(2) The handing out only takes place if the requesting party obliges itself for the duration of the effect of the patent or until the application is withdrawn or rejected.

1. not to make available to third parties a sample of the biological material deposited or a material derived therefrom and

2. not to use a sample of the deposited biological material or a material derived therefrom for anything else but experimental purposes unless the applicant or the patentee explicitly renounces such an obligation.

(3) Until the completion of the technical preparation for the publication of the application the applicant may request that the access designated in paragraph (1) shall be granted only by handing out a sample to an independent expert.

1. until the grant of the patent or

2. in case of a withdrawal or rejection of the application for the duration of 20 years beginning with the application date.

(4) As an expert as defined by paragraph (3)

1. any natural person, as far as the requestor proves, that the appointment happens with approval of the applicant,

2. any natural person, who is acknowledged by the President of the Patent Office as expert and is registered in the expert register, which is maintained by the Patent Office

can be appointed. With the appointment a declaration of the expert shall be presented, in which he undertakes the obligations to the applicant under paragraph (2).

(Patent Act, Section 81a)

AZ - AZERBAIJAN

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1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

BH - BAHRAIN

National Patent Office
Diplomatic Area
Manama
Kingdom of Bahrain

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1. Requirements for Deposit

No provision

2. Time of Deposit

No provision

3. Duration of Storage

No provision

4. Conditions for the Furnishing of Samples

No provision

BY - BELARUS

National Center of Intellectual Property
20, ul. Kozlova
220034 Minsk

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Internet: http://www.belgospatent.by

1. Requirements for Deposit

The sufficiency in the invention that relates to microorganisms, plant or animal cell cultures or the way they are used is proved by supplying information as to the deposit of a microorganism (the name of the depositary authority, the accession number given by the depositary authority to the deposit).

(Regulations on Substantive Examination of an Application for an Invention Patent, Rule 79)

2. Time of Deposit

The deposit of a microorganism must be made before or on the priority date of an application.

(Regulations on Substantive Examination of an Application for an Invention Patent, Rule 79)

3. Duration of Storage

For the purposes of patent procedure, the deposit is considered to have been made if a microorganism has been placed with any international depositary authority guaranteeing its viability for at least the term of the patent.

(Regulations on Substantive Examination of an Application for an Invention Patent, Rule 79)

4. Conditions for the Furnishing of Samples

No provision.

BE - BELGIUM

Intellectual Property Office
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1210 Brussels

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Website: http://economie.fgov.be/opri-die.jsp?

1. Requirements for Deposit

Section 17, paragraph 1, subparagraph 2 of the Patent Law of March 28, 1984, as amended by the Law of April 28, 2005 amending the Patent Law of March 28, 1984 on the patentability of biotechnological inventions:

"Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purpose of patent law unless the biological material is deposited not later than the day of filing the patent application with a recognized depositary institution and the requirements laid down by the King are fulfilled."

Section 10, paragraph 1 of the Royal Decree of December 2, 1986 on patent applications, grants and maintenance, as amended by Section 1 of the Royal Decree of February 27, 2007:

"Paragraph 1. In the case provided for in Section 17, paragraph 1, subparagraph 2 of the law, the description shall be considered inadequate unless the patent application contains such relevant information as is available to the applicant on the characteristics of the biological material deposited, as well as information on the depositary institution and the number of the deposit.

International depositary institutions are recognized as depositary institutions following acquisition of such status in accordance with Article 7 of the Budapest Treaty of April 28, 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Information on the depositary institution and the number of the deposit shall be communicated:

(a) within a period of 16 months as from the filing date or, if a priority is claimed, as from the date of priority;

(b) up to the date of submission of a request to bring forward the granting of the patent under Section 22, paragraph 2, subparagraph 2 of the law."[1]

1 Section 22, paragraph 2 of the law of March 28, 1984: "paragraph 2. The decision shall be issued as soon as possible following expiry of a period of 18 months as from the filing date of the patent application or, if the priority right under the Paris Convention has been claimed in accordance with Section 19, as from the earliest priority stated in the priority declaration".

Section 10*bis* of the Royal Decree of December 2, 1986 on the application, grant and maintenance of patents, as amended by Section 1 of the Royal Decree of February 27, 2007, introduced by Section 2 of the Royal Decree of February 27, 2007:

"Paragraph 1. Where the biological material deposited, in accordance with Section 10, ceases to be available from the recognized depositary institution, a new deposit of the material shall be permitted within a period of three months as from the date on which the interruption was notified to the applicant or to the owner of the patent, either by the recognized depositary institution or by the Office.

A copy of the receipt for the new deposit issued by the recognized depositary institution, accompanied by the number of the patent application, or the patent itself, shall be communicated to the Office within four months as from the date of the new deposit.

Paragraph 2. Where the interruption is due to the non-viability of the culture, the new deposit shall be made with the recognized depositary institution with which the original deposit was made. In other cases, it may be made with another recognized depositary institution.

Paragraph 3. Any new deposit shall be accompanied by a statement signed by the applicant certifying that the newly deposited biological material is the same as that originally deposited".

2. Time of Deposit

The deposit must be made on the date of filing the patent application.

(Section 17, paragraph 1, subparagraph 2 of the Patent Law of March 28, 1984 and Section 10, paragraph 1, subparagraph 1 of the Royal Decree of December 2, 1986 on the application, grant and maintenance of patents, *in fine*)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Section 10, paragraphs 2, 5 and 6 of the Royal Decree of December 2, 1986 on the application, grant and maintenance of patents, as amended by Section 1 of the Royal Decree of February 27, 2007:

"Paragraph 2. Access to the material shall be provided by the furnishing of a sample:

(a) up to the first publication of the patent application, only to the applicant or his representatives;

(b) between the first publication of the patent application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

Paragraph 5. Requests from the applicant under paragraph 2(b) and paragraph 4 may only be brought up to the date on which the technical preparations for publication of the patent application are deemed to have been completed.

Paragraph 6. Failing such designation by agreement between the applicant and the person requiring access to the deposited biological material, the independent expert referred to in paragraph 2(b) and paragraph 4 shall be designated by the competent judge".

(ii) Restrictions Concerning the Furnishing of Samples

Section 10, paragraphs 3 and 4 of the Royal Decree of December 2, 1986 on the application, grant and maintenance of patents, as amended by Section 1 of the Royal Decree of February 27, 2007:

"Paragraph 3. The furnishing of a sample shall be made only if the person requesting it undertakes, for the term during which the patent is in force:

(a) not to make the biological material or any material derived from it available to third parties; and

(b) not to use the biological material or any material derived from it except for experimental purposes, unless the patent applicant or proprietor expressly waives such an undertaking.

Paragraph 4. At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In that case, paragraph 3 shall apply."

BA - BOSNIA AND HERZEGOVINA

Institute for Intellectual Property of Bosnia and Herzegovina

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88000 Mostar

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E-mail: mostar@ipr.gov.ba, info@ipr.gov.ba
Internet: http://www.ipr.gov.ba

Branch Offices:
Kralja Petra Prvog karadjordjevica 83A
78000 Banja Luka

Telephone: (387-51) 22 68 40
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and

Hamdije Ćemerlića 2/9
71000 Sarajevo

Telephone: (387-33) 65 27 65
Telefax: (387-33) 65 27 57
E-mail: sarajevo@ipr.gov.ba

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

BN - BRUNEI DARUSSALAM

Brunei Intellectual Property Office (BruIPO)
4th Floor, Block 2D
Jalan Kumbang Pasang
Bandar Seri Begawan, BA 1311
Negara Brunei Darussalam

Telephone: (673) 223 01 11
Telefax: (673) 23 80 54 5
E-mail: enquiries@bruipo.com.bn
Internet: http://bruipo.com.bn/

1. Requirements for Deposit

The deposit of a microorganism shall be made if an invention requires for its performance the use of a microorganism which is not available to the public at the date of filing of the patent application and which cannot be described in such a manner as to enable the invention to be performed by a person skilled in the art. The name of the international depositary authority, the date when the culture was deposited and the accession number of the deposit should be given in the specification of the application.

(a) within 16 months from

(i) the declared priority date; or

(ii) the date of filing the application where there is no declared priority date;

(b) where, on a request made by the applicant, the Registrar publishes the application before the end of the period prescribed for the purposes of section 27(1), before the date of the request; or

(c) where the Registrar sends notification to the applicant that, in accordance with section 105(4), he has received a request by any person for information and inspection of documents under subsection (1) of that section, before the end of one month after his sending to the applicant notification of his receipt of the request, whichever is the earliest.

(The Patents Rules, 2012 – Schedule 4, paragraph 1)

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(The Patents Rules, 2012 – Schedule 4, paragraph 1(2)(a)(i))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A culture of a deposited microorganism is available on request before publication of the relevant patent application to a person to whom Section 105(4) applies and who has made a request under Section 105(1) and is available upon such publication to any person.

(The Patent Rules, 2012 – Schedule 4, paragraph 2(1))

(ii) Restrictions for the Furnishing of Samples

A request authorizing the furnishing of samples shall comprise, on the part of the person to whom the request relates, undertakings for the benefit of the applicant for, or proprietor of, the patent,

(a) not to make the culture, or any culture derived from it, available to any other person; and

(b) not to use the culture, or any culture derived from it, otherwise than for experimental purposes relating to the subject matter of the invention.

Both undertakings shall have effect during any period before the application for a patent has been withdrawn, has been treated as having been abandoned, has been refused or is treated as having been refused (including any further period allowed under rule 110, 120(1) or (6) but excluding, where an application is reinstated under either of those rules, the period before it is reinstated).

If a patent is granted, the undertaking set out in sub-paragraph (a), above, shall also have effect during any period for which the patent is in force and during the period of 6 months referred to in section 35(3).

The undertaking set out in sub-paragraph (b), above, shall not have effect after the date of publication in the Official Patents Journal of a notice that the patent has been granted.

The request for the furnishing of samples should be made on Patents Form 55 together with the form provided for by the Regulations under the Budapest Treaty (BP/12).

(The Patents Rules, 2012 – Schedule 4, paragraph 2(1) and (3))

Before the preparations for publication under Section 27 of an application for a patent have been completed, the applicant gives notice to the Registrar on Patents Form 56 of his intention that a sample of the micro-organism should be made available only to an expert.

Where this has been done, the Registrar will publish with the application a notice to this effect and persons requesting samples must nominate an expert who must have given undertakings in accordance with subparagraphs (a) and (b), above. The request for furnishing of samples in these circumstances should be made on Patents Form 57. The Registrar shall specify the period within which the patent applicant may object to the furnishing of a sample of the microorganism to the particular expert nominated.

In the case of an international application, the applicant's notice that a sample should be furnished only to an expert should be given in writing to the International Bureau under Rule 13bis.3 of the Regulations under the Patent Cooperation Treaty before technical preparations for international publication are complete.

(The Patents Rules, 2012 – Schedule 4, paragraph 2(1) and (3))

BG – BULGARIA

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1040 Sofia

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E-mail: bpo@bpo.bg
Internet: http://www.bpo.bg

1. Requirements for Deposit

If an invention involves a strain of a microorganism, it should be deposited with the Bulgarian depositary institution or with an international depositary authority with a separate deposit number.

(Instructions for Drafting and Examining Applications for Inventions by the Chairman of the State Committee for Science and Technological Progress of August 4, 1969, Sections 2.20, 3.11 and 7.3)

Under the practice of the Bulgarian industrial property office, a culture of a microorganism should be deposited with the National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC), if the microorganism is not available to the public or the invention involving that microorganism cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art.

The applicant should file a copy of the document proving the deposit of the microorganisms issued by the depositary authority at the time of filing the application. The applicant must indicate the deposit number of the microorganism and the name of the depositary authority with which such microorganism has been deposited.

2. Time of Deposit

Under the existing practice, the deposit must be made not later than the filing date of the application or, if priority is claimed, the priority date.

3. Duration of Storage

Under the existing practice, the duration of storage is unlimited.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Under the existing practice, the deposited culture should be available to the public as from the date of the grant of the relevant title of protection.

(ii) Restrictions Concerning the Furnishing of Samples

Under the existing practice, samples of the deposited microorganism should be furnished only to the requesting party who undertakes vis-à-vis the patentee to use the samples for experimental purposes only and not to make the samples available to any third party.

CA - CANADA

Canadian Intellectual Property Office
50 Victoria Street
Gatineau, Quebec

Mailing address:
The Commissioner of Patents
Canadian Patent Office
Ottawa, Ontario K1A OC9

Telephone: (1-866) 997 19 36 (toll-free from Canada and US)
(1-819) 934 05 44 (local and international)
Telefax: (1-819) 953 24 76 / 953 67 42
E-mail: cipo.contact@ic.gc.ca
Internet: http://cipo.gc.ca

1. Requirements for Deposit

Where a specification in a patent application, or in a patent issued on the basis of such an application, refers to a deposit of biological material, the deposit of the biological material is considered to be in accordance with the Patent Regulations if it has been made by the applicant with an international depositary authority. The applicant must inform the Commissioner of Patents of the name of the international depositary authority, the date of the original deposit and the accession number given by the international depositary authority to the deposit. The said information must be included in the description of the patent application and must be provided before the application is open to public inspection.

(Patent Rules 1996[1], Sections 103 and 104)

2. Time of Deposit

The deposit of the biological material must be made with an international depositary authority on or before the filing date of the patent application.

(Patent Rules, Section 104)

3. Duration of Storage

No provision.

[1] The Patent Rules 1996, also contain provisions concerning *Applications Filed in the Period Beginning on October 1, 1989 and Ending on October 1, 1996* (Sections 159 to 166) and *Applications Filed Before October 1, 1989* (Sections 183 to 187)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Before the patent application is open to public inspection, the applicant may file a notice with the Commissioner of Patents stating the applicant's wish that, until either a patent has been issued on the basis of the application, or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, a sample of the deposited biological material be furnished only to an independent expert nominated by the Commissioner.

(Patent Rules, Subsection 104(4))

The Intellectual Property Office publishes in the *Canadian Patent Office Record* a form for making a request for the furnishing of a sample of the deposit.

(Patent Rules, Subsection 107(1))

Where the specification in a Canadian patent or in a patent application filed in Canada that is open to public inspection refers to a deposit of biological material by the applicant, and where a person files with the Commissioner of Patents a request made on the form referred to in Subsection 107(1), the Commissioner makes the certification referred to in Rule 11.3(a) of the Regulations under the Budapest Treaty in respect of that person and sends a copy of the request, together with the certification, to the person who filed the request.

(Patent Rules, Subsections 107(2) and (3))

(ii) Restrictions Concerning the Furnishing of Samples

Until either a patent has been issued on the basis of the patent application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, the Commissioner of Patents does not make the certification referred to in subsection 107(2) in respect of a person unless the Commissioner has received an undertaking by that person to the applicant:

- not to make any sample of biological material furnished by the international depositary authority or any culture derived from such sample available to any other person before either a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn; and

- to use the sample of biological material furnished by the international depositary authority and any culture derived from such sample only for the purpose of experiments that relate to the subject-matter of the application until either a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn.

(Patent Rules, Section 108)

Where a notice has been filed with the Commissioner of Patents pursuant to subsection 104(4) in respect of a patent application, the Commissioner, upon request of any person that an independent expert be nominated and with the agreement of the applicant, nominates, within a reasonable time, a person as an independent expert for the purposes of that application.

If no agreement can be reached on the nomination of an independent expert within a reasonable time after the request is made, the notice of the applicant referred to in subsection 104(4) is deemed never to have been filed.

(Patent Rules, Section 109)

Where a notice has been filed with the Commissioner of Patents pursuant to subsection 104(4) in respect of a patent application, until a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, a request pursuant to section 107 may only be filed by an independent expert nominated by the Commissioner in accordance with section 109.

Where the Commissioner of Patents makes a certification pursuant to subsection 107(2) in respect of an independent expert nominated by the Commissioner, a copy of the request, together with the certification, is sent to the applicant and to the person who requested the nomination of the independent expert.

(Patent Rules, Section 110)

CL - CHILE

National Industrial Property Institute
Av. Libertador Bernardo O'Higgins 194
Piso 1
Santiago

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E-mail: inapi@inapi.cl
Internet: http://www.inapi.cl

1. Requirements for Deposit

Where a specification in a patent application, on the basis of such application refers to a deposit of biological material, the deposit of the biological material is considered to be in accordance with the Patent Regulations if it has been made by the applicant with an international depositary authority.

The applicant must inform the name of the international depositary authority, the date of the original deposit and the accession number given by the international depositary authority to the deposit, that is the applicant must deliver the certificate of deposit. The said information must be included in the description of the patent application and it should be provided upon request of the office.
(Patent Rules, art. 39, section 4)

2. Time of Deposit

The proof of deposit of the biological material should be provided upon request of the Chilean office. However, this information could be given at the time of filing the patent application.
(Patent Rules, art. 39, section 4)

3. Duration of Storage

No provision

4. Conditions for the Furnishing of Samples

A sample of biological material becomes available from the date on which the information is included in the application, if the application became public.

CN - CHINA

State Intellectual Property Office of the People's Republic of China
6 Xituchenglu
Haidian District
100088 Beijing

Mailing address:
P.O. Box 8020
100088 Beijing

Telephone: (86-10) 62 08 32 68
Telefax: (86-10) 62 01 96 15
Internet: http://www.sipo.gov.cn

1. Requirements for Deposit

Where an invention for which a patent is applied for concerns a new biological material which is not available to the public and which cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicant shall deposit a sample of the biological material with a depositary institution designed by the Patent Administration Department under the State Council.

The applicant shall give, in the application document, relevant information of the characteristics of the biological material.

Where the application relates to the deposit of the biological material, the applicant shall indicate in the request and in the description the scientific name (with its Latin name) and the title and address of the depositary institution, the date on which the sample of the biological material was deposited and the accession number of the deposit; where, at the time of filing, they are not indicated, they shall be supplied within four months from the date of filing; where after the expiration of the time limit they are not supplied, the sample of the biological material shall be deemed not to have been deposited.

(Implementing Regulations of the Patent Law of 2001, Rule 25)

2. Time of Deposit

The deposit of a sample of the biological material with a depositary institution designated by the Patent Administration Department under the State Council shall be made before, or, at the latest, on the date of filing (or the priority date where priority is claimed). The applicant shall submit, at the time of filing, or at the latest, within four months from the filing date, a receipt of deposit and the viability proof from the depositary institution. Where the said information is not submitted within the specified time limit, the sample of the biological material shall be deemed not to have been deposited.

(Implementing Regulations of the Patent Law, Rule 25(1))

3. Duration of Storage

The microorganism shall be stored for a period of at least 30 years from the date of deposit.

(Regulations on the Deposit of the Biological Material for the Purposes of Patent Procedure, Section 7; the Budapest Treaty, Rule 9(1))

4. Conditions for the Furnishing of Samples

Where the application for a patent for invention has deposited a sample of the biological material in accordance with the provision of Rule 25 of the Implementing Regulations, and after the application for patent for invention is published, any entity or individual that intends to make use of the biological material to which the application relates, for the purpose of experiment, shall make a request to the Patent Administration Department under the State Council, containing the following items:

1. the name and address of the requesting person;

2. an undertaking not to make the biological material available to any other person;

3. an undertaking to use the biological material for experimental purpose only before the grant of the patent right.

(Implementing Regulations, Rule 26)

CR – COSTA RICA

Registry of Industrial Property
Ministry of Justice
Apartado postal 523
2010 Zapote
San Jose

Telephone: (506) 2234 1537
Telefax: (506) 2234 1537
E-mail: cmena@rnp.go.cr, kquesada@rnp.go.cr
Internet: http://www.rnpdigital.com/propiedad_industrial/index/htm

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

HR – CROATIA

Croatian Intellectual Property Office
Ulica grada Vukovara 78
10000 Zagreb

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Internet: http://www.dziv.hr

1. Requirements for Deposit

(Patent Act and Patent Regulations Provisions (totally harmonized with Budapest Treaty))

2. Time of Deposit

(Patent Act and Patent Regulations Provisions (totally harmonized with Budapest Treaty))

3. Duration of Storage

(Patent Act and Patent Regulations Provisions (totally harmonized with Budapest Treaty))

4. Conditions for the Furnishing of Samples

(Patent Act and Patent Regulations Provisions (totally harmonized with Budapest Treaty))

CU - CUBA

Cuban Industrial Property Office
Calle Picota No. 15 entre Luz y Acosta
La Habana Vieja
La Habana 10100

Telephone: (537) 861 01 85, 862 97 71, 862 43 79, 861 36 02, 862 43 95
Telefax: (537) 833 56 10
Telex: 511290 acp cu
E-mail: ocpi@ocpi.cu
Internet: http://www.ocpi.cu

1. Requirements for Deposit

Patent applications involving a microorganism must be accompanied by a document proving the deposit of the microorganism.

(Methodology for the Elaboration of Application Documents for the Protection of Inventions)

2. Time of Deposit

At the time of filing the patent application or three months thereafter.

(Methodology for the Elaboration of Application Documents for the Protection of Inventions)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

CZ – CZECH REPUBLIC

Industrial Property Office
Antonína Čermáka 2a
160 68 Praha 6

Telephone: (420) 220 383 111
Telefax: (420) 224 324 718
E-mail: posta@upv.cz
Internet: http://www.upv.cz

1. Requirements for Deposit

The invention must be disclosed in the application for an invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Where the invention concerns an industrial microorganism for the purposes of production, the microorganism must be kept in a public collection as from the date on which the applicant's priority right begins.

(Law No. 527/1990 Coll. on Inventions and Rationalization Proposals, as amended, Section 26(2); Law No. 206/2000 Coll. on the Protection of Biotechnological Inventions, Section 5(1))

In accordance with the practice, the applicant must attach to the patent application proof that the microorganism has been deposited.

2. Time of Deposit

The deposit of the microorganism must be made not later than the date of filing of the patent application (see 1, above).

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A deposited biological material becomes available from the date on which the patent application is made available to the public.

(Law No. 206/2000 Coll. on the Protection of Biotechnological Inventions, Section 5(2))

(ii) Restrictions Concerning the Furnishing of Samples

The applicant may request that a sample of the deposited biological material shall only be available to an independent expert. This restriction shall be notified to the Industrial Property Office ("Office") at the latest on the date on which the preparations for publishing the patent application have been completed. The Office will publish such a limitation of access to the deposited biological material together with patent application in the Bulletin of the Office.

(Law No. 206/2000 Coll. on the Protection of Biotechnological Inventions, Section 5(5))

KP - DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA

Invention Office of the Democratic People's Republic of Korea
Kinmaul 1 dong
Pipha Street
Moranbong District
Pyongyang

Telephone: (850-2) 381 60 25
Telefax: (850-2) 381 44 10, 381 44 16, 381 44 27, 381 21 00
Telex: 5972 TECH KP
E-mail: kpipo@co.chesin.com

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

DK – DENMARK

Danish Patent and Trademark Office
Helgeshøj Allé 81
2630 Taastrup

Telephone: (45-43) 50 80 00
Telefax: (45-43) 50 80 01
E-mail: pvs@dkpto.dk
Internet: http://www.dkpto.dk

1. Requirements for Deposit

A sample of biological material must be deposited if the carrying out of the invention involves the use of biological material which is neither available to the public nor describable in the documents of the patent application in such a manner as to enable a person skilled in the art to carry out the invention.

(Consolidated Patents Act of 2009, Section 8a (1))

2. Time of Deposit

A sample of biological material shall be deposited not later than on the date of filing of the patent application.

(Consolidated Patents Act, Section 8a (1))

3. Duration of Storage

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of biological material becomes available from the date on which the application is made available to the public.

(Consolidated Patents Act, Section 22 (6))

(ii) Restrictions Concerning the Furnishing of Samples

The applicant may request that, until a patent has been granted, the furnishing of a sample shall only be affected to an expert in the art. If an application is refused, withdrawn or deemed to be withdrawn, the applicant may request that a sample of the deposited material shall only be furnished to an expert in the art for 20 years from the date on which the patent application was filed.

(Consolidated Patents Act, Section 22 (7))

The request for the furnishing of a sample shall be filed with the Patent Authority and shall contain a declaration to observe the restrictions on the use of the sample which appear from rules laid down by the Minister for Economic and Business Affairs. If the sample is to be furnished to an expert in the art, the declaration shall instead be given by the latter.

(Consolidated Patents Act, Section 22 (8))

DO – DOMINICAN REPUBLIC

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State Secretariat for Industry and Commerce
Avenida Los Próceres No. 11
Jardines del Norte
Santo Domingo

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Telefax: (809) 732 77 58
E-mail: e.ramirez@onapi.gob.do
Internet: http://www.seic.gov.do/onapi

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

SV - EL SALVADOR

Intellectual Property Registry
National Center of Registries (CNR)
Módulo 3
1ª Calle Poniente y 45 Avenida Norte Nº 2310
Colonia Flor Blanca
San Salvador

Telephone: (503) 2261 84 64; 2261 86 57
Telefax: (503) 2261 08 13
E-mail: propiedad.intelectual@cnr.gob.sv
Internet: http://www.cnr.gob.sv

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

EE - ESTONIA

Estonian Patent Office
Toompuiestee 7
0100 Tallinn

Telephone: (372) 6 277 900
Telefax: (372) 645 13 42
E-mail: patendiamet@epa.ee
Internet: http://www.epa.ee

1. Requirements for Deposit

If the subject of the invention is a biological material, including microorganism, or the invention requires the use of a biological material and if the said biological material is not available to the public and it cannot be described in the description of the invention in a manner which would enable a person skilled in the art to carry out the invention, the applicant must submit the document proving the deposit of the biological material.

(Patent Law of 1994, as amended to 2005, Article 19(2)(3))

2. Time of Deposit

A biological material must be deposited with an international depositary authority not later than the filing date of the patent application. The document proving the deposit of the biological material must be filed together with the patent application.

(Patent Law, *ibid*)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

FI - FINLAND

Finnish Patent and Registration Office (PRH)
Arkadiankatu 6A
00100 Helsinki

Mailing address:
P.O. Box 1160
00101 Helsinki

Telephone: (358) (0)29 509 50 00
Telefax: (358) (0)29 509 53 28
E-mail: registry@prh.fi
Internet: http://www.prh.fi

1. Requirements for Deposit

A sample of biological material shall be deposited if the carrying out of the invention involves the use of a biological material which neither is available to the public nor describable in the patent application in such a manner as to enable a person skilled in the art to carry out the invention.

(Patents Act of 1967, Section 8a)

The deposit shall be made with an international depositary authority under the Budapest Treaty or with another depositary authority recognized by the European Patent Office.

(Patents Decree of 1980, Section 17(a))

Within 16 months from the filing date of the patent application or, where priority is claimed, of the date of the claimed priority, the applicant shall inform the National Board of Patents and Registration in writing of the name of the depositary authority, and the access code given to the deposit. In case of a PCT application, this information may be filed by the applicant with the International Bureau of WIPO.

In case the applicant makes a request that the application documents be made available to the public earlier than 18 months from the date of filing or, if priority is claimed, from the priority date, the above-mentioned information shall be submitted, at the latest, together with the request for publication.

(Patents Decree of 1980, Section 17(b))

2. Time of Deposit

The deposit of the biological material shall be made no later than on the date the patent application was filed.

(Patents Act of 1967, Section 8(a))

3. Duration of Storage

The deposit shall be made in accordance with the Budapest Treaty (Patents Decree of 1980, Section l7(a)). Therefore, the duration of the storage of the biological material is the same as in Rule 9 of the Budapest Treaty.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Samples become available when the patent application is laid open to the public, that is to say, 18 months from the filing date or, if priority is claimed, from the priority date, except when the applicant requests an earlier disclosure of his application.

If the applicant so requests, samples of the deposited biological material are furnished only to an expert, until a patent has been granted or during a period of 20 years from the filing date of the application if a final decision not resulting in the grant of a patent has been taken on the application. Such a request shall be made within l6 months of the filing date of the application or, where priority is claimed, of the claimed priority date. In case of a PCT application the request may be filed by the applicant with the International Bureau of WIPO.

(Patents Act of 1967, Section 22; Patents Decree of 1980, Section 25(b))

(ii) Restrictions Concerning the Furnishing of Samples

The applicant may request that samples of the deposited biological material shall only be available to a special expert, until a patent has been granted or during a period of 20 years from the filing date of the application if a final decision not resulting in the grant of a patent has been taken on the application. An expert is a person who has declared himself willing to act as an expert according to the Finnish Patents Act and whose name is included in a list of experts published by the National Board of Patents and Registration. The expert can also be any person approved by the applicant in the individual case.

(Patents Act of 1967, Section 22; Patents Decree of 1980, Section 25(b))

The request for the furnishing of a sample shall be filed in writing with the National Board of Patents and Registration and shall contain a declaration of compliance with the following restrictions on the use of the sample:

A person wishing to obtain a sample shall give an undertaking to the applicant or the proprietor of the patent to the effect that no sample containing the deposited biological material or any material obtained from it will be used for other than experimental purposes and that no sample containing the deposited biological material or any material obtained from it will be made available to anyone else before a final decision has been given on the application or, if a patent has been granted, before the patent has expired.

If a sample may be issued only to a special expert, the request for the sample shall state the person to be called upon as an expert. The request shall be accompanied by a written undertaking from the expert to the applicant to the effect that the sample will not be used for

other than experimental purposes and will not be made available to anyone else before a patent granted on the invention has expired or before 20 years have lapsed from the filing date of the application if a final decision not resulting in the grant of a patent has been taken on the application.

The same undertaking as is prescribed with respect to a sample shall also be given with respect to biological material derived from the sample which has retained those characteristics of the deposited biological material that are essential for carrying out the invention.

The undertaking shall be attached to the request.

(Patents Decree of 1980, Section 25(a), Section 25(b))

FR - FRANCE

National Institute of Industrial Property
15, rue des Minimes
92400 Courbevoie

Telephone: (33) 1 53 04 53 04
Telefax: (33) 1 56 65 86 00
Internet: http://www.inpi.fr

1. Requirements for Deposit

Where an invention using biological matter which is not available to the public cannot be described in such a way as to allow a person skilled in the art to carry out the invention, its description shall be considered inadequate unless the biological matter has been deposited with an authorized body.

(Article L.612-5 of the Intellectual Property Code, as amended by the Law of December 8, 2004)

The description must specify:

1. the information available to the applicant on the characteristics of the microorganism;

2. the authorized body with which a sample of the culture has been deposited, and the number of the deposit.

The information specified in subparagraph 2 of the previous paragraph may be furnished either within 16 months from the filing date or the earliest date of the patent application or, if a priority is claimed, from the date of priority; or when the applicant requests publication of his or her application, if this request is submitted before the expiry of this period.

(Article R. 612-14 of the Intellectual Property Code)

2. Time of Deposit

The culture must be deposited not later than the date of filing the patent application.

(Article R. 612-14 of the Intellectual Property Code)

3. Duration of Storage

The duration of storage of deposited microorganisms is a minimum of 30 years.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Any person may ask to have access to a deposited microorganism, either as from the day of publication of the patent application (which takes place 18 months from the filing date or, if a priority is claimed, from the date of priority), or before that date if a copy of the patent application has been conveyed to him or her.

(Decree of 1995, Article R. 612-42)

(ii) Restrictions Concerning the Furnishing of Samples

The request must be filed in writing with the National Institute of Industrial Property. It must contain the name and address of the requesting party and an undertaking on his part:

(a) not to communicate the culture or a culture derived therefrom to any person unless the patent application has been refused or withdrawn or the patent has ceased to produce its effects;

(b) to use the culture or a culture derived therefrom solely for experimental purposes, except where the patent application has been refused or withdrawn, or where the fact of grant has been published. Such an undertaking, however, will not prevent the use of the sample by virtue of a compulsory or *ex officio* license.

The applicant for the patent may indicate, by a written declaration made before the completion of the technical preparations for the publication of the patent application that, until the publication of the grant of the patent or the withdrawal or refusal of the application, the deposited culture shall only be accessible to an expert designated by the applicant.

The conditions of accessing the culture and the undertaking by the expert are those mentioned above for the requesting party.

(Articles R. 612-42 and 612-43 of the Intellectual Property Code)

GE – GEORGIA

Sakartvelos Intelektualuri Sakutrebis Erovnuli Tsentri
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3300 Mtskheta

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E-mail: info@sakpatenti.org.ge
Internet: http://www.sakpatenti.org.ge

1. Requirements for Deposit

If the microorganism is given in the patent application, but it cannot be described in the application completely as to enable the skilled person to realize it or it is not commonly available, it should be deposited with an international depositary authority and the document on it is to be enclosed to materials of the application.

2. Time of Deposit

The microorganism must be deposited with an international depositary authority before the date of a priority of the application.

3. Duration of Storage

Deposited with an international depositary authority the microorganism should be stored there during the term of validity of the patent.

4. Conditions for the Furnishing of Samples

Samples of the microorganism deposited with an international depositary authority should be available to any requesting party during the term of validity of the patent.

DE – GERMANY

German Patent and Trade Mark Office
Zweibrückenstrasse 12
80331 Munich

Mailing address:
80297 Munich

Telephone: (49-89) 21 95 0
Telefax: (49-89) 21 95 22 21
E-mail: info@dpma.de
Internet: http://www.dpma.de

1. Requirements for Deposit

The requirements of a valid deposit in Germany are set forth in the Ordinance on the deposit of biological material in patent and utility model procedures (*Verordnung über die Hinterlegung von biologischem Material in Patent- und Gebrauchsmusterverfahren- Biomaterial- Hinterlegungsverordnung- BioMatHintV)*, published in the Federal Law Gazette (*Bundesgesetzblatt- BGBI)* Part I No. 6 of 28 January 2005 and in the official gazette *Blatt für Patent-, Muster- und Zeichenwesen (BIPMZ)* 2005, p. 102, and set forth in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, signed at Budapest on 28 April 1977, and the Regulations under the Budapest Treaty (German version: BIPMZ 1981, pp. 53, 59 and 237).

Under Sec. 1(1), BioMatHintV, the description required under Sec. 34(3) No. 4, Patent Law, will be deemed sufficient for granting patent protection for biological material or the use of biological material if, in addition to the description, the biological material has been deposited with a recognized depositary institution. Consequently, a deposit is to be considered if the invention cannot be described in such a manner as to enable a person skilled in the art to carry out the invention (Sec. 34(8) 1st sentence, Patent Law). The deposit may ensure that the requirement of disclosure of the invention under Sec. 34(4), Patent Law, is met.

The applicant has a choice of **two ways** of depositing biological material: the first option is a deposit **under the Budapest Treaty** and the Regulations with a recognized international depositary authority (Secs. 8,1, BioMatHintV).

Alternatively, the sample can be deposited outside the Budapest Treaty with a "recognized scientific institution" under Sec. 2, BioMatHintV. This scientific institution must guarantee that samples will be duly stored and furnished in accordance with the Ordinance on the deposit of biological material (*Biomaterial- Hinterlegungsverordnung)*. The institution must be legally, economically and organisationally independent of the applicant and the depositor. International depositary authorities recognized under the Budapest Treaty and the Regulations meet these requirements.

2. Time of Deposit

The biological material must be deposited with a recognized depositary institution not later than the date of filing or, if a priority has been claimed, the priority date (Sec. 1(1) No. 1, BioMatHintV).

If the biological material has previously been deposited by a third party with a recognized depositary institution and is available to profession circles, and if it is ensured that it can be used for the duration of the prescribed storage period (cf. item 3), another deposit is not required (Sec. 1(3), BioMatHintV).

3. Duration of Storage

Where a deposit is made **under the Budapest Treaty**, the minimum storage period is five years after the most recent request for furnishing a sample of the deposited biological material was received by the depositary authority and, in any case, 30 years from the date of deposit (Rule 9.1, Regulations under the Budapest Treaty).

Where a deposit is made **outside the Budapest Treaty**, the deposited biological material must be stored for a period of five years from the receipt of the most recent request for furnishing a sample of the deposited biological material and, in any case, for at least another five years after expiry of the maximum statutory term of protection of all IP rights referring to the deposited biological material (Sec. 7, BioMatHintV).

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Where a deposit is made **under the Budapest Treaty**, samples of deposited biological material shall be available from the date of publication under the conditions provided for in Rule 11 of the Regulations under the Budapest Treaty. It is not necessary to issue a specific declaration of release. However, the depositor must undertake not to take back the material during the fixed storage period.

Where a deposit is made **outside the Budapest Treaty**, the applicant must issue an irrevocable declaration of release (Sec. 4, BioMatHintV) making the deposited biological material available without reservation to the depositary institution from the date of filing until the end of the period of storage for the purpose of issuing samples in accordance with Sec. 5, BioMatHintV. In case of a third party deposit, the applicant must furnish documentary evidence that the deposited biological material has been made available accordingly by the depositor (Sec. 4(1) 2nd sentence, BioMatHintV).

(ii) Restrictions Concerning the Furnishing of Samples

Where a deposit is made **outside the Budapest Treaty**, samples of the material will be furnished only to the depositor himself or to the German Patent and Trade Mark Office prior to the date of advertisement of the mention of the publication of the application (Sec. 32(5) Patent Law) concerning the patent whose subject matter involves the deposited biological material. During this period, third parties will receive a sample of the deposited biological material only by decision of the German Patent and Trade Mark Office granting file inspection under Sec. 31(1), 1st sentence, Patent Law, or by court decision (Sec. 5(1), No. 1c, BioMatHintV).

The deposited biological material shall be available upon request to any person from the date of advertisement of the mention of the publication of the application until the grant of the patent (Sec. 5(1), No. 2, BioMatHintV). For this period, however, the depositor may request that a sample of the deposited biological material be furnished exclusively to an independent expert, nominated by the requester (Sec. 5(1), No. 2, 2nd half-sentence, BioMatHintV). In case of this so-called "expert option", the sample will be furnished to the nominated expert alone (Sec. 5(1), No. 2, 2nd half-sentence, BioMatHintV).

After the patent grant, samples of the deposited material will be furnished upon request to any person (Sec. 5(1), No. 3, BioMatHintV).

For gaining access to the deposited biological material, the requester must enter into an undertaking vis-à-vis the applicant, and in case of a third party deposit also vis-à-vis the depositor, not to make samples of the deposited biological material or a material derived from it available to third parties for the duration of validity of any IP right referring to the deposited biological material. He must also undertake to use the deposited biological material or a material derived from it for experimental purposes only (Sec. 6(1) Nos. 1 and 2, BioMatHintV).

The German language leaflet "*Merkblatt für die Hinterlegung von biologischem Material für die Zwecke von Patent- und Gebrauchsmusterverfahren*", available at http://www.dpma.de/docs/service/formulare/patent/x1200.pdf, contains more information on this topic.

GR - GREECE

Industrial Property Organization (OBI)
5, Gianni Stavroulaki St.
Paradissos Amaroussiou
15125 Athens

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E-mail: info@obi.gr
Internet: http://www.obi.gr

1. Requirements for Deposit

If an invention relates to biological material not available to the public nor can it be described in the patent application in a manner that a person skilled in the art is able to carry out the invention or entails the use of such material, the description is considered adequate only if:

a) the biological material has been deposited with a recognized depositary authority,
b) the application contains information on the characteristic features of the deposited biological material,
c) the depositary authority and the reference number of the deposit are specified.

All international depositary authorities recognized by virtue of article 7 of the Budapest Treaty of April 28, 1997 are considered recognized depositary authorities.

(Article 11 par. 1 of Presidential Decree No. 321/2001)

2. Time of Deposit

The biological material shall be deposited with a recognized depositary authority no later than the date of filing of the patent application.

(Article 11 par. 1 a of Presidential Decree No. 321/2001)

3. Duration of Storage

As provided in Rule 9.1 of the Budapest Treaty i.e. five years after the most recent request for the furnishing of a sample, and, in any case, thirty years after the date of deposit.

(Law no. 2128/1993)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

a) Samples are furnished to anyone authorized under international treaties or under national patent law up to the first publication of the patent application.
b) Between publication and grant of the patent, samples can be furnished to anyone or to an independent expert only, if the applicant requests so. Such requests can be made before completion of the technical preparations for the publication of the patent application.
c) Samples are available to anyone upon grant of the patent.

(Article 11 par. 2 and par. 5 of Presidential Decree No. 321/2001)

In case of a withdrawn or refused patent application, following an applicant's request, samples are available only to independent experts for 20 years from the date of filing of the patent application. Such requests can be made before completion of the technical preparations for the publication of the patent application.

(Article 11 par. 4 and 5 of Presidential Decree No. 321/2001)

(ii) Restrictions Concerning the Furnishing of Samples

The person requesting the sample undertakes the following during the term of the patent:

a) not to make the biological material or any material derived from it available to third parties,
b) not to use the biological material or any material derived from it, except for experimental purposes, unless the applicant or proprietor of the patent expressly grant a waiver.

(Article 11 par. 3 of Presidential Decree No. 321/2001)

If the biological material deposited ceases to be available from the recognized depositary authority, a new deposit of the material should take place under the terms laid down in the Budapest Treaty. Following such a deposit, a statement signed by the depositor certifying that the newly deposited biological material is the same as that originally deposited, should be filed before the Industrial Property Organization.

(Article 12 of Presidential Decree No. 321/2001)

GT – GUATEMALA

Registry of Intellectual Property
Ministry of Economic Affairs
7a avenida 7-61, Zona 4, Primer Nivel
Ciudad Guatemala C.A. 01004

Telephone: (502) 23 24 70 70
Telefax: (502) 23 32 01 16
E-mail: repiweb@rpi.gob.gt
Internet: www.rpi.gob.gt

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

HN - HONDURAS

Secretary for Industry and Commerce
Directorate General of Intellectual Property
Planta Baja - Edificio Fenaduanah
Boulevard Kuwait
Tegucigalpa

Telephone: (504) 235 4088
Telefax: (504) 235 3685

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

HU - HUNGARY

Hungarian Intellectual Property Office (HIPO)
Garibaldi u. 2
1054 Budapest

Mailing address:
P.O. Box 552
1374 Budapest

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Telefax: (36-1) 331 25 96
E-mail: sztnh@hipo.gov.hu
Internet: http://www.hipo.gov.hu

1. Requirements for Deposit

If an invention involving the use of or concerning biological material which is not available to the public cannot be disclosed in the patent application as required in Article 60(1) of Act XXXIII of 1995 on the Protection of Inventions by Patents (herein after referred to as: Patents Act), it must be proved that the biological material has been deposited no later than the date of filing of the patent application under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

(Article 63(1) Patents Act)

2. Time of Deposit

The biological material shall be deposited no later than the date of filing of the patent application.

The proof that the biological material has been deposited shall be submitted within a period of 16 months after the date of the earliest priority.

(Article 63(1) and 63(3) Patents Act)

3. Duration of Storage

The National Collection of Agricultural and Industrial Microorganisms stores biological material for a period of at least five years after the most recent request for the furnishing of a sample of the deposited biological material was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

(Article 1(2) of the Government Decree 61/2006 (III. 23) in conjunction with Rule 9.1 of the Regulations under the Budapest Treaty)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Access to the deposited biological material shall be provided through the supply of a sample:

1. up to the publication of the patent application, to those persons who are authorized to inspect the files under the provisions of Article 53(1) Patents Act;

2. between the publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

3. after the patent has been granted, and notwithstanding revocation or cancellation thereof, to anyone requesting it.

(Article 63(4) Patents Act)

(ii) Restrictions Concerning the Furnishing of Samples

The person to whom a sample has been supplied may not make the sample or any material derived from it available to third parties before the termination of the patent granting procedure or before the lapse of the definitive patent protection and, with the exception of a holder of a compulsory license, he may use the sample or any material derived from it only for experimental purposes, unless the applicant or the patentee expressly waives the prescription of such obligation. A material is deemed to be derived if it has those characteristics of the deposited biological material, which are essential to carry out the invention.

(Article 63(5) Patents Act)

IS - ICELAND

The Icelandic Patent Office
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150 Reykjavik

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Internet: http://www.els.is

1. Requirements for Deposit

Art. 8(6) of the Patents Act No. 17/1991 (as amended in 2004):

If it is necessary for the invention to use biological material which is neither available to the public nor can be described in the application in such a manner that, based on the application, a person skilled in the art would be able to execute the invention, a sample of the biological material must be deposited no later than the filing date of the application.

Art. 44 of Regulation on Patents No. 477/2012:

Samples of biological material as referred to in Art. 8(6) of the Patents Act must be deposited with an institution which is an internationally recognized depositary under the Treaty done at Budapest 28 April 1977 on the International Recognition of the Deposit of Biological Material for the Purposes of Patent Procedure (the Budapest Treaty) or with other depositaries recognized by the European Patent Office.

Deposits shall be in accordance with the provisions of the Budapest Treaty.

WIPO publishes a list of those institutions which are internationally recognized depositaries for biological material under the Budapest Treaty.

2. Time of Deposit

Art. 8(6) of the Patents Act No. 17/1991 (as amended in 2004):

[…a sample of the biological material must be deposited no later than the filing date of the application.]

Art. 45 of Regulation on Patents No. 477/2012:

If an applicant has deposited a sample of biological material, he/she shall, within 16 months from the date of filing or, if priority is claimed, from the priority date, inform the Icelandic Patent Office in writing of the institution where the deposit has been made and which deposit number the institution has allotted the sample. In the case of international applications, WIPO shall be provided with this information within the same time limit.

If, prior to the expiry of the time limit referred to in the first paragraph, the applicant requests that documents relating to the application be made available to the public

earlier than prescribed in Art. 22(1) and (2) of the Patents Act, the applicant shall provide the information referred to in the first paragraph at the latest when the request is submitted. If, prior to the expiry of the time limit referred to in the first paragraph, the applicant requests early publication of the application under Art. 21(2)b of the PCT, the applicant shall provide WIPO with the said information at the latest when the request is submitted.

If a deposited sample of biological material has been transferred from one international depositary to another, as provided for in Rule 5.1 of the Regulations under the Budapest Treaty, the applicant shall, as soon as possible after receiving a receipt for the transfer of the sample, inform the Icelandic Patent Office of the new deposit number and the depositary.

The Icelandic Patent Office may require the applicant to submit a copy of the receipt issued by the depositary for deposit of a sample as referred to in the first or third paragraph.

3. Duration of Storage

Art. 8(6) of the Patents Act No. 17/1991 (as amended in 2004):

From that time on, the sample shall remain constantly on deposit so that whoever has authorization according to this Act will be able to receive a sample of the biological material in this country. Regulations shall stipulate where such deposits may be made.

4. Conditions for the Provision of Samples

Art. 22(6)-(8) of the Patents Act No. 17/1991 (as amended in 2004):

If a sample of biological material has been deposited in accordance with the provisions of Article 8, anyone may be supplied a sample in accordance with the provisions of Paragraphs 1, 2 and 3. However, this does not mean that anyone is to be supplied with a sample who according to regulations or legal provisions is unauthorized to deal with deposited biological material. Nor shall samples be supplied to anyone who due to the harmful properties of the biological material is considered incompetent of processing the sample without considerable risk.

Notwithstanding the provisions of Paragraph 6, the applicant may demand that a sample of the biological material be supplied only to independent experts until a patent is granted. If an application has been refused or dismissed or may be considered withdrawn the applicant may, for 20 years from the filing date of the application, demand that samples of the biological material be supplied only to independent experts. The Minister issues rules on such requests, on time limits for presenting such requests and on who may be considered independent experts according to this stipulation.

The request for the furnishing of a sample shall be filed in writing with the Patent Authority and shall contain a declaration of observance of the restriction on the use of the sample in accordance with the rules laid down by the Minister. If the sample is to be furnished to an expert in the art then he shall make the declaration rather than the person requesting the sample.

Art. 47 of Regulation on Patents No. 477/2012:

A request for provision of a sample of deposited biological material as referred to in Art. 22(8) of the Patents Act shall be presented in accordance with Rule 11 of the Regulations under the Budapest Treaty.

If a request is made, cf. the first paragraph, before a final decision has been made on the application to which the deposited sample relates, the person requesting the sample shall undertake to use the sample solely for research until a final decision has been made on the application. The person concerned shall also undertake not to allow any other person access to the sample until a final decision has been taken on the application or, if a patent is granted, until that patent has ceased to have effect. The above shall also apply to specimens of deposited samples which relate to a patent granted.

The person requesting the sample shall make the same undertakings in regard to cultures which are derived from the samples and which still exhibit those characteristics important for the use of the invention.

A request for a sample shall be accompanied by a written declaration that the person requesting the sample undertakes to fulfil the obligations above.

Art. 48 of Regulation on Patents No. 477/2012:

An applicant's request pursuant to Art. 22(7) of the Patents Act, to the effect that samples be provided only to independent experts, must be submitted to the Icelandic Patent Office no later than the date on which the application is made available to the public as provided for in Art. 22 of the Act.

The Icelandic Patent Office shall lay down requirements as to who are to be considered independent experts. Only those persons who satisfy the requirements or who are approved by an applicant or patent holder in each instance may be provided with samples.

A request for provision of a sample as referred to in Art. 22(7) of the Patents Act shall be presented in accordance with Rule 11 of the Regulations under the Budapest Treaty. If a sample may only be provided to an expert, the request shall state the name of the expert who is requested to undertake examination of the sample. Furthermore, the request shall be accompanied by a statement from the expert obliging him-/herself towards the applicant to the extent described in Art. 47(2) and (3) of this Regulation.

Art. 50 of Regulation on Patents No. 477/2012:

If a request for a sample has been submitted, and nothing in the Patents Act or this Regulation prevents it being granted, the Icelandic Patent Office shall issue a statement to that effect. The Icelandic Patent Office shall send the request for provision of the sample and the statement to the institution where the biological material is deposited, with a copy to the applicant or patent holder.

If the Icelandic Patent Office is of the opinion that the statement referred to in the first paragraph cannot be issued, the party requesting provision of the sample shall be notified thereof. Such a decision may be referred to the Board of Appeal for Industrial Intellectual Property Rights within two months of the notification by the Icelandic Patent Office.

5. New deposit of a sample

Art. 8(7) of the Patents Act No. 17/1991 (as amended in 2004):

If a deposited biological material becomes inactive or it is impossible for other reasons to supply samples of it, it may be exchanged with a sample of the same culture within the prescribed time and in other aspects in accordance with the provisions of regulations. In such instances, the new deposit is considered to have been made on the same date as the previous deposit.

Art. 46 of Regulation on Patents No. 477/2012:

A new deposit of a sample of a biological material, as referred to in Art. 8(7) of the Patents Act, must comply with the provisions of the Budapest Treaty and the Regulations under the treaty regarding new deposits. The new deposit shall be made within three months from the date on which the depositor received notification from the depositary that provision of a sample of the deposited biological material was not possible.

If a depositary recognised under the Budapest Treaty or by the European Patent Office has ceased operations as an international depositary for the type of biological material which the deposit involved, or if the depositary no longer fulfils the requirements stipulated for depositaries, and if the depositor has not obtained knowledge of this within 6 months of WIPO publishing an announcement thereof, the new deposit may be made within nine months of the publication of that announcement.

The applicant shall, within four months of the date on which the new sample of biological material was deposited with another institution, provide the Icelandic Patent Office with information on the deposit with the new depositary. If the time limit provided for in Art. 45(1) and (2) expires later, however, it will suffice to provide the information within that time limit.

6. Deposit of derived samples

Art. 49 of Regulation on Patents No. 477/2012:

In spite of the issuance of a statement, as referred to in Articles 47 and 48, the deposit of a sample of biological material, which is derived from a specimen provided, is permitted for a new patent application if deposit of the derived sample is necessary for the new application.

IN – INDIA

Indian Patent Office
Intellectual Property Office Building
Sector-14, Block No. 32
Dwarka
New Delhi 110 075

Telephone: (91-11) 25 30 02 00, 28 03 43 10
Telefax: (91-11) 28 03 43 01
E-mail: kolkata-patent@nic.in
Internet: http://www.ipindia.nic.in

1. Requirements for Deposit

It is obligatory.

2. Time of Deposit

Not later than the date of filing the application in India.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

Access to the samples should be available only after the date of application for patent in India or if a priority is claimed after the date of priority.

IE – IRELAND

Patents Office
Government Buildings
Hebron Road
Kilkenny

Telephone: (353-56) 772 01 11
Telefax: (353-56) 772 01 00
E-mail: patlib@patentsoffice.ie
Internet: http://www.patentsoffice.ie

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

IL - ISRAEL

Israel Patent Office
Technology Park
Building 5, Malcha
Jerusalem 96951

Mailing address:
P.O. Box 53420
Jerusalem 91533

Telephone: (972-2) 565 1670
Telefax: (972-2) 565 1700
E-mail: OritR@Justice.gov.il
Internet: http://index.justice.gov.il/units/rashamhaptentim/pages/default.aspx

1. Requirements for Deposit

If the subject of the invention is a biological material or a process for the production of a biological material or an invention that involves the use of a biological material, and if the biological material was deposited with a deposit institution, then part of the description of the invention or of the manner of its performance may consist of referral to that deposit.

For purposes of this paragraph, a biological material is a biological material that is not easily available to the public, which cannot be described in a manner that will enable a skilled person to perform the invention, on condition that the biological material can be duplicated or reproduced, either independently or in a host animal or plant cell.

Article 12(b) to The Patent Law, 5727-1967)

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

IT - ITALY

Italian Patent and Trademark Office
19, via Molise
00187 Roma

Telephone: (39-06) 47 05 5800
Telefax: (39-06) 47 05 5635
E-mail: contactcenteruibm@mise.gov.it

1. Requirements for Deposit

Where an invention deals with or involves the use of biological material which neither is available to the public nor describable in the patent application in such a way as to enable a person expert in the field to carry out the invention, a sample of this biological material shall be deposited at an international depositary authority under the Budapest Treaty, so that the description can be considered sufficient according to Article 51, paragraph 3, of the Intellectual Property Code (Legislative Decree No. 30/2005 as amended by the Legislative Decree No.131/2010).

Furthermore, the description must specify:

- the relevant information available to the applicant about the characteristics of the biological material
- the authorized depositary authority where the culture of the biological material has been deposited, as well as the number and the date of the said deposit

(Article 162, paragraph 1, of the Legislative Decree No. 30/2005)

The information specified above may be provided either within 16 months from the filing date or earlier in the case of anticipated public accessibility or notification to third parties according to Article 53, paragraphs 3 and 4, of the Legislative Decree No. 30/2005.

2. Time of Deposit

The deposit must be made not later than the filing date of the patent application.

3. Duration of Storage

On the basis of the Budapest Treaty, the expected minimum storage period is five years after the most recent request for providing a sample of the deposited biological material was received by the depositary authority and, in any case, 30 years from the date of deposit (Rule 9.1, Regulations under the Budapest Treaty).

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited biological material becomes available:

- from the date on which the patent application is open to public inspection (normally, l8 months after the filing date) until the grant of the patent application
- or for a period of 20 years from the filing date in the case in which the patent application is rejected or withdrawn

(Article 162, paragraphs 3a and 3b, of the Legislative Decree No. 30/2005)

(ii) Restrictions Concerning the Furnishing of Samples

The requesting party should undertake vis-à-vis the applicant or the proprietor not to make the culture available to any third party and also undertake that the culture will only be used through a named qualified expert for experimental purposes unless the applicant or the patent proprietor expressly waives such an undertaking. The designated expert is equally responsible for any abuse by the requesting party.

(Article 162, paragraph 4, of the Legislative Decree No. 30/2005)

JP - JAPAN

Japan Patent Office
Tokkyocho
4-3 Kasumigaseki 3-Chome
Chiyoda-ku
Tokyo 100-8915

Telephone: (81-3) 35 92 13 08
Telefax: (81-3) 35 81 06 59, 35 01 06 59
Internet: http://www.jpo.go.jp

1. Requirements for Deposit

If an invention involves or uses a microorganism which is not available to the public, a culture of the microorganism must be deposited with an official depositary authority designated by the Commissioner of the Japan Patent Office or with an international depositary authority under the Budapest Treaty. The International Patent Organism Depositary (IPOD), attached to NITE International Patent Organism Depositary (NITE-IPOD), and NITE Patent Microorganisms Depositary (NPMD), attached to the National Institute of Technology and Evaluation (NITE), are designated as official depositary authorities.

(Regulations under the Patent Law, Rule 27*bis*)

2. Time of Deposit

A person desiring to file a patent application for an invention involving or using a microorganism shall attach to the request a copy of the latest receipt referred to in Rule 7 of the Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as "Treaty") for the deposit of the microorganism issued by the international depositary authority defined in Article 2(viii) of the Treaty, or a document certifying the fact that the microorganism has been deposited with an institution designated by the Commissioner of the Patent Office, except where the microorganism is readily available to a person skilled in the art to which the invention pertains.

(Regulations under the Patent Law, Rule 27*bis*)

3. Duration of Storage

Under the patent practice of Japan, with regard to national deposits, a deposited microorganism is to be kept in storage until the expiration of the relevant patent, whereas, with regard to international deposits, the duration of storage of microorganisms is at least 30 years.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available as from the time of registration for the establishment of a patent right.

A sample is available, however, even before the time of the said registration, provided that the requesting party is either:

(a) a person who has received a written warning asking him to pay compensation for having commercially worked the invention involving or using the microorganism in question; or

(b) an applicant who has received notice of refusal from the Patent Office, in which case the applicant must reply to such notice.

(Regulations under the Patent Law, Rule 27*ter*)

(ii) Restrictions Concerning the Furnishing of Samples

The furnishing of samples of deposited microorganisms is restricted to the cases where the samples are used for experiments or research purposes. The released sample may not be transferred to third parties.

(Regulations under the Patent Law, Rule 27*ter*)

JO – JORDAN

Industrial Property Protection Directorate
Ministry of Industry and Trade
El-Difah El Madani Street
P.O. Box 2019
11181 Amman

Telephone: (962 6) 562 90 30
Telefax: (962 6) 568 23 31

1. Requirements for Deposit

The patent owner shall file complete particulars on the applications on the same patent subject matter which he filed in other countries including the results of such applications. If applications relating to biologic substances or microorganisms are filed, the applicant shall submit a proof that he filed specimen to one of the specialized centers.

(Patent Law No. 32 of 1999 and its amendments - Article 8(2))

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

KZ - KAZAKHSTAN

National Institute of Intellectual Property
Left Bank, House of Ministries,
8 Orynbor Street,
Entrance 18B, block n° 4
Astana

Telephone: 8 (7172) 50 25 75
Telefax: 8 (7172) 50 25 66
E-mail: kazpatent@kazpatent.kz
Internet: www.intellkaz.kz, www.kazpatent.kz

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

KG – KYRGYZSTAN

State Service of Intellectual Property and Innovation
under the Government of the Kyrgyz Republic

62, Moskovskaya Street
Bishkek 720021

Telephone: (996-312) 680819
Telefax: (996-312) 681703
E-mail: info@patent.kg; inter@patent.kg
Internet: http://www.patent.kg

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

LV - LATVIA

Latvian Patent Office
7(70) Citadeles iela
1010 Riga

Telephone: (371) 709 96 22
Telefax: (371) 709 96 50
E-mail: valde@lrpv.gov.lv
Internet: http://www.lrpv.gov.lv

1. Requirements for Deposit

If an invention relates to the use of a specific microorganism with restricted availability, the applicant must submit a document to the Patent Office on the deposit of the culture of the respective microorganism in one of the international depositary authorities.

(Patent Law, 1995, Article 7(8))

2. Time of Deposit

The document on the deposit of the culture of the respective microorganism should be filed with the Patent Office either along with the application or no later than three months from the filing date of the application.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

LI – LIECHTENSTEIN

Swiss Federal Intellectual Property Institute
Einsteinstrasse 2
3003 Berne
Switzerland

Telephone: (41-31) 325 25 25
Telefax: (41-31) 325 25 26
E-mail: spedition@ipi.ch
Internet: http://www.ipi.ch

[Swiss law applies]

LT - LITHUANIA

State Patent Bureau of the Republic of Lithuania
Kalvarijų str. 3
09310 Vilnius

Telephone: (370-5) 278 02 50
Telefax: (370-5) 275 07 23
E-mail: spb@vpb.gov.lt
Internet: http://www.vpb.lt/index.php?l=EN

1. Requirements for Deposit

A specification must disclose the invention in such full and clear terms as to enable any person skilled in the art to which it pertains to use the invention. Where a patent application is filed for an invention involving the use of or concerning biological material which is not available to the public and which cannot be described in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description of the invention shall be considered inadequate. This provision shall not apply, if the biological material has been deposited no later than the date on which the patent application was filed with a depositary institution and a document confirming the deposit has been submitted to the State Patent Bureau.

(Patent Law of the Republic of Lithuania (1994, as amended in 2011), Art. 16).

The patent application filed with the State Patent Bureau shall be accompanied by a document about the deposition of such biological material. The document shall contain the name and address of the depository institution and (or) collection, the name and address of the depositor, identification indications of the deposited material (symbol, registration number, etc.), the date when the biological material was deposited and the signature of the authorized person of the depositary institution.

(Rule on Filing and Examination of Patent Applications and Granting Patents (2011) Para XIV)

2. Time of Deposit

Deposit date must be earlier than the date of filing a patent application or, if priority is claimed, the date of priority.

(Rule on Filing and Examination of Patent Applications and Granting Patents (2011) Para XIV)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

LU – LUXEMBOURG

Intellectual Property Office (Luxembourg)
Ministry for Economy and Foreign Trade
19-21, Boulevard Royal
2449 Luxembourg-Ville

Mailing address:
2914 Luxembourg

Telephone: (352) 247 841 13
Telefax: (352) 22 26 60 (Group 3)
E-mail: dpi@eco.etat.lu
Internet: http://www.eco.public.lu/

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

MX – MEXICO

Mexican Institute of Industrial Property
Arenal 550
Col. Pueblo Santa Maria Tepepan
C.P. 16020
Mexico D.F.

Telephone: (52-5) 334 07 24, 334 07 00 (ext. 10025, 10078, 10095)
Telefax: (52-5) 555 44 31
E-mail: buzon@impi.gob.mx
Internet: http://www.impi.gob.mx

1. Requirements for Deposit

The Industrial Property Law and the Regulations thereunder provide for the compulsory requirement of the deposit of biological material for the purposes of granting a patent.

The articles of the Industrial Property Law and the Regulations thereunder, together with the requirements for deposits subject to national rules, are as follows:

Industrial Property Law

Article 47: The patent application shall be accompanied by:

I. A description of the invention, which shall be sufficiently clear and complete to be fully understood and where appropriate to serve as a guide for a person with average skill in the art to make it; it shall also mention the best method known to the applicant of carrying out the invention when this is not clear from the description thereof.

In the case of biological material where the description of the invention cannot itself be sufficiently detailed, the application shall be completed with a record of the deposit of the material at an institution recognized by the Institute, in accordance with the provisions of the Regulations under this Law;

Regulations under the Industrial Property Law

Article 28: The description shall be drafted according to the following rules:

V. Where the deposit of biological material is required under the provisions of the second paragraph of Article 47.I of the Law, it shall mention that the said deposit has been made and shall state the name and address of the depository institution, the date on which the deposit was made and the number allocated to it by the said institution, describing also, to the extent possible, the nature and characteristics of the deposited material in so far as they are relevant to the disclosure of the invention;

Article 34: The record of deposit of biological material referred to in the second paragraph of Article 47.I of the Law shall be submitted within six months following the date on which the applicant files the corresponding patent application, and the said applicant shall retain the right to the recognition by the Institute of the date and hour of the handing over of the application as the date and hour of filing, provided that the record of deposit shows that the deposit occurred prior to the date and hour of the handing over of the application, failing which the date on which the record was shown to the Institute shall be recognized as the filing date of the application.

Where the applicant fails to show the record in the specified period, the application shall be considered abandoned.

Article 35: For the purposes of the second paragraph of Article 47.I of the Law, the Institute shall accord recognition to institutions that have the character of international depository authorities for biological material, and also to national institutions, in accordance with internationally recognized criteria and rules.

The Institute shall publish a list of the institutions recognized under this Article in the *Diario Oficial (Federal Gazette)*.

Article 37: For the purposes of the second paragraph of Article 47.I of the Law, a record of the deposit of biological material shall be required in the following cases:

I. Where a microorganism is claimed in itself;

II. Where the biological material referred to in the application is not publicly available, and

III. Where a description that has been given of the biological material is insufficient for a person skilled in the art to reproduce it.

To date, no Mexican institutions exist which are recognized as authorities for the deposit of microorganisms, in accordance with the Budapest Treaty, which satisfy the requirements established in said treaty, the Regulations thereunder and the Guides to the Deposit of Microorganisms under the Budapest Treaty. For these reasons, to date the only institutions recognized for the deposit of microorganisms for patent purposes are the international authorities for the deposit of biological material, recognized under the Budapest Treaty.

2. Time of Deposit

The record of deposit of biological material must be submitted within six months of the date on which the applicant files the patent application. In such a case, the applicant retains the right to recognition by the Institute of the date and hour of handing over of the application as the date and hour of filing, provided that the deposit record establishes that said deposit was made prior to the date and hour of handing over of the patent application.

Where the deposit has not been made subject to the conditions referred to above, Article 34 of the Regulations under the Industrial Property Law states that the Institute shall recognize as the application filing date the date on which the corresponding record of deposit is shown to the Institute, i.e. that where the deposit is not handed over within six months of the application filing date, the legal application filing date changes to become the date on which the record of deposit of the biological material is shown.

Similarly, Article 34 of the Regulations under the Industrial Property Law states that where the applicant does not show the record of deposit within the prescribed deadlines, the application shall be considered abandoned.

No provisions exist in the Industrial Property Law or in the Regulations thereunder relating to the validity or lapse of the deposit during the period of validity of a patent. For such characteristics of validity or lapse the standards established by the Budapest Treaty, the Regulations thereunder and the Guides to the Deposit of Microorganisms under the Budapest Treaty therefore apply.

3. Duration of Storage

No provisions exist in the Industrial Property Law or in the Regulations thereunder in relation to the duration of storage of the “microorganism” deposited, for which reason the standards established by the Budapest Treaty, the Regulations thereunder and the Guides to the Deposit of Microorganisms under the Budapest Treaty shall apply for that purpose.

4. Conditions for the Furnishing of Samples

Since no Mexican institutions exist which are recognized as Authorities for the Deposit of Microorganisms, in accordance with the Budapest Treaty, and which satisfy the requirements of said treaty, the Regulations thereunder and the Guides to the Deposit of Microorganisms under the Budapest Treaty, no requirements are therefore established in the Industrial Property Law, or in the Regulations thereunder, for the conditions in which the furnishing of samples of biological material has to take place.

Nor do requirements exist in the national rules, i.e. in the Industrial Property Law or the Regulations thereunder, in relation to the conditions in which the furnishing of samples of biological material has to take place.

In turn, no conditions are established in the Industrial Property Law or in the Regulations thereunder as regards the availability of the samples deposited by an interested party, nor are there rules regarding information on the deposited samples with regard to the restrictions on the availability of the samples of the deposited organisms.

In view of the above, in order to satisfy the requirements for the furnishing of samples, information thereon and availability restrictions therefor, the standards established in the Budapest Treaty, the Regulations thereunder and the Guides to the deposit of Microorganisms under the Budapest Treaty shall apply.

MC - MONACO

Intellectual Property Division
Department of Economic Expansion
9, rue du Gabian
98000 Monaco (Principauté)

Telephone: (377) 98 98 84 39
Telefax: (377) 92 05 75 20
E-mail: mcpi@gouv.mc
Internet: http://www.gouv.mc

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

ME - MONTENEGRO

Intellectual Property Office
Bulevar Revolucije 5
81000 Podgorica

Telephone: (382-20) 24 64 99
Telefax: (382-20) 24 64 96
E-mail: ziscg@cg.yu
Internet: http://www.gov.me

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

MA – MOROCCO

Industrial and Commercial Property of the Office of Morocco (OMPIC)
RS 114 Km 9,5 Route de Nouasseur
Sidi Maârouf
Casablanca
Morocco

Telephone: (212) 658 855 20 - (212 22) 533 51 67
Telefax: (2122) 523 354 80
E-mail : adil.elmaliki@ompic.org.ma - elmaliki@ompic.org.ma

1. Requirements for Deposit

No provision

2. Time of Deposit

No provision

3. Duration of Storage

No provision

4. Conditions of Furnishing of Samples

No provision

NL - NETHERLANDS

Netherlands Patent Office
Prinses Beatrixlaan 2
2595 AL Den Haag

Mailing address:
P.O. Box 10366
2501 HJ Den Haag

Telephone: (31-88) 602 66 60
Telefax: (31-88) 602 90 24
E-mail: octrooien@rvo.nl
Internet: http://www.rvo.nl/octrooien

1. Requirements for Deposit

Where an invention involves the use of a microorganism,

(1) The specification of the invention shall:

(a) contain the data at the disposal of the applicant which are relevant to the properties of the microorganism;

(b) mention the institution with which, the number under which and the date on which the culture of the microorganism has been deposited.

(2) Together with the application shall be submitted:

(a) a declaration to the effect that the applicant, pursuant to Section 31F, irrevocably gives permission for the furnishing of samples of the culture of the microorganism deposited by him;

(b) a copy of the receipt issued by the institution with which the culture of the microorganism has been deposited;

(c) a copy of the declaration referred to in Section 31D.

(3) The number referred to in paragraph (1)(b) and the copy referred to in paragraph (2)(b) may also be furnished within a time limit of one month after the filing of the application.

(Patents Rules, as amended to 1991, Section 31B)

A deposit of a microorganism shall be accompanied by a written statement of the depositor, containing:

(a) a declaration stating the circumstances as well as the properties of the microorganism which are of interest for the cultivation, the storage, the handling and the viability of the microorganism;

(b) an indication of the method permitting the checking of the presence of the microorganism;

(c) an identification reference and, where possible, the scientific description and the proposed taxonomic designation of the microorganism.

(Patents Rules, as amended to 1991, Section 31D)

(4) The deposit of cultures of microorganisms may be effected with:

(a) an institution which, pursuant to Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure has acquired the status of international depositary authority, or

(b) an institution designated by the Patent Office.

(Patents Rules, as amended to 1991, Section 31C(1))

2. Time of Deposit

The deposit of a microorganism must be made at the date of filing of the patent application.

(Patents Rules, as amended to 1991, Section 31B)

3. Duration of Storage

The depositary institution shall store the deposited microorganisms at least for 30 years after the date of deposit.

(Patents Rules, as amended to 1991, Section 31C(c))

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

(1) The culture of a deposited microorganism shall be available from the date of filing of the relevant patent application for the furnishing of samples in pursuance of Section 31F until the date on which it has become certain no patent will be granted on this application or until the date on which the patent granted on that application has lost its effect.

(2) Where the culture of a microorganism ceases to be available with the institution with which the culture has been stored because the microorganism is not viable any more or the institution is not capable of furnishing samples of that culture for other reasons and the culture has not been transferred to another institution as referred to in Section 31C(1) where it remains accessible, it shall nevertheless be considered to have remained available where within a time limit of three months after the date on which the institution or the Patent Office

has notified the depositor of the fact that the culture is no longer available, a new deposit of the relative microorganism is effected and a copy of the receipt of the new deposit, issued by the relevant institution, indicating the number of the patent application or the patent, has been sent to the Patent Office.

(3) Paragraph (2) shall apply mutatis mutandis where the institution with which the culture has been stored has discontinued the performance of its functions in respect of the cultures of microorganisms deposited with it or where it does not comply any more with the specification in Section 31C(1), provided that the time limit of three months referred to in paragraph (2) shall begin on the date on which that fact has been notified in the Journal referred to in Section 38.

(4) Any new deposit as referred to in paragraph (2) shall be accompanied by a statement signed by the depositor that the culture of the microorganism deposited anew is identical to the original deposit.

(5) Where a fact as referred to in paragraph (3) presents itself, the Patent Office shall as soon as possible make notification of it in the Journal referred to in Section 38.

(Patents Rules, as amended to 1991, Section 31E)

(ii) Restrictions Concerning the Furnishing of Samples

(1) Any person who is entitled in pursuance of Section 28A of the Patents Act of the Kingdom to inspection of the documents referred to in that Section in respect of a patent application or a patent may make a request for the furnishing of a sample of the culture of a microorganism, deposited pursuant to Section 22B(2) of the Patents Act of the Kingdom, to which that application or that patent is related.

(2) The request shall be addressed to the Patent Office by means of a form prescribed by the Patent Office. It shall be accompanied by a statement written by the person who makes the request declaring that he commits himself in respect of the deposited culture or a culture derived from it vis-à-vis the person who filed the patent application or the proprietor of the patent until the date on which it has become certain no patent will be granted on that patent application or, where a patent has been granted, for the period it remains in force:

(a) not to make it available to third parties;

(b) to use it exclusively for tests, unless the person who made the request uses the culture as the proprietor of a license ensuing from the provisions of Section 34 or Section 34B of the Patents Act of the Kingdom or as a person entitled to do so pursuant to Section 34A of the Patents Act of the Kingdom.

(3) The applicant for a patent may until the date on which the application is laid open to public inspection pursuant to Section 22C of the Patents Act of the Kingdom or, where this takes place on an earlier date, until the date of publication of the application pursuant to Section 25 of that Act of the Kingdom, notify the Patent Office on a form prescribed for the purpose by the Patent Office that until the date on which the patent is granted or until the date on which it is certain that no patent will be granted on the application, furnishing of samples

of the culture of a microorganism deposited by him in pursuance of paragraph (1) may only be performed to an expert designated by the person who made the request. The statement referred to in paragraph (2), second sentence shall be co-signed in that case by the relative expert.

(4) As an expert may be designated:

(a) any natural person relative to whom the person who makes the request proves on filing the request that the applicant for the patent has approved of his designation;

(b) any natural person acknowledged as an expert by the President of the Patent Office.

(5) By a derived culture shall be meant for the application of paragraph (2) any culture preserving the properties of the deposited culture essential for the carrying out of the invention. The commitments referred to in paragraph (2) shall not form an impediment for the deposit of a derived culture necessary for the procedure for the grant of a patent.

(6) The Patent Office shall send the request to the institution. At the same time the Patent Office shall mention whether a patent application containing notification of the deposit of the microorganism has been filed and whether the person who made the request is entitled to being furnished with a sample of that microorganism. The Patent Office shall send a copy of the request to the applicant for a patent or the proprietor of the patent.

(Patents Rules, as amended to 1991, Section 31F)

NI - NICARAGUA

Office of the Industrial Property Registry
General Directorate for Industry
Ministry for Economy and Development
Esquina Este del Hotel Intercontinental
Managua

Telephone: (505) 267 4551
Telefax: (505) 267 5393
E-mail: rpi@mific.gob.ni
Internet: www.rpi.gob.ni

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

NO - NORWAY

Norwegian Industrial Property Office (NIPO)
Sandakerveien 64
0484 Oslo

Mailing address:
Postboks 8160 Dep
0033 Oslo

Telephone: (47-22) 38 73 00
Telefax: (47-22) 38 73 01
E-mail: mail@patentstyret.no
Internet: http://www.patentstyret.no

1. Requirements for Deposit

If, when carrying out an invention, this involves the use of biological material which is not available to the public and cannot be described in the application documents in such a manner as to enable a person skilled in the art to carry out the invention on the basis thereof, a sample of the biological material shall be deposited not later than on the date of filing of the application.

(Patents Act, Section 8a, paragraph 1, first sentence)

The application shall contain information about whether the application comprises deposited biological material in accordance with section 8a of the Patents Act.

(Patent Regulations, Section 2, paragraph 1, seventh sentence)

The deposit of biological material in accordance with section 8a, first paragraph, of the Patents Act shall be made in accordance with the Budapest Treaty on the International Recognition of Deposit of Microorganisms for the Purposes of Patent Procedure of April 28, 1977. The material shall be deposited with an institution that is an international depositary institution in accordance with the Budapest Treaty or with an institution that has been approved by the European Patent Office.

(Patent Regulations, Section 12, paragraph 1)

When a sample of biological material has been deposited, the applicant shall notify the Norwegian Industrial Property Office in writing about the depositary institution with which the material has been deposited and the reference number that the institution in question has accorded the deposited material. The information shall be provided not later than 16 months after the filing date or, if priority has been claimed, the claimed priority date. If deposited biological material is transferred to another international depositary institution in pursuance of Rule 5(1) of the Implementing

Regulations to the Budapest Treaty, the applicant or the patent holder shall notify the Norwegian Industrial Property Office hereof and of the reference number that the institution has accorded the deposited material.

(Patent Regulations, Section 12, paragraph 2)

The Norwegian Industrial Property Office may demand a copy of the receipt that the depositary institution has issued as proof of the correctness of the information provided in accordance with the second and third paragraphs.

(Patent Regulations, Section 12, paragraph 4)

A request in accordance with section 22, eighth paragraph, of the Patents Act that samples of biological material shall only be issued to a specially appointed expert must be filed with the Norwegian Industrial Property Office not later than the day before the application becomes available to the public in accordance with section 22 of the Patents Act.

(Patent Regulations, Section 12, paragraph 5)

2. Time of Deposit

If, when carrying out an invention, this involves the use of biological material which is not available to the public and cannot be described in the application documents in such a manner as to enable a person skilled in the art to carry out the invention on the basis thereof, a sample of the biological material shall be deposited not later than on the date of filing of the application.

(Patents Act, Section 8a, paragraph 1, first sentence)

3. Duration of Storage

The sample shall thereafter always be deposited so that anyone who under this Act is entitled to be furnished with a sample of the biological material should be furnished with a sample in Norway.

(Patents Act, Section 8a, paragraph 1, second sentence)

If a deposited culture of a microorganism ceases to be viable or a sample of the culture cannot be furnished for other reasons, it may be replaced by a new culture of the same microorganism within the prescribed time limit and on the other conditions laid down by the King. In that case, the new deposit shall be deemed to have been made on the date that the previous deposit was made.

(Patents Act, Section 8a, paragraph 2)

A new deposit of biological material in accordance with section 8a, second paragraph, of the Patents Act shall be made in accordance with the Budapest Treaty. The applicant or the patent holder shall notify the Norwegian Industrial Property Office of the new deposit of biological material and of the reference number that this institution has accorded the deposited material within four months from when the material was deposited or within the time limit stipulated in the second paragraph.

(Patent Regulations, Section 12, paragraph 3)

The Norwegian Industrial Property Office may demand a copy of the receipt that the depositary institution has issued as proof of the correctness of the information provided in accordance with the second and third paragraphs.

(Patent Regulations, Section 12, paragraph 4)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

If a sample of biological material has been deposited according to section 8a, anyone has the right to be furnished with a sample of the material when the documents of the application have been made available in accordance with the first, second or third paragraph. After a patent has been granted anyone who requests a sample of the material shall be furnished with a sample, even if the patent has been determined or annulled.

(Patents Act, Section 22, paragraph 7, first and second sentence)

An applicant for a patent who invokes his application against another party before it has been made available to the public shall, upon request, be obliged to give that party access to the documents of the application. If the application involves the deposit of a sample of biological material of the microorganism as referred to in section 8a, the other party shall have the right to be furnished with a sample of the culture. The provisions of section 22, seventh paragraph, third and fourth sentences, and the eighth and ninth paragraphs shall apply correspondingly.

(Patents Act, Section 56, paragraph 1)

(ii) Restrictions Concerning the Furnishing of Samples

If a sample of biological material has been deposited according to section 8a, anyone has the right to be furnished with a sample of the material when the documents of the application have been made available in accordance with the first, second or third paragraph. After a patent has been granted anyone who requests a sample of the material shall be furnished with a sample, even if the patent has been determined or annulled. This does not mean, however, that a sample shall be issued to anyone who in consequence of a law or regulation is not entitled to handle the deposited material.

Moreover, the provision of the first sentence does not mean that a sample shall be issued to anyone whose handling of the sample must be assumed to involve considerable risk due to the harmful properties of the material.

(Patents Act, Section 22, paragraph 7)

Until a patent has been granted or the application has been finally decided upon without a patent having been granted, the applicant may, notwithstanding the provisions of the seventh paragraph, request that a sample only be issued to a specially appointed expert. If the patent application has been refused or withdrawn the same rule applies for a sentence of 20 years from the date when the patent application was filed. The King shall prescribe a time limit for submitting a claim to limit issuing of the material and shall determine who may be appointed as an expert.

(Patents Act, Section 22, paragraph 8)

A request for the issue of a sample shall be made in writing to the Norwegian Industrial Property Office and must contain a declaration to the effect that the restrictions laid down by the King concerning the use of the sample will be observed. If the sample may only be issued to a specially appointed expert, the declaration shall be made by the expert instead.

(Patents Act, Section 22, paragraph 9)

A request for the issue of a sample of biological material in accordance with section 22, ninth paragraph, of the Patents Act shall be worded in accordance with the provisions in Rule 11 of the Implementing Regulations to the Budapest Treaty.

(Patent Regulations, Section 26, paragraph 1)

If the request concerns a sample of deposited biological material connected with an application for which a final decision has not yet been made, the party requesting the sample must submit a declaration in which he undertakes vis-à-vis the applicant not to use the sample for any other purposes than for experiments that concern the invention itself and to refrain from granting other parties access to the sample until a final decision has been made regarding the application or, if a patent is granted, until the patent has expired. If the request concerns a sample of deposited biological material connected with a patent, the party requesting the sample must submit a declaration in which he undertakes vis-à-vis the patent holder not to use the sample for any other purposes than experiments that concern the invention itself and to refrain from granting other parties access to the sample until the patent has expired. The first and second periods of this paragraph shall apply correspondingly to biological material that is derived from the sample and that has retained the characteristic features of the material that are important for carrying out the invention. The request for the issue of the sample shall contain a declaration that the requester undertakes these obligations.

(Patent Regulations, Section 26, paragraph 2)

If a sample may only be issued to a special expert, the request for the issue of the sample shall designate the expert in question. The Norwegian Industrial Property Office will draw up a list of persons who can be used as experts. Only persons who are entered in said list, or whom the applicant accepts in the individual case, may be used as experts. If an expert is used, the request for the issue of a sample shall contain a declaration from the expert in accordance with the second paragraph.

(Patent Regulations, Section 26, paragraph 3)

The second and third paragraphs shall not apply if it is necessary to deposit derived biological material in connection with a subsequent application.

(Patent Regulations, Section 26, paragraph 4)

When a request has been made for the issue of a sample of biological material and the requirements for this have been complied with, the Norwegian Industrial Property Office shall issue a declaration to this effect. The Norwegian Industrial Property Office shall send the request for the issue of a sample and the declaration to the depositary institution with which the material has been deposited. A copy of the request for the issue of a sample and the declaration shall concurrently be sent to the patent applicant or the patent holder. If the Norwegian Industrial Property Office does not issue such a declaration, the party requesting the sample shall be notified hereof.

(Patent Regulations, Section 26, paragraph 5)

OM – OMAN

Directorate of Organisations and Commercial Relations
Intellectual Property Department
Ministry of Commerce and Industry
P.O. Box 550
Muscat 113

Telephone: (968) 24 771 6241
Telefax: (968) 24 771 7238 / 24 771 2030

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

PA - PANAMA

Directorate General of the Industrial Property Registry
Ministry of Commerce and Industries
Edison Plaza
Ricardo J. Alfaro Avenue
P.O. Box 0815-01119
Zona 4 Panamá
Republic of Panama

Telephone: (507) 560 0600 / 0700 /2351 /2353
Telefax: (507) 560 0741
E-mail : dgrpi@mici.gob.pa - digerpi@sinfo.net
Internet :

1. Requirements for Deposit

No provision

2. Time of Deposit

No provision

3. Duration of Storage

No provision

4. Conditions for the Furnishing of Samples

No provision

PE – PERU

National Institute for the Defense of Competition and Intellectual Property Protection
Ministry of Industry, Tourism, Integration and International Trade Negotiations
Calle de la Prosa No. 104
San Borja
Lima 41

Telephone: (51-1) 224 7800
Telefax: (51-1) 224 0348 or 224 0349
E-mail: postmaster@indecopi.gob.pe
Internet: http://www.indecopi.gob.pe

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

PH – PHILIPPINES

Intellectual Property Office of Philippines (IPOPHIL)
G/F, 2/F, 14/F, 16/F Intellectual Property Center
#28 Upper McKinley Road
MacKinley Hill Town Center
Fort Bonifacio
Taguig City
1634 Philippines

Telephone: (632) 238 63 00
Telefax: (632) 553 94 80
E-mail: mail@ipophil.gov.ph
Internet: http://www.ipophil.gov.ph

l. Requirements for Deposit

The deposit of a culture of biological material with an international depositary institution/authority recognized by the IPO is required if an invention concerns a microbiological process or the product thereof and involves or relates to the use of a microorganism or other biological material which is not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art. Otherwise, the disclosure is not considered to have satisfied the requirements of sufficiency.

A list of recognized depositary institutions is available at the Bureau of Patents.

(Implementing Rules and Regulations on Inventions, Rules 408 and 409; Manual of Substantive Examination Practice, Chapter II, Sections 6.2 and 6.4)

2. Time of Deposit

The deposit of the culture of the microorganism must be made not later than the date of filing of the application.

(Implementing Rules and Regulations on Inventions, Rule 408(a); Manual of Substantive Examination Practice, Chapter II, Section 6.2(a))

3. Duration of Storage

The depositary institution should be under contractual obligation to place the culture in permanent collection.

(Implementing Rules and Regulations on Inventions, Rule 409(c))

4. Conditions for the Furnishing of Samples

The depositary institution must provide access to persons who shall have interest therein in regard to matters relating to the patent application as published.

(Implementing Rules and Regulations on Inventions, Rule 409(c))

PL - POLAND

Patent Office of the Republic of Poland
Al. Niepodległości 188/192
00-950 Warsaw

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00-950 Warsaw

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E-mail: jwaz@uprp.pl
Internet: http://www.uprp.pl

1. Requirements for Deposit

The three following organizations are appointed by the Patent Office to perform the functions of national depositary institutions: The IAFB Collection of Industrial Microorganisms (Institute of Agricultural and Food Industry), the Polish Collection of Microorganisms (Institute of Immunology and Experimental Therapy) and the National Public Health Institute.

The requirements of deposit of microorganisms with the said Institutes are in conformity with the Budapest Treaty.

2. Time of Deposit

Under the existing practice, the deposit must be made at the filing date of the patent application, at the latest.

3. Duration of Storage

Under the existing practice, the duration of storage is that of the life of the patent, plus three additional years.

4. Conditions for the Furnishing of Samples

Under the existing practice, samples of deposited microorganisms are furnished to the Patent Office, upon request, and to any other requesting party, on condition that the request is communicated to the depositor and that the requesting party declares that he will use the sample only for experimental purposes and that he will not make it available to any third party.

PT - PORTUGAL

Portuguese Institute of Industrial Property
Campo das Cebolas
1149-035 Lisbon

Telephone: (351-21) 881 81 00
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E-mail: atm@inpi.pt
Internet: http://www.inpi.pt

1. Requirements for Deposit

If the patent application relates to or involves the use of a biological material which may not be described in such a way as to enable those skilled in the art to carry out the invention, and if the material is not available to the public, the application must be completed by depositing the material with an authorized depositary institution.

All the available characteristics of the biological material required for it to be correctly identified must be submitted to the National Institute of Industrial Property with the patent application, including the name and address of the depositary institution and the date and number of the deposit.

(Industrial Property Code, Decree Law No. 36/2003 of 5 March, Article 63(1)(a), (b) and (c))

2. Time of Deposit

The biological material must be deposited no later than the date of the patent application in Portugal.

(Industrial Property Code, Article 63(1)(a))

3. Duration of Storage

In accordance with the Budapest Treaty.

(Budapest Treaty of 28 April 1977, Rule 9)

4. Conditions for the Furnishing of Samples

Access to the deposited biological material shall be provided through the supply of a sample:

(a) up to the first publication of the patent application, only to those persons who are authorized under national patent law;

(b) between the first publication of the patent application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

(a) not to make it or any material derived from it available to third parties, and

(b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

(Industrial Property Code, Article 63(2), (3) and (4))

QA – QATAR

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Ministry of Economy and Commerce
Doha
Qatar

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Facsimile: (974) 4429 4338
E-mail: kjalhitmi@mec.gov.qa

1. Requirements for Deposit

No provision

2. Time of Deposit

No provision

3. Duration of Storage

No provision

4. Conditions for the Furnishing of Samples

No provision

KR – REPUBLIC OF KOREA

Korean Intellectual Property Office (KIPO)
Government Complex-Daejeon
189 Cheongsa-ro, Seo-gu
Daejeon 302-701

Telephone: (82-42) 481 51 94
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Internet: http://www.kipo.go.kr

1. Requirements for Deposit

If an invention involves or uses a microorganism which cannot be easily obtained by any person skilled in the art, the patent applicant must deposit a culture of the microorganism at a depositary institution designated by the commissioner of the Korea Intellectual Property Office or a depositary institution having acquired the status of international depositary authority under the Budapest Treaty, and attach a document certifying that the microorganism has been deposited at an approved depositary institution to the patent application.

Furthermore, the patent applicant shall state in the specifications prescribed in Article 42(2) of the Patent Act, the date of deposit and the deposit number issued by the depositary institution.

(Enforcement Decree of the Patent Act, Article 2, 3)

2. Time of Deposit

The microorganism must be deposited no later than the date of filing of the patent application.

(Enforcement Decree of the Patent Act, Article 2, 3)

3. Duration of Storage

The depositary institution shall store the deposited microorganism for at least 30 years from the date of deposit and at least 5 years after the most recent request for the furnishing of a sample of the deposited microorganism.
(Official KIPO Notification for the Designation of the Depositary Institution)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Samples of a deposited microorganism become available to any requesting party from the date of the publication of the patent application or the registration of establishment of the concerned patent right.

The samples may be available, however, before the date of the said publication or the said registration, provided that the requesting party has prepared a written opinion as designated in Article 63(1) of the Patent Act.

(ii) Restrictions Concerning the Furnishing of Samples

The furnishing of samples of a microorganism is only available in the cases where the samples are used for experimental and research purposes. The requesting party should not allow any third party to make use of the deposited microorganism. (Enforcement Decree of the Patent Act, Article 4)

MD – REPUBLIC OF MOLDOVA

State Agency on Intellectual Property (AGEPI)
24/1 Andrei Doga Str.
2024 Chisinau

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Telefax: (373 22) 440 094, (373 22) 440 119
E-mail: office@agepi.gov.md
Internet: http://www.agepi.gov.md

1. Requirements for Deposit

(1) The patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

(2) Where the invention refers to biologically reproducible material which is not available to the public, the conditions referred to in paragraph (1) shall only be fulfilled if the applicant proves with a document that, prior to the filing date of the patent application or the acknowledged priority, the biological material has been deposited with an international depositary authority or a depositary institution designated by the Government.

Law on the Protection of Inventions No. 50-XVI of 7 March 2008 (hereinafter "Law"), *(Art. 36)*

If the invention concerns reproducible biological material which is not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the patent application shall contain an attestation certifying the deposit of that biological material with the National Collection of Nonpathogenic Microorganisms, the Regulations of which is approved by the Government Decision No. 56 of January 26, 2004, (Official Gazette of the Republic of Moldova, 2004, No. 22-25, Art. 184) or with a depositary institution having the status of international depositary authority.

Regulations on the Procedure of Filing and Examination of a Patent Application and of Grant of a Patent, approved by Government Decision of the Republic of Moldova No. 528 of 1 September 2009 (hereinafter "Implementing Regulations"), Rule 49

The document certifying the deposit of reproducible biological material with a national depositary institution designated by the Government or with an international depositary institution shall contain:

a) the name and the address of the officially recognized national or international collection with which the microorganism was deposited;

b) the date (year, month, day) of deposit of the microorganism with the officially recognized national or international collection;

c) the denomination of the microorganism;

d) the number of deposit of the biological material;

e) the biochemical, morphological and taxonomic characteristics of the microorganism deposited.

(Implementing Regulations, Rule 156)

Where the biological material has been deposited by a person other than the applicant, a document shall be annexed to the patent application providing evidence that the latter has authorized the applicant to refer to the deposited biological material in the application and has given his consent to the deposited material being made available to the public.

(Implementing Regulations, Rule 157)

2. Time of Deposit

Where the invention refers to biologically reproducible material which is not available to the public, the conditions referred to in paragraph (1) shall only be fulfilled if the applicant proves with a document that, prior to the filing date of the patent application or the acknowledged priority, the biological material has been deposited with an international depositary authority or a depositary institution designated by the Government.

(Law, Art. 36(2))

3. Duration of Storage

No provision is provided in the national legislation. The provision of Rule 9.1 of the Implementing Regulations under the Budapest Treaty is applied.

4. Conditions for the Furnishing of Samples

The availability of deposited biological material shall be effected by the issue of a sample of the biological material:

1) prior to the publication of the patent application:

a) at the request of the AGEPI, if such sample is necessary for the patenting procedure or if the patent application is in a litigation before AGEPI;

b) to the applicant, upon his request;

c) to any authority or any natural or legal person authorized by the applicant;

d) to any person having the right to inspect the files under Article 96, paragraph (2), of the Law;

2) between the publication of the application and the grant of the patent – to any requester or, at the request of the applicant – only to an independent expert;

3) after the grant of the patent even in the case of revocation or cancellation thereof, to any requester.

(Implementing Regulations, Rule 50)

The sample shall be available only if the requester has undertaken throughout the existence of a patent application or a valid patent:

a) not to make the sample or any biological material derived therefrom available to any third party;

b) to use that sample or any biological material derived therefrom for experimental purposes only, unless the applicant for an owner of a patent expressly waives such an undertaking.

(Implementing Regulations, Rule 51)

Where the patent application is refused or withdrawn, the availability of deposited biological material may be limited upon request to an independent expert for a period of 20 years from the filing date of the patent application. In such a case, the provisions of Rule 51 of the present Regulations shall apply.

(Implementing Regulations, Rule 52)

The requests of the applicant referred to in Rule 50, paragraph 1), letter b), and in Rule 52 of the present Regulations shall only be filed before completion of the technical preparations for publication of the patent application.

(Implementing Regulations, Rule 53)

If biological material deposited ceases to be available from the recognized depositary institution, a new deposit of that material is necessary to be made in accordance with the requirements established by Article 4 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, to which the Republic of Moldova has adhered by the Decree of the President of the Republic of Moldova No. 229 of December 30, 1993. The document confirming the new deposit of biological material shall be forwarded to AGEPI within four months of the date of the new deposit. Any new deposit shall be accompanied by a statement signed by the depositor certifying that the newly deposited biological material is the same as the originally deposited.

(Implementing Regulations, Rule 54)

RO - ROMANIA

State Office for Inventions and Trademarks
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E-mail: office@osim.ro
Internet: http://www.osim.ro

1. Requirements for Deposit

(1) Where an invention relates to a biological material or to the use of a biological material which was not available to the public and cannot be described in the patent application in a way which should enable a person skilled in the art to carry out the invention, the invention is deemed to be exposed only if:

(a) a sample of biological material was deposited with an international depositary authority;

(b) the patent application, as filed, contains information available to the applicant with regard to the features of the biological material;

(c) the patent application comprises the indication of the international depositary authority and the order number of the deposited biological material.

(2) Where the biological material was deposited by another person than the applicant, the name and the address of the depositor shall be mentioned in the patent application, and a document shall be submitted to OSIM to prove that the depositor authorized the applicant to make reference in the patent application to the deposited biological material, and unreservedly and irrevocably approved to render the deposited material available to the public.

(3) The indications mentioned in paragraph (1) letter (c) and paragraph (2), as the case may be communicated:

(a) within 16 months from the filing date or, if a priority is claimed, from the priority date, the time limit being considered to be observed if the indications are communicated until the end of the technical procedures with the view of publishing the patent application;

(b) up to the date of presenting the request for publication of the patent application.

(4) After the communication of these indications, the applicant shall be considered to have the possibility to authorize unreservedly and irrevocably the rendering of the biological material, available to the public.

(Art. 18, paragraph 3, Patent Law 64/1991, amended and republished in 2002; Rule 61, Governmental Decision No. 499/2003 on the Implementing Regulation of the republished Patent Law)

2. Time of Deposit

The deposit must be made with an international depositary authority prior to the date of filing of the application or the date of the recognized priority.

(Rule 61, Implementing Regulation of the republished Patent Law)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Access to the Biological Material Deposit

(1) The biological material deposited, may be accessed based on a request, by any person, starting on the date of publication of the patent application, the access being made by the delivery of a biological material sample to the person who made the request.

(2) Delivering the sample of deposited biological material, mentioned in paragraph (1) shall be made only when the interested person makes the commitment before the applicant or patent owner not to communicate the biological material or a derived biological material to third parties and to use the biological material only for experimental purposes up to the date when the patent application is rejected, withdrawn or considered to be withdrawn, as the case may be, except where the applicant or patent owner expressly gives up such a commitment.

(3) The commitment to use the biological material only for experimental purposes shall not be applicable when the interested person makes use of this material for an exploitation which results from a compulsory license.

(4) The request provided in paragraph (1) accompanied by the proof of payment of the fee for the certification of an official document shall be addressed to OSIM that certifies that a patent application referring to a biological material deposit has been filed with OSIM and that the interested person or the expert appointed by that person, has the right to be delivered this sample.

(5) The request provided for in paragraph (1) may be addressed to OSIM even after the grant of the patent for invention.

(6) OSIM shall transmit a copy of the request referred to in paragraph (1), accompanied by the certification referred to in paragraph (4) to the international depositary institution as well as to the applicant and to the patent owner.

(Rule 62, Implementing Regulation of the republished Patent Law)

(ii) Appointment of an expert

(1) The applicant may communicate to OSIM that:

(a) up to the end of the preparations for the publication of the patent application; or

(b) up to the publication of the mention of the decision to grant the patent for invention; or, where appropriate

(c) during the 20-year period of time starting from the patent application filing date, if the patent application is rejected, withdrawn or considered to be withdrawn, the access can be allowed only by delivering a sample of biological material to an expert appointed by an interested party.

(2) The appointed expert may be:

(a) any natural person, provided that the interested person, according to paragraph (1), makes the evidence that the appointment of the expert was made with the agreement of the applicant on the date of filing the request for the delivery of the sample;

(b) the natural person that is recognized to be an expert by OSIM, according to some instructions.

(Rule 63, Implementing Regulation of the republished Patent Law)

RU – RUSSIAN FEDERATION

Federal Service for Intellectual Property (Rospatent)
30-1, Berezhkovskaya nab.
125993 Moscow

Telephone: (74-95) 531 63 64
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E-mail: rospatent@rupto.ru, fips@rupto.ru
Internet: http://www.rupto.ru, http://www1.fips.ru

1. Requirements for Deposit

For invention relating to a microorganism strain, a line of plant or animal cells or consortium of strains, the description of method of strain, line of cells and consortium production should be presented. If the said description is insufficient for the realization of invention, the information about deposit of strain, line of cells, consortiums of strains of the consortium (the official name or the abbreviation of the depositary institution, its post address, the deposit number given by said institute to the deposited object) should be submitted.

(Administrative Regulation of the Federal Service for Intellectual Property, Patents and Trademarks to Fulfill the Functions Incurred by the State on Organization of Filing of Applications to Grant Patent for Invention, their Registration, Examination and Grant in due course of Patents of the Russian Federation for Inventions, par. 10.7.4.5(3)).

The document about deposit should be enclosed with the application for an invention relating to a microorganism strain, a line of plant or animal cells or the means with the using of unknown microorganism strain or a line of cells, if said application has an indication about deposit which has been carried out with the authority depositary-institute.

(Administrative Regulation of the Federal Service for Intellectual Property, Patents and Trademarks to Fulfill the Functions Incurred by the State on Organization of Filing of Applications to Grant Patent for Invention, their Registration, Examination and Grant in due course of Patents of the Russian Federation for Inventions, par. 10.3(3)).

The claims, characterizing a microorganism strain should contain its species and generic name in Latin, the purpose of the strain.

In the claims, characterizing a line of plant or animal cells, their name and purpose should be included.

If a strain or a line of plant has been deposited, the official name or abbreviation of authority depositary-institute and the deposit number given by said institute to the deposited object should be presented.

In cases when a strain or a line of plant has not been deposited, the claims should contain the requirements of subparagraph (1) of par. 10.8.1.4 of the present Regulation.

(Administrative Regulation of the Federal Service for Intellectual Property, Patents and Trademarks to Fulfill the Functions Incurred by the State on Organization of Filing of Applications to Grant Patent for Invention, their Registration, Examination and Grant in due course of Patents of the Russian Federation for Inventions, par. 10.8.4).

2. Time of Deposit

The date of deposit of a strain, line of cells, consortium or strains of consortium should be not later than the date of filing of the application or the priority date if priority is claimed.

(Administrative Regulation of the Federal Service for Intellectual Property, Patents and Trademarks to Fulfill the Functions Incurred by the State on Organization of Filing of Applications to Grant Patent for Invention, their Registration, Examination and Grant in due course of Patents of the Russian Federation for Inventions, par. 10.7.4.5(3)).

3. Duration of Storage

For depositing with an international depositary authority under the Budapest Treaty, the provisions of the Rule 9 of the Regulations under the said Treaty are applied.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Under the existing practice, samples of the deposited microorganism become available as from the date of publication of the application under the conditions provided for in Rule 11 of the Regulations under the Budapest Treaty.

(ii) Restrictions Concerning the Furnishing of Samples

Provisions concerning conditions for furnishing of samples are under preparation.

RS – SERBIA

Intellectual Property Office
Zmaj Jovina 21
11000 Belgrade

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E-mail: zis@zis.gov.rs
Internet: http://www.zis.gov.rs

1. Requirements for Deposit

If a microorganism is the subject of a microbiological invention, which is not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be performed by a person skilled in the art with no additional effort, the invention will be considered as described in a sufficiently clear and complete manner in accordance with Article 78(2) of the Law on the Protection of Inventions, Technical Improvements and Distinctive Signs, only if the following conditions have been fulfilled:

- the sample of the microorganism has been deposited in a recognized depositary institution under Article 24 of the Rules of Procedure, at the latest on the day of filing of the patent application;

- the patent application contains all data on the microorganism known to the applicant;

- the patent application contains the name and address of the depositary institution, the official number and date of deposit.

(Rules of Patent Grant Procedure, Article 21(1))

2. Time of Deposit

The deposit of the microorganism must be made not later than the date of filing of the patent application.

(Rules of Patent Grant Procedure, Article 21(1)(i))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a deposited microorganism becomes available to everyone as from the date of publication of the patent application.

(Rules of Patent Grant Procedure, Article 22(1))

(ii) Restrictions Concerning the Furnishing of Samples

From the date of publication of the patent application, a sample of the deposited microorganism is available to everyone, on request. The availability of the microorganism on request depends on the following conditions:

(a) the request must be filed with the Patent Office, in two copies, on the form prescribed by the Office;

(b) the Office confirms, on the request form, that the patent application has been filed, on which the requesting party states the existence of the deposit of the microorganism and his right to ask that a sample of the microorganism should be made available to him;

(c) the requesting party is obliged not to make the requested sample of the microorganism available to third persons until the conclusion of the examination procedure concerning the patent application;

(d) the requesting party makes the undertaking to the patent applicant that the requested sample of the deposited microorganism shall be used exclusively for experimental or research purposes until the publication of the decision to grant the patent.

The obligation under point (d) above does not apply if the requesting party uses the furnished sample of the deposited microorganism on the basis of a compulsory or ex officio license.

(Rules of Patent Grant Procedure, Article 22(2) and (3))

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1. Requirements for Deposit

The deposit of a microorganism shall be made if an invention requires for its performance the use of a microorganism which is not available to the public at the date of filing of the patent application and which cannot be described in such a manner as to enable the invention to be performed by a person skilled in the art. The name of the international depositary authority, the date when the culture was deposited and the accession number of the deposit should be given in the specification of the application

(a) within 16 months from

(i) the declared priority date; or
(ii) the date of filing the application where there is no declared priority date;

(b) where, on a request made by the applicant, the Registrar publishes the application before the end of the period prescribed for the purposes of Section 27(1), before the date of the request; or

(c) where the Registrar sends notification to the applicant that, in accordance with Section 108(4), he has received a request by any person for information and inspection of documents under subsection (1) of that section, before the end of one month after his sending to the applicant notification of his receipt of the request;

whichever is the earliest.

(The Patents Rules 1995, Schedule 4, paragraph 1)

2. Time of Deposit

The deposit must be made not later than the date of filing the patent application.

(The Patents Rules 1995, Schedule 4, paragraph 1(2)(a)(i))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A culture of a deposited microorganism is available upon request before publication of the relevant patent application to a person to whom Section 108(4) applies and who has made a request under Section 108(1) and is available upon such publication to any person.

(The Patent Rules 1995, Schedule 4, paragraph 2(1))

(ii) Restrictions for the Furnishing of Samples

A request authorizing the furnishing of samples shall comprise on the part of the person to whom the request relates, undertakings for the benefit of the applicant for, or proprietor of, the patent:

(a) not to make the culture, or any culture derived from it, available to any other person; and

(b) not to use the culture, or any culture derived from it, otherwise than for experimental purposes relating to the subject matter of the invention.

Both undertakings shall have effect until the patent application has been withdrawn, has been taken to be withdrawn, has been treated as having been abandoned, has been refused or is treated as having been refused (including any further period allowed under Rule 100 or Rule 108(1) or (4) but excluding, where an application is reinstated under either of those rules, the period before it is reinstated).

Where the patent is granted, the undertaking in subparagraph (a), above, shall also have effect during the validity of the patent and during the period of six months referred to in Section 36(3).

The undertaking set out in subparagraph (b), above, shall not have effect after the date of publication in the Official Journal (Patents) of a notice that the patent has been granted.

The request for the furnishing of samples should be made on Patents Form 49.

(The Patents Rules 1995, Schedule 4, paragraph 2(1) and (3))

Before the preparations for publication of a patent application under Section 27 have been completed, the applicant may give notice to the Registrar on Patents Form 50 of his intention that a sample of the microorganism should be furnished only to an expert. Where this has been done, the Registrar will publish with the application a notice to this effect and persons requesting samples must nominate an expert who must have given undertakings in accordance with subparagraphs (a) and (b), above. The request for the furnishing of samples in these circumstances should be made on Patents Form 51. The Registrar shall specify the period within which the patent applicant may object to the furnishing of a sample of the microorganism to the particular expert nominated.

In the case of an international application, the applicant's notice that a sample should be furnished only to an expert should be given in writing to the International Bureau under Rule 13bis.3 of the Regulations under the Patent Cooperation Treaty before technical preparations for international publication are complete.

(The Patent Rules 1995, Schedule 4, paragraph 3(1), (3), (4) and (5))

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1. Requirements for Deposit

The deposit of a sample of the biological material with a recognized depositary institution is required if a subject matter of an invention is biological material or its utilization, which is not available to the public and which cannot be described in the application in such a manner as to enable the invention to be performed by a person skilled in the art.

(Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts (The Patent Act) as Amended, Article 38(1))

The application as filed must contain information as it is available to the applicant on the characteristics of deposited biological material and must state the name and the seat of the recognized depositary institution, as well as the accession number of the deposited sample.

(The Patent Act, Article 38(1)(b) and Article 38(1)(c))

In case of doubts about accessibility of the biological material to the public or about sufficiency of description pursuant to Article 38(1), it shall be deemed that the accessibility condition or the sufficiency of description condition is not met unless proved otherwise. In accordance with the practice followed, the applicant must on the basis of the notice of the Office submit a copy of the receipt of the deposit of the biological material.

(The Patent Act, Article 38(6))

2. Time of Deposit

The deposit of the biological material in a recognized depositary institution must be made not later than on the date of filing the patent application.

(The Patent Act, Article 38(1)(a))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A deposited biological material shall be available by providing a sample upon request from the publication day of a patent application up to granting a patent.

(The Patent Act, Article 38(2))

A deposited biological material shall be available by providing a sample upon request after granting a patent irrespective of its cancellation or lapse.

(The Patent Act, Article 38(3))

(ii) Restrictions for the Furnishing of Samples

A deposited sample may be provided only if a requesting person or independent expert shall bind himself that during the term of a patent

(a) he shall provide neither sample nor material derived from it to third party,

(b) he shall utilize sample and material derived from it only for experimental purposes, unless an applicant or a patent owner explicitly repeals this obligation for him.

(The Patent Act, Article 38(4))

An applicant shall be entitled upon request filed with the Office before publication of a patent application to limit an access to deposited biological material for time limit of 20 years from the day of filing an application only for independent experts for case that an application would be refused or proceedings on application would be suspended.

(The Patent Act, Article 38(2) and Article 38(5))

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1. Requirements for Deposit

If an invention relates to biological material which is not available to the public and cannot be described in a manner to be carried out by a person skilled in the art, the description of the invention shall be supplemented by a certificate of the deposit of biological material with an international depository authority under the Budapest Treaty.

(Industrial Property Act, 2001, as last amended in 2006, Article 87(3))

The patent application must include all information on biological material that are known to the applicant, and should state the name and address of the international depository authority, the accession number given to the deposit by that authority and the date of deposit.

(Regulations Concerning the Contents of Patent Applications and the Procedure for Divisional Patents, 2001, Article 10(b), (c))

2. Time of Deposit

A sample of biological material must be deposited no later than the date of filing of the patent application.

(Regulations Concerning the Contents of Patent Applications and the Procedure for Divisional Patents, 2001, Article 10(a))

3. Duration of Storage

No specific provision. However, as ensues from Article 12 of Regulations Concerning the Contents of Patent Applications and the Procedure for Divisional Patents, and Article 112(1)(b) of Industrial Property Act, the term of deposit shall not expire prior to the term of the patent.

4. Conditions for the Furnishing of Samples

(i) Time of availability of Samples

A deposited sample of biological material is available upon request from the date of publication of the patent application to any person fulfilling the conditions for handling biological material.

(Regulations Concerning the Contents of Patent Applications and the Procedure for Divisional Patents, Article 11(1))

(ii) Restrictions Concerning the Furnishing of Samples

Biological material is available to any person under the following conditions:

(a) that the request is submitted to the Office in two copies;

(b) that the Office has certified on the request that the patent application referring to the deposit of the biological material has been published, and that the requesting party is entitled to the issue of a sample of that material;

(c) that the person making the request has undertaken vis-à-vis the owner of the patent not to make the requested sample of deposited biological material available to any third party and to use that sample, before the expiry of the patent, for experimental purposes only.

The Office transmits a copy of the request, with the certification attesting to the publication of the patent application referring to the deposit of the biological material and the entitlement of the requesting party to the issuance of a sample of biological material, to the international depository authority and to the owner of the patent.

(Regulations Concerning the Contents of Patent Applications and the Procedure for Divisional Patents, Article 11(2), (3))

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1. Requirements for Deposit

If the complete specification accompanying a patent application claims as an invention a microbiological process or a product thereof, and requires for the performance of the invention the use of a microorganism which is not available to the public on the date of lodging the application and which cannot be made or obtained on the basis of the written description in the specification, a culture of the microorganism must be deposited with a depositary institution which has acquired the status of international depositary authority under the Budapest Treaty.

The complete specification must state the name of the international depositary authority with which the culture was deposited, the date of deposit and the accession number given to the deposit by the international depositary authority. This information may be added to the patent specification at any time before the date of publication or before the opening to public inspection of the patent application, whichever is the earlier.

The complete specification, as lodged, must give such relevant information as is available to the applicant on the characteristics of the microorganism.

(Patents Act No. 57 of 1978, Section 32(6); Patent Regulations 1978, as amended to 1997, Rule 28A(1) and (2))

2. Time of Deposit

A culture of a microorganism must be deposited not later than the date of filing of the patent application.

(Patent Regulations, Rule 28A(1)(a))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The communication in the patent specification of the information concerning the microorganism is considered as constituting the unreserved and irrevocable consent of the applicant to make the deposited culture available to the public from the date of publication or after the opening to public inspection of the patent application, whichever is earlier.

(Patent Regulations, Rule 28A(3))

(ii) Restrictions Concerning the Furnishing of Samples

A sample of the deposited culture is furnished to any requesting party from the date of publication or after the opening to public inspection of the patent application, provided that the requesting party makes a valid request therefor to the international depositary authority with which the culture is deposited.

A request for the furnishing of a sample of the deposited culture is valid if it is made on Patents Form P23 on which the Registrar has certified that a patent or patent application referring to the deposit of the culture has been published or has come open to public inspection and that the requesting party is entitled to the furnishing of a sample of the deposited culture.

The Registrar does not make the certification unless the Registrar has received an application on a Patents Form P24 requesting the certification. The application must contain an undertaking from the requesting party *vis à vis* the patentee that the requesting party will not make the deposited culture, or any culture derived therefrom, available to any third party until the patent ceases to have effect by way of expiration, revocation, voluntary surrender, or lapsing without the possibility of renewal in accordance with Section 46 of the Patents Act.

The undertaking *vis à vis* the patentee does not prevent the requesting party from depositing with an international depositary authority a derived culture or the culture itself necessary for the purpose of complying with section 32(6) of the Patents Act.

A derived culture is deemed to be any culture of the microorganism which exhibits those characteristics of the deposited culture which are essential to the carrying out of the invention described in the complete specification in which reference is made to the deposited culture.

(Patent Regulations, Rule 28A(4)(5)(6)(7) and (8))

ES - SPAIN

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1. Requirements for Deposit

If an invention concerns biological material which is not available to the public or involves the use of it, and which cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 25.1 if the following requirements are met:

(a) a sample of the biological material has been deposited not later than the date of filing of the application with a recognized depositary institution. In any case, all international depositary institutions having this status in conformity with Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of April 28, 1977, will be recognized.

(Spanish Patent Law, Article 25(2)(a))

2. Time of Deposit

The deposit must be made not later than the date of filing of patent application.

(Spanish Patent Law, Section 25(2)(a))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

(1) Biological material deposited in accordance with Article 25 shall be available:

a. Before the first publication of the application, only to any person having the right to inspect the files under Article 44.

b. Between the date of publication of the patent application and the date of granting, to any person upon request or only by the issue of a sample to an expert nominated by the applicant, if he so wishes.

c. After the granting of the application, to any person upon request, even if the patent expires or is refused.

(2) Said access shall be provided only if the requester has undertaken during the time as the patent application is valid:

a. Not to make the biological material or any biological material derived there from available to any third party.

b. And to use that material for experimental purposes only, unless the applicant for or proprietor of the patent expressly waives such an undertaking.

(3) In case of withdrawal or refusal of the patent application, the availability shall be limited, upon request of the applicant and during twenty years, to an independent expert.

(Spanish Patent Law, Article 45)

SE – SWEDEN

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1. Requirements for Deposit

If an invention refers to a biological material which is neither generally available nor can be described in the application in such a manner that a person skilled in the art using the teachings of the document could exercise the invention; or if the invention includes the use of such a material, the biological material shall be deposited on the day the application is made, at the latest. Thereafter the biological material shall be made continuously available at the depositary institution so that those who are entitled by this law to obtain a sample of the material can have their sample delivered to them within Sweden. The government prescribes where the deposits may be made. If a deposited biological material ceases to be viable or if for any other reason a sample cannot be supplied from the material, it may be replaced by a new deposit of the same biological material within the time and in the manner prescribed by the government. Once this is done, the new deposit is considered to have been made when the earlier deposit was made. Law (2004:159).

(Patents Act, Section 8 (a))

2. Time of Deposit

The biological material shall be deposited on the day the application is made, at the latest.

(Patents Act, Section 8 (a))

Such a deposit as referred to in Section 8a first paragraph of the Patent Act is made in an institution which is an international deposit authority in accordance with the agreement decided upon in Budapest the 28 April 1977 regarding the international recognition of the deposit of micro-organisms in connection with patent cases (The Budapest Treaty).

The deposit is made according to the Budapest Treaty.

The patent office establishes a list of those institutions which are international deposit authorities according to the Budapest Treaty.

(Patent Decrees, Section 17 (a))

3. Duration of Storage

The deposit is made according to the Budapest Treaty.

(Patent Decrees, Section 17 (a))

If a biological material has been deposited in accordance with Section 8, everyone, with the limitations described in this and the following paragraphs, has the right to obtain samples from the material once the case has been made available to the general public in accordance with the first, second or third paragraph. This is the case regardless of if the patent has been terminated or declared invalid. Samples may not be given to a person who according to the law or another constitution may not be in possession of the deposited material. Neither is it permitted to give a sample to a person whose possession of the sample could be considered as an obvious risk with regard to the material's destructive properties.

Until a patent has been communicated/granted or a patent application has been processed without leading to a patent, a sample from a deposit may only be given to an expert in the field, if the applicant permits it. If the patent application is rejected or withdrawn, the equivalent applies during a period of 20 years starting from the day the application was submitted. The government prescribes the time scale within which a request for confinement may be made and who of those persons who wish to obtain the sample shall be appointed as the expert. A person who wishes to obtain a sample shall submit both a written request to the patent office and a statement, the contents of which are prescribed by the government in order to prevent misuse of the sample. If the sample may be given to only one particular expert, the statement is instead submitted by that expert. Law (2004:159).

(Patents Act, Section 22)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of a microorganism becomes available as from the date on which the patent application is made available to the public.

If a culture of a microorganism has been deposited according to Section 8a, any person has the right to obtain a sample from the culture after the documents have become available to anyone in accordance with the following rules.

When l8 months have passed from the day when the patent application was filed or, if priority is claimed, from the day from which priority is claimed, the documents shall be available to anyone, even if the application has not been laid open to public inspection. However, if a decision has been made to dismiss or reject an application, the documents shall be made available only if the applicant requests that the application be resumed, lodges appeal, or makes a petition pursuant to Section 72 or 73 of the Patents Act.

At the applicant's request, the documents shall be made available earlier than set out in the first and second paragraphs.

When the documents become available pursuant to either of the two aforementioned circumstances, this fact shall be announced.

If a document contains business secrets and if it does not concern the invention for which a patent is sought, the Patent Authority, upon request and if there are special reasons for this, may order that the document shall not be made available. If such a request has been made, the document shall not be made available until the request has been refused by a decision which has taken legal effect.

(Patents Act, Section 22)

(ii) Restrictions Concerning the Furnishing of Samples

The patentee may request that a sample of the deposited microorganism be available only to an expert in the art until the patent application has been laid open to public inspection or has been finally decided upon without having been laid open to public inspection. An expert is a person whose name is included in a list published in the Patent Office for the purpose of handling samples of deposited microorganisms.

This does not mean, however, that samples are issued to anyone who in consequence of provisions in a law or other ordinance may not handle the deposited microorganism. Nor does this mean that samples are issued to anyone whose handling of the sample can be assumed to involve an evident risk in view of the harmful properties of the organism.

(Patents Act, Section 22; Patents Decree, Section 25(b))

According to section 22 paragraph seven of the Patent Act, a request that a sample may only be given to a particular expert shall be made on the day that the technical preparations to make the patent application available to the public are considered to have been completed, at the latest.

The patent office establishes a list of suitable persons who have stated they are willing to undertake the position of expert. The decision concerning which persons are included in the list of experts shall be announced in the manner described in section 49. If a sample may only be given to one particular expert, it shall be stated in the description of the sample who shall be appointed as the expert. A written statement shall be attached to the description from the designated expert to the patent applicant corresponding to the statement prescribed in section 25a first-third paragraphs. If the

description refers to samples which shall be given out according to section 22 paragraph seven, second sentence, the Patent Act, the legally binding statement shall be valid for 20 years from the day the patent application was submitted. Those persons who are named in the list may be appointed as experts or in special cases a person accepted by the patent applicant. Regulation (2004:162).

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1. Requirements for Deposit

Article 50*a*(1) and (2) of the Federal Act on Patents for Inventions (LBI): biological material

Where an invention entails the manufacture or use of biological material and cannot be sufficiently described, the disclosure shall be supplemented by the deposit of a sample of the biological material and, in the description, by information relating to the essential characteristics of that material and by a reference to the deposit.

Article 45*b* of the Ordinance on Patents for Inventions (OBI): Obligation of deposit
Where an invention involves biological material, or the manufacture or use of biological material that is not accessible to the public, and that invention cannot be described in such a way as to allow a person skilled in the art to carry it out, it shall not be deemed to have been disclosed in accordance with the provisions of Articles 50 and 50*a* of the Law, unless:

a. a sample of the biological material has been deposited with a depositary institution recognized as such at the date of filing or, if priority is claimed, at the date of priority;

b. at the date of filing, the description contains the information available to the applicant on the essential characteristics of the biological material; and

c. the patent application contains, at the date of filing, the indication of the depositary institution and the reference number of the deposited biological material.

2. Time of Deposit

Article 50*a*(3) of the LBI:

The invention shall not be deemed to have been disclosed as per Article 50 until the sample of the biological material has been deposited, no later than the filing date of the application, with a recognized depositary institution and unless the patent application as initially filed contains information on the biological material and a reference to the deposit.

3. Duration of Storage

The provisions of Rule 9 of the Regulations Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure shall be applied and the duration of storage shall be a minimum of 30 years. Article 45*j* of the OBI states that the duration of storage shall be exclusively governed by the Budapest Treaty and the Regulations thereunder.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Article 45*e*(1) of the OBI: availability of the deposited biological material

From the date of deposit onwards and throughout the entire duration of storage referred to in Article 45*h*, the applicant shall make the deposited biological material unconditionally and irrevocably available to the depositary institution for the purposes of the furnishing of samples (Article 45*f*).

(ii) Restrictions Concerning the Furnishing of Samples

Article 45*g* of the OBI: Declaration of undertaking

(1) In order to have access to samples, the requesting party shall undertake, with regard to the patent applicant or holder and, where the deposit has been carried out by a third party, with regard to the depositor also, during the period of validity of any exclusive right relating to the deposited biological material, not to make the samples of deposited biological material or of material derived therefrom available to a third party and only to use such samples for experimental purposes.

(2) The patent applicant or holder and, where the deposit has been carried out by a third party, the depositor, may renounce the right to require that the requesting party make said undertaking.

(3) Where a sample is furnished to an independent expert, he shall be obliged to provide a declaration through which he makes the undertaking referred to in paragraph (1). With regard to the expert, the requesting party shall be deemed to be a third party as per paragraph (1).

(4) The requesting party shall not be obliged to undertake only to use the biological material for experimental purposes if he uses it for exploitation under a compulsory license.

TJ - TAJIKISTAN

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1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

MK – THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

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1. Requirements for Deposit

If the patent application relates to microorganism which is not available to the public, and which cannot be described in the application in such a manner as to enable the invention to be performed by a person skilled in the art, shall be treated as described in sufficiently precise and complete way, if the microorganism has been deposited with a competent depositary institution with the requirements prescribed in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

2. Time of Deposit

The microorganism has to be deposited with a competent depositary institution no later than the filing date of the patent application. Filing the evidence for deposit of the microorganism may of valid reasons to be filed additionally, in terms of 90 days following the date of filing the request for granting or from requested priority right or until the day of filing the request for premature proceeding the application in case of dispute.

3. Duration of Storage

The microorganism must be stored by the international depositary during the whole period of validity of the patent.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Since the day of publishing a granted patent, deposited microorganisms shall be available to anyone, under the following conditions:

(1) Request to be filed in two copies at the Office;

(2) Upon request, the Office to confirm that a patent application was filed, in which applicant refer to the viable biological material or microorganism that has been deposited, as well that the person who has made a request has a right to ask release of the material;
(3) The applicant to oblige himself at the Office and at the applicant of the patent applicant that he shall not make available to a third person the requested material before expiry of the period for which the patent is in force;

(4) The person who has made the request to oblige himself at the Office and at the applicant of the patent application that he shall use the requested material exceptionally for experimental or research goals, since the procedure for granting a patent shall not be ended not matter of the results from the research, except when the request is based on the ground of issued enforce license.

(5) The Office shall send to the authorized institution one copy of the request and certificate that the filed patent application for viable biological material or microorganism and that the applicant has a right to release sample of the material.

(ii) Restrictions Concerning the Furnishing of Samples

If the material is no longer available at the depositary authority, nor is transferred to other depositary authority, shall be considered that the invention is not described in sufficiently precise and complete way.

The Office shall not reject the patent application, if the following conditions are fulfilled:

(1) If a depositor in term of 90 days from the day of receiving notification from a depositary authority that the deposited material became unavailable, shall deposit microorganism once more;

(2) If a depositor during the second deposit shall file signed statement that the deposited material is the same as the one previously has been deposited;

(3) If the Office in term of 90 days from the day of the repeated deposit, received copy of the certificate issued from the depositary authority for deposit of microorganism, which contain number of the patent application, or number of the patent to which deposit relates.

If the cause for unavailability of the material is no longer viable, it shall be deposited again at the same depositary authority, and if other cause exist, than the material may be deposited at the other depositary authority.

If the authorized institution at which the material has been deposited, shall loose the status of authorized institution or shall cease operating as an authorized institution for depositing microorganisms in relation to certain kind of microorganisms or in general, a depositor in terms of 6 months shall not be informed for the change, a term of 90 days for re-deposit shall begin from the day of publishing such change in the Official Gazette of the International Bureau.

TT - TRINIDAD AND TOBAGO

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1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

TN - TUNISIA

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Mailing address:
B.P. 23
Tunis – Belvédère

Telephone: (216-71) 78 59 22
Telefax: (216-71) 78 15 63
E-mail: INORPI@email.ati.tn

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

TR – TURKEY

Turkish Patent Institute
Necatibey Cad. No. 49
06440 Kizilay
Ankara

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Telefax: (90-312) 232 54 37
E-mail: info@turkpatent.gov.tr
Internet: http://www.tpe.gov.tr

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

UA – UKRAINE

State Intellectual Property Service of Ukraine (SIPSU)
45, Urytskogo str.
Kyiv-35, MSP, 03680

Telephone: +38 (044) 494 06 06
Telefax: +38 (044) 494 06 67
E-mail: post@sips.gov.ua
Internet: http://sips.gov.ua/en/

State Enterprise "Ukrainian Institute of Industrial Property"
1, Hlazunova Street
Kyiv-42, 01601

Telephone: +38 (044) 494 05 05, 494 05 04
Telefax: +38 (044) 494 05 06 (general matters)
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Requirements concerning the procedure of the deposit of microorganisms for the purposes of patent procedure pursuant to the national legislation of Ukraine are established in the Instructions on the procedure of the deposit of microorganisms strains in Ukraine for the purposes of patent procedure approved by the Order of the State Patent Office of Ukraine, the National Academy of Sciences of Ukraine on June 26, 1995 No. 106/115 and in the Rules on drafting and filing of an application for invention and utility model approved by the Ministry of Education and Science of Ukraine on January 22, 2001, No. 22.

1. Requirements for Deposit

Ukraine recognizes the deposit of microorganisms for the purposes of patent procedure in any international depositary authority. Such recognition includes the fact and date of the deposit referred to by the International Depositary Authority, as well as recognition of the fact that, what is passed off as a pattern, is a pattern of the deposited microorganism.

Information on deposit of microorganism strain should include:
- name and location of the depositary authority where deposit was performed;
- date of the deposit in this depositary;
- registration number assigned to the deposited strain of microorganism.

(Article 3 Budapest Treaty; items 2.1.-2.2., 4.2. Instructions on the procedure of the deposit of microorganisms strains in Ukraine for the purposes of patent procedure; item 12.2.5. Rules on drafting and filing of an application for invention and utility model).

2. Time of Deposit

The time of deposit of a strain, line of cells, consortium or strains of consortium should be not later than the date of filing of the application or the priority date if priority is claimed.

(item 1.2. Instructions on the procedure of the deposit of microorganisms strains in Ukraine for the purposes of patent procedure and item 12.2.4. Rules on drafting and filing of an application for invention and utility model).

3. Duration of Storage

For depositing with an international depositary authority under the Budapest Treaty, the provisions of the Rule 9 of the Regulations under the said Treaty are applied.

A deposit must be made for a term of at least 30 years after the date of deposit and at least five years after the most recent request for furnishing a sample of the deposit.

(items 2.3. and 5.6. Instructions on the procedure of the deposit of microorganisms strains in Ukraine for the purposes of patent procedure).

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Under the existing practice, samples of the deposited microorganism become available as from the date of publication of the application under the conditions provided for in Rule 11 of the Regulations under the Budapest Treaty.

(ii) Restrictions concerning the Furnishing of Samples

In conformity with Rule 11 Regulations under the Budapest Treaty.

(items 6.1.-6.3. Instructions on the procedure of the deposit of microorganisms strains in Ukraine for the purposes of patent procedure).

GB - UNITED KINGDOM

Intellectual Property Office
Room 2Y44
Concept House
Cardiff Road
Newport, South Wales NP10 8QQ

Telephone: (44-1633) 81 40 00
Telefax: (44-1633) 81 49 91
E-mail: information@ipo.gov.uk
Internet: https://www.gov.uk/government/organisations/intellectual-property-office

1. Requirements for Deposit

The deposit of biological material must be made if an invention which involves the use of or concerns biological material is not disclosed in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art. In addition to the requirement for a deposit, the specification of the patent application as filed must contain such relevant information as is available to the applicant on the characteristics of the biological material.

The name of the depositary institution, the date where the material was deposited and the accession number of the deposit should be given in the specification of the patent application or patent. The latest date such information may be added to the specification is whichever expires first of:

- the period of 16 months after the declared priority date or, where there is not declared priority date, the date of filing of the application;

- where the applicant has requested accelerated publication under section 16(1), the date of that request;

- where in accordance with rule 52(2) the comptroller notifies the application that a request has been made for information or inspection of documents under section 118(4), the period of one month from the date of that notification.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraphs 2 and 3)

2. Time of Deposit

The deposit must be made on or before the date of filing the patent application.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 3(1)(a))

Where the biological material ceases to be available at the depositary institution because:

(i) it is no longer viable;
(ii) the depositary institution is unable to supply the biological material; or
(iii) the place where the biological material is deposited is no longer a depositary institution for that type of material (whether temporarily or permanently);

then a new deposit must be made within three months of the date of the depositor is notified of (i), (ii), or (iii), or, where it expires later, within three months of the date of advertisement of (i), (ii), or (iii) in the journal. The deposit should be accompanied by a signed statement that the biological material is the same as that originally deposited. Within the same time period the applicant or proprietor must apply to the comptroller to amend the specification of the patent application or patent so that it provides the appropriate details. Where the biological material ceases to be available because it is no longer viable then the new deposit should be made at the depositary institution where the original deposit was made.

If the biological material is transferred to a different depositary institution then the specification must also be amended within three months of the date the depositor is notified or, where it expires later, within three months of the date of advertisement in the journal.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 8)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of deposited biological material may be requested:

(a) before publication of the relevant patent application, by a person to whom section 118(4) applies and who has made a request under section 118(1) and

(b) after publication, by any person.

A request must be made on Patents Form 8.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 4)

(ii) Restrictions Concerning the Furnishing of Samples

A request for a sample of biological material must include an undertaking:

(a) not to make the biological material, or any material derived from it, available to any other person; and

(b) not to use the biological material, or any material derived from it, except for experimental purposes relating to the subject matter of the invention.

The patent applicant or proprietor may agree to limit the effect of the undertaking in a particular case. The undertaking will cease to have effect when the application for a patent is terminated or withdrawn (but it will continue to have effect if the application is reinstated or resuscitated) or when the patent ceases to have effect.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 5)

Before the preparations for publication of a patent application under section 16 have been completed, the applicant may give notice to the comptroller on Patents Form 8A that a sample of the biological material should only be made available to an expert. This restriction lasts until the date on which the patent is granted or, where the application is terminated or withdrawn, for 20 years from the date of filing. A similar restriction applies in relation to an international application for a patent (UK) where the applicant has made reference to the deposited biological material in accordance with the Patent Cooperation Treaty.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 6)

A request for a sample to be made available to an expert must be made on Patents Form 8 and must include details of the expert, who must have given undertakings in accordance with subparagraphs (a) and (b) above. Before the end of the period of one month beginning with the date on which a copy of Patents Form 8 is sent to the application by the comptroller, the applicant may give notice of his objection to the particular expert, and where he objects the comptroller shall determine the matter.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 7)

US – UNITED STATES OF AMERICA

United States Patent and Trademark Office (USPTO)
600 Dulany Street
Alexandria, VA 22314

Mailing address:
Director of the U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Telephone: (1-571) 272 10 00
Telefax: (1-571) 273 83 00
E-mail: IP.Policy@uspto.gov
Internet: http://www.uspto.gov

1. Requirements for Deposit

The applicant must deposit the biological material with a depositary authority, if the biological material is required to make and use the invention and the biological material is either not known or readily available to the public, or could not have been made or isolated without undue experimentation at the time the invention was made. The depositor may make the required deposit in an international depositary authority recognized under the Budapest Treaty or in a depositary institution recognized by the USPTO and meeting the same requirements.

(37 CFR 1.802 and 1.803; U.S. Patent and Trademark Office, Manual of Patent Examining Procedure, 2001, Sections 2402 and 2404)

2. Time of Deposit

The deposit of the biological material must be made by the time the patent issue fee is paid, but the USPTO strongly encourages the deposit to be made on or before the filing date of the application.

(37 CFR 1.804 and 1.809(c); Manual, Sections 2406 and 2411.03)

3. Duration of Storage

A deposit must be made for a term of at least 30 years after the date of deposit and at least five years after the most recent request for furnishing a sample of the deposit.

(37 CFR 1.806; Manual, Section 2408)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The deposited biological material must be made available to the public at the date of the grant of the patent.

(37 CFR 1.808; Manual, Section 2410.01)

The deposited biological material may be made available during pendency of the patent application which makes reference to the biological material if the person requesting a sample is determined by the USPTO to be entitled thereto. Upon such determination, the Director of the USPTO will make the certification referred to in Rule 11.3(a) of the Regulations under the Budapest Treaty in respect to that person, and will send a copy of the request, together with the certification, to the person who filed the request.

(37 CFR 1.808(a)(1))

(ii) Restrictions Concerning the Furnishing of Samples

Any restriction of public access to samples of deposited biological material must be irrevocably removed as of the date of grant of the relevant patent.

(37 CFR 1.808(a)(2) and Manual, Section 2410.01)

UZ – UZBEKISTAN

State Patent Office of the Republic of Uzbekistan
2a, Toitepa St.
100047 Tashkent

Telephone: (998-71) 232 00 13
Telefax: (998-71) 233 45 56
E-mail: info@patent.uz
Internet: www.patent.uz

1. Requirements for Deposit

No provision.

2. Time of Deposit

No provision.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

No provision.

AP - AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO)

11 Natal Road
Belgravia
Harare
Zimbabwe

Mailing address:
P.O. Box 4228
Harare

Telephone: (263-4) 79 40 54, 79 40 65, 79 40 66, 79 40 68, 79 40 74
Telefax: (263-4) 79 40 73, 79 40 72
E-mail: mail@aripo.org
Internet: www.aripo.org

1. Requirements for Deposit

(Harare Protocol, Section 3(1A), Rule 6*bis*.1, Rule 6*bis*.(4))

2. Time of Deposit

(Harare Protocol, Rule 6*bis*.1(b)(i), Rule 6*bis*.(2)(a))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(Harare Protocol, Rule 6*bis*.2, Rule 6*bis*.3)

EA – EURASIAN PATENT ORGANIZATION (EAPO)

2, M. Cherkassky per.
Moscow 109012
Russian Federation

Telephone: (7-495) 411 61 50
Telefax: (7-495) 621 24 23
E-mail: info@eapo.org
Internet: http://www.eapo.org

1. Requirements for Deposit

(1) The Eurasian application shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

(2) Where the Eurasian application relates to a biotechnological product or a process involving the use of such a strain that cannot be disclosed in the application in a manner sufficiently clear and complete for invention to be carried out by a person skilled in the art and there is no free access to such biotechnological product, the application shall contain information or a document evidencing the deposit of such a biotechnological product with a competent depositary authority in accordance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of April 28, 1977, or with any other depositary institution recognized by the Administrative Council.

(Rule 11 of the Patent Regulations under the Eurasian Patent Convention (EAPR))

2. Time of Deposit

The deposit shall be effected no later than on the filing date of the Eurasian application.

(Rule 11 EAPR)

Where the application claims a priority and where the invention, in order to be sufficiently disclosed, requires a deposit, that deposit must have been made not later than the date of filing of the previous application whose priority is claimed.

(Item 2.5.6.4.1 of the Rules of Compilation, Filing and Consideration of Eurasian applications at the Eurasian Patent Office)

3. Duration of Storage

As provided for in Rule 9 of the Budapest Treaty.

4. Conditions for the Furnishing of Samples

No provision.

EP - EUROPEAN PATENT ORGANISATION (EPO)

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80469 Munich
Germany

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80298 Munich

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(49-89) 2399-5221 (Directorate International Legal Affairs)
(49-89) 2399-5211 (Directorate Patent Law)
Telefax: (49-89) 23 99 4560
E-mail: info@epo.org; International_legal_affairs@epo.org
Internet: http://www.epo.org

1. Requirements for Deposit

If an invention which is the subject of a European patent application involves the use of or concerns biological material which is not available to the public and which cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicant must make the deposit of the biological material with a recognized depositary institution on the same terms as those laid down in the Budapest Treaty *(Rule 31(1)(a) EPC).*

Furthermore the depositary institution and the accession number of the deposited biological material shall be stated in the application and where the biological material has been deposited by a person other than the applicant, the name and address of the depositor shall be stated in the application and a document shall be submitted to the EPO providing evidence that the depositor has authorized the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public *(Rule 31(1)(c), (d) EPC).*

This information may be submitted:

- within a period of 16 months after the date of filing of the European patent application or, if priority is claimed, after the priority date; this time limit is deemed to have been met if the information is communicated before the technical preparations for publication of the application are completed *(Rule 31(2)(a) EPC)*;

- up to the date of submission of a request for early publication of the application under Article 93(1)(b) EPC;

- within one month after the EPO has communicated to the applicant that a right to inspection of the files, pursuant to Article 128(2) EPC, exists *(Rule 31(2)(b) EPC).*

The ruling period is the one which is the first to expire. The communication of this information is considered as constituting the unreserved and irrevocable consent of the applicant to the deposited biological material being made available to the public in accordance with Rule 33 EPC *(Rule 31(2)EPC).*

The EPO publishes in its Official Journal the list of depositary institutions and experts recognized for the purpose of Rules 31 to 34 EPC *(Rule 33(6) EPC).*

Requirements for New Deposit of Biological Material

If biological material deposited in accordance with Rule 31 EPC ceases to be available from the recognized depositary institution, an interruption in availability shall be deemed not to have occurred:

- if a new deposit of that material is made with a recognized depositary institution on the same terms as those laid down in the Budapest Treaty, and

- if a copy of the receipt of the new deposit issued by the depositary institution is forwarded to the EPO within four months of the date of the new deposit, stating the number of the European patent application or the European patent.

(Rule 34 EPC)

2. Time of Deposit

A sample of the biological material shall be deposited not later than the date of filing of the European patent application *(Rule 31(1)(a) EPC).*

Where the European patent application claims a priority, the deposit of the biological material must have been made no later than the date of filing of the previous application whose priority is claimed.

3. Duration of Storage

As provided for in Rule 9 of the Budapest Treaty and in point 11 of the bilateral agreements between the EPO and the depositary institutions (at least five years after the most recent request for furnishing a sample of the deposited biological material and in any case at least thirty years after the date of deposit).

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The deposited biological material becomes available upon request to any person from the date of publication of the European patent application and to any person having the right to inspect the files pursuant to Article 128(2) EPC, prior to such date *(Rule 33(1) EPC).*

(ii) Restrictions Concerning the Furnishing of Samples

(a) Undertaking of the Requester vis-à-vis the Applicant or the Proprietor of the Patent

A sample of the deposited biological material can only be issued to the requesting party if such a party undertakes *vis-à-vis* the applicant or the proprietor of the patent:

- not to make the deposited biological material or any biological material derived therefrom available to any third party and

- to use the deposited biological material or any biological material derived therefrom for experimental purposes only, until such time as the patent application is refused or withdrawn or is deemed to be withdrawn, or before the European patent has expired in the designated State in which it last expires,

unless the applicant or the proprietor of the patent expressly waives such an undertaking.

The undertaking to use the biological material for experimental purposes only does not apply in so far as the requesting party is using the culture under a compulsory license. The term "compulsory license" includes *ex officio* licenses and the right to use patented inventions in the public interest.

(Rule 33(2) EPC)

(b) Expert Solution

Until completion of the technical preparations for publication of the application, the applicant may inform the EPO that:

- until the publication of the mention of the grant of the European patent or, where applicable,

- for twenty years from the date of filing if the application has been refused or withdrawn or deemed to be withdrawn,

the availability of the deposited biological material referred to in Rule 33 EPC is effected only by the issue of a sample to an expert nominated by the requester.

(Rule 32(1) EPC)

May be nominated as an expert:

- any natural person provided that the requester furnishes evidence, when filing the request, that the nomination has the approval of the applicant;

- any natural person recognized as an expert by the President of the EPO.

The nomination must be accompanied by a declaration from the expert *vis-à-vis* the applicant in which he enters into the undertaking given pursuant to Rule 33 EPC until either the date on which the patent expires in all the designated States or, where the application has been refused, withdrawn or deemed to be withdrawn, until the date referred to in Rule 32(1)(b) EPC, the requester being regarded as a third party.

(Rule 32(2) EPC)

c) Request for the Issue of a Sample of Deposited Biological Material

The request of a sample of the deposited biological material must be submitted to the EPO on a form recognized by that Office:

- EPO Form 1140: Request for the issue of a sample of deposited biological material

- EPO Form 1141: Declaration for the purposes of obtaining a sample of deposited biological material

- EPO Form 1142: Request for deposited biological material to be made available by issuing a sample to an expert

The EPO certifies on the form that a European patent application referring to the deposit of the biological material has been filed, and that the requester or the expert nominated by him is entitled to the issue of a sample of that material. After grant of the European patent, the request must also be submitted to the EPO *(Rule 33(4) EPC).*

The EPO transmits a copy of the request, with the certification, to the depositary institution as well as to the patent applicant or the proprietor of the patent *(Rule 33(5) EPC).*

APPENDIX 1

CHECKLISTS OF POINTS TO BE ATTENDED TO WHEN DEPOSITING MICROORGANISMS AND REQUESTING SAMPLES UNDER THE BUDAPEST TREATY

The purpose of these checklists is to enable depositors and requesting parties to see at a glance whether they have omitted any essential step in making a deposit or asking for a sample of a microorganism, as the case may be. The points on the checklists are intentionally brief and the main body of the Guide should be consulted as necessary for more detailed information, explanation and/or discussion. To facilitate this, each point on the checklists is followed by reference to those sections or paragraphs of the Guide where more detailed information may be found and, where relevant, to the pertinent provisions of the Treaty itself.

Checklists for Depositors

(a) Making the Original Deposit (Section A)

(i) Check the latest date by which deposit must be made (Section E).

(ii) Start the deposit procedure in good time (43 to 49; 53).

(iii) Check that the IDA can accept your microorganism (25 and 26; 49; 54; Section D; Rule 6.4(a)(i) and (ii)).

(iv) Check the requirements of the IDA (17 to 22; 55; 59; Section D; Rule 6.3(a)).

(v) Ask for the appropriate forms (18; 55; Section D; Appendix 3; Rule 6.3(a)(ii)).

(vi) Complete the forms fully and correctly and sign them (11 to 15; 56; Rule 6.1(a)).

(vii) Make it clear to whom the IDA should send official communications (50; 57; Rules 7; 10; 11.4(g); Article 4(1)(a); Rule 5.1(a)(iii)).

(viii) Give the name and address of your patent agent and state if he should receive copies of the receipt and viability statement (50; 58; Rules 7; 10).

(ix) Ensure your microorganism is in the form and quantity required by the IDA (17; 59; Section D; Rule 6.3(a)(i)).

(x) Ensure your microorganism is correctly packaged (27; 46; Rule 6.4(a)(iii)).

(xi) Do not lose the receipt and/or viability statement (32 to 39; 63).

(xii) Test promptly any preparations the IDA sends for authenticity checking (62; Section D).

(xiii) If you are converting an existing deposit into a Budapest deposit, attend to points (iv) to (viii) and (xi) and (xii), above (30; 31; 64; Rule 6.4(d)).

(xiv) If, despite the exhortations in the Guide, you have left making a deposit until the last minute, give priority to sending the microorganism itself to the IDA (29; 61; Rule 6.4(c)).

(b) Making a New Deposit (Section B)

(i) Note the date on which you received notification from the IDA of its inability to furnish samples, and the reason for such inability (65; 77; Article 4(1)(a)).

(ii) Calculate the latest date by which your new deposit must be made (67 to 69; 77; Article 4(1)(d)).

(iii) Start the deposit procedure in good time (43 to 49; 75).

(iv) If the reason in (i), above, is discontinuance or loss of status, ask the IDA if your deposits will be transferred to a substitute IDA under Rule 5.1(a)(i) (69; 77; 83; 84; 86; Rule 5).

(v) If the answer to (iv), above, is YES, then you do not have the right to make a new deposit (66; Article 4(2)).

(vi) If the answer to (iv), above, is NO, or if import/export restrictions make a new deposit with another IDA necessary (65; Article 4(1)(b)(i) and (ii)), check that the IDA you select can accept your microorganism (79; Section D; Rule 6.4(a)(i) and (ii)).

(vii) Check the requirements of the IDA (79; Rule 6.3(a)).

(viii) If you are making a new deposit with another IDA or with the original IDA, ask for the appropriate forms for making a new deposit under Article 4 (18; 55; Section D; Appendix 3).

(ix) Complete the forms fully and correctly and sign them (11 to 15; 56; 66; Rules 6.1(a) and 6.2(a) and (b)).

(x) Unless the forms provide space for it, ensure that you append a signed statement giving:

- the reason for making a new deposit;
- the date on which you received notification form the IDA of its inability to furnish samples; and
- a declaration that the microorganism you are submitting is the same as that previously deposited (66; 81; Article 4(1)(c); Rule 6.2(a)(ii)).

(xi) Ensure that you enclose with the forms and statement copies of the receipt, the latest viability statement and, where applicable, the latest scientific description/taxonomic designation in respect of the previous deposit (66; 82; Rule 6.2(a)).

(xii) Attend to points (vii) to (xii) and (xiv) of checklist (a), above.

Checklists for Requesting Parties (Section C)

In all cases , before requesting a sample, ensure that you have complied with any import, quarantine, health and safety, etc., requirements (107).

(a) Requesting a Sample with the Authorization for the Depositor (90; 93; 94; 101; Rules 11.2(ii) and 11.4(a), (c) and (d)(i) and (ii))

Attempt this route to obtaining a sample only if you know the identity of the depositor, in which case either:

(i) ask the IDA for WIPO model form BP/11, if it keeps copies of this form (Section D; Appendix 3); and

(ii) complete parts I, III and IV of the form, then send it to the depositor asking him to complete part II; or

(iii) write to the depositor asking him for an appropriate declaration of authorization (90; 101; Rule 11.4(a), (c) and (d) (i) and (ii)).

(iv) send completed form BP/11 or the depositor’s declaration, as the case may be, to the IDA together with your request and purchase order.

(v) When requested, pay the fee charged by the IDA for furnishing the sample (97; Rule 12.1(a)(iv)).

(b) Requesting A Sample with Industrial Property Office Certification (91; 93; 94; 102; 103; Rules 11.3(a) and 11.4(a), (c) and (d))

(i) Ask the industrial property office or the IDA for the appropriate form (Section E; Appendix 3).

(ii) Complete that part of the form to be filled in by "the requesting party."

(iii) Send the form to the industrial property office (Section E).

(iv) When the form, endorsed by the industrial property office, is returned, send it and any certificate to the IDA together with a purchase order.

(v) When requested, pay the fee charged by the IDA for furnishing the sample (97; Rule 12.1(a)(iv)).

(c) Requesting a Sample of an Unrestricted Deposit (92 to 94; 106; Rules 11.3(b) and 11.4(a), (c) and (e))

To request a sample of a microorganism which is the subject of a granted and published patent, which is available without the need for certification, and of which the accession number has been communicated by the industrial property office to the IDA:

(i) write to the IDA with purchase order giving your name and address and quoting the accession number of the microorganism (106; Rule 11.3(b)).

(ii) When requested, pay the fee charged by the IDA for the furnishing of the sample (97; Rule 12.1(a)(iv)).

(d) Requesting a Sample of a Microorganism which is the Subject of a Published US patent (92 to 94; 104)

(i) Ask the IDA if it is aware that the relevant US patent has issued (92; 105).

(ii) If the answer to (i), above, is YES, proceed as in (c), above.

(iii) If the answer to (i), above, is NO, include with your request and purchase order evidence of the publication of the relevant US patent (92; 105).

(iv) If you cannot comply with (iii), above, expect a delay until the IDA has verified the fact of publication (92).

(v) When asked, pay the fee charged by the IDA for the furnishing of the sample (97; Rule 12.1(a)(iv)).

[Appendix 2 follows]

APPENDIX 3

FORMS

UNDER THE BUDAPEST TREATY AND REGULATIONS

1. This Appendix contains 14 forms, numbered BP/1 to BP/14. They have been drawn up by the International Bureau of WIPO on the basis of the discussions held by the Interim Advisory Committee for the preparation of the entry into force of the Budapest Treaty at its second session (April 30 to May 3, 1979) and on the basis of the discussions held by the Assembly of the Budapest Union at its second session (January 12 to 20, 1981) and at its eighth session (September 24 to October 2, 1990).

2. The forms which appear in this Appendix are not all provided for in the Regulations under the Budapest Treaty. The Regulations in fact provide only for the forms for the receipt in the case of an original deposit (BP/4), for the receipt in the case of a new deposit (BP/5) and for the receipt in the case of a transfer (BP/6) (see rule 7.2(a) of the Regulations), the form for the viability statement (BP/9) (see Rule 10.2(d)) and the form relating to the furnishing of samples to parties legally entitled (BP/12) (see Rule 11.3)).

3. As for the other forms, which in this Appendix bear the numbers BP/1, 2, 3, 7, 8, 10, 11, 13 and 14, the Assembly considered it useful to have these drawn up as models. It should be noted that, in the situations to which they relate, the use of forms will not be mandatory, and still less the use of the models that appear in this document.

4. Forms BP/4, 5, 6, and 9, called “international forms,” relate to the receipt and the viability statement. In each of the situations to which they relate, the use of an “international form” is mandatory. Each “international form” is issued by the competent international depositary authority on the basis of a model established by the Director General of WIPO in the languages designated by the Assembly. With regard to the language question, the Assembly decided that the model “international forms” should be established in English, French, Russian and Spanish, and it was understood that an international depositary authority whose official language or one of whose official languages, as indicated under Rule 3.1(b)(v), was a language other than any of the four languages mentioned could draw up the “international forms” in that language (see paragraph 38 of document BP/A/II/11).

5. Finally, Form BP/12, which relates to the furnishing of samples to parties legally entitled, is a form whose contents were fixed by the Assembly of the Budapest Union. In the situation to which it relates, the use of a form is mandatory. Each industrial property office may either use Form BP/12 as it appears in this Appendix (in other words, with the same layout) or draw up its own form (in other words, with a different layout, but with contents corresponding to the contents fixed by the Assembly). In the latter case, the industrial property office is responsible for the conformity of the contents of its form with the contents of Form BP/12, on the understanding that no international depositary authority is required to verify such conformity.

Table of Contents

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

STATEMENT IN THE CASE OF AN ORIGINAL DEPOSIT
pursuant to Rule 6.1

TO

NAME AND ADDRESS OF
INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED HEREBY DEPOSITS UNDER THE BUDAPEST TREATY THE MICROORGANISM IDENTIFIED HEREUNDER AND UNDERTAKES NOT TO WITHDRAW THE DEPOSIT FOR THE PERIOD SPECIFIED IN RULE 9.1 [1]

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference [2]:	☐ Mixture of microorganisms (Mark with a cross where applicable)
II. CONDITIONS FOR CULTIVATION	☐ [3]

[1] This form may also be used if the undersigned converts into a deposit under the Budapest Treaty the deposit of a microorganism that he or his predecessor in title has already deposited outside the Budapest Treaty, with the same depositary institution either before (Rule 6.4(d)) or after the acquisition by that institution of the status of international depositary authority.

[2] Number, symbols, etc., given to the microorganism by the depositor.

[3] Mark with a cross if additional information is given on an attached sheet.

III. CONDITIONS FOR STORAGE ☐ [3]
IV. CONDITIONS FOR TESTING VIABILITY ☐ [3]
V. COMPONENTS OF MIXTURE (where applicable) ☐ [3]
Description of components: Method(s) for checking presence of components:

[3] Mark with a cross if additional information is given on an attached sheet.

VI. PROPERTIES DANGEROUS TO HEALTH OR ENVIRONMENT

☐ [4] The microorganism identified under I above has the following properties which are or may be dangerous to health or the environment: ☐ [3]

☐ [4] The undersigned is not aware of such properties.

VII. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION [5] ☐ [3]

Scientific description:

Proposed taxonomic designation:

VIII. ADDITIONAL DATA ☐ [6]

IX. DEPOSITOR

Name: Address:	Signature [7]: Date:

[3] Mark with a cross if additional information is given on an attached sheet.

[4] Mark with a cross the applicable box.

[5] It is strongly recommended that the scientific description and/or proposed taxonomic designation of the microorganism be indicated.

[6] Mark with a cross if additional information (other than the information referred to in footnote [3]) is given on an attached sheet, such as the source of the microorganism, the name(s) and address(es) of any other depositary institution(s) with which the microorganism has been deposited, or the criterion used when drafting the proposed taxonomic designation. (The supplying of such information is optional.)

[7] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

STATEMENT IN THE CASE OF A NEW DEPOSIT
WITH THE SAME INTERNATIONAL DEPOSITARY AUTHORITY
pursuant to Rule 6.2

TO

NAME AND ADDRESS OF
INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED HEREBY MAKES A NEW DEPOSIT UNDER ARTICLE 4 OF THE BUDAPEST TREATY AND CONFIRMS HIS UNDERTAKING NOT TO WITHDRAW THE DEPOSIT FOR THE PERIOD SPECIFIED IN RULE 9.1

I. REASON FOR MAKING THE NEW DEPOSIT

☐ [1] The microorganism which was the subject of the previous deposit is no longer viable.

☐ [1] The sending or receipt of samples of the microorganism which was the subject of the previous deposit is prevented:

- ☐ [1] by export restrictions, or
- ☐ [1] by import restrictions.

☐ [1] other reason [2]:

Date of receipt of the notification referred to in Article 4(1)(a):

II. STATEMENT UNDER ARTICLE 4(1)(c)

The undersigned hereby alleges that the newly deposited microorganism is the same as that which was the subject of the previous deposit.

[1] Mark with a cross the applicable box.

[2] Indicate the relevant reason.

III. [3] MOST RECENT SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION INDICATED IN CONNECTION WITH THE PREVIOUS DEPOSIT [5]	☐ [4]
Scientific description: Proposed taxonomic designation:	
IV. DEPOSITOR	
Name: Address:	Signature [6]: Date:

[3] Not to be filled in if neither a scientific description nor a proposed taxonomic designation has been indicated in connection with the previous deposit.

[4] Mark with a cross if additional information is given on an attached sheet.

[5] Use form BP/7 if, when making the new deposit, it is desired to furnish for the first time or amend a scientific description or a taxonomic designation.

[6] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

Enclosures: Copy of the receipt of the previous deposit.

Copy of the most recent statement concerning the viability of the microorganism which was the subject of the previous deposit indicating that the microorganism is viable.

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

STATEMENT IN THE CASE OF A NEW DEPOSIT
WITH ANOTHER INTERNATIONAL DEPOSITARY AUTHORITY
pursuant to Rule 6.2

TO

NAME AND ADDRESS OF
INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED HEREBY MAKES A NEW DEPOSIT UNDER ARTICLE 4 OF THE BUDAPEST TREATY OF THE MICROORGANISM IDENTIFIED HEREUNDER AND CONFIRMS HIS UNDERTAKING NOT TO WITHDRAW THE DEPOSIT FOR THE PERIOD SPECIFIED IN RULE 9.1

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference [1]:	☐ Mixture of microorganisms (Mark with a cross where applicable)
II. CONDITIONS FOR CULTIVATION	☐ [2]

[1] Number, symbols, etc., given to the microorganism by the depositor.

[2] Mark with a cross if additional information is given on an attached sheet.

III. CONDITIONS FOR STORAGE ☐ [2]

IV. CONDITIONS FOR TESTING VIABILITY ☐ [2]

V. COMPONENTS OF MIXTURE (where applicable) ☐ [2]

Description of components:

Method(s) for checking presence of components:

VI. PROPERTIES DANGEROUS TO HEALTH OR ENVIRONMENT

☐ [3] The microorganism identified under I above has the following properties which are or may be dangerous to health or the environment: ☐ [2]

☐ [3] The undersigned is not aware of such properties.

[2] Mark with a cross if additional information is given on an attached sheet.

[3] Mark with a cross the applicable box.

VII. INTERNATIONAL DEPOSITARY AUTHORITY WITH WHICH THE PREVIOUS DEPOSIT WAS MADE

Name:

Address:

VIII. ACCESSION NUMBER GIVEN TO THE PREVIOUS DEPOSIT

IX. REASON FOR MAKING NEW DEPOSIT

☐ [3] The International Depositary Authority with which the previous deposit was made has ceased to have the status of International Depositary Authority or has discontinued the performance of its functions, and the microorganism has not been transferred to another International Depositary Authority which is in a position to furnish samples thereof.

- ☐ [3] Date of receipt of the notification referred to in Article 4(1)(a):
- ☐ [3] Date of the publication referred to in Article 4(1)(e):

☐ [3] The sending or receipt of samples of the microorganism which was the subject of the previous deposit is prevented:

- ☐ [3] by export restrictions, or
- ☐ [3] by import restrictions.

Date of receipt of the notification referred to in Article 4(1)(a):

[3] Mark with a cross the applicable box.

X. STATEMENT UNDER ARTICLE 4(1)(c)	
The undersigned hereby alleges that the microorganism identified under I above is the same as that which was the subject of the previous deposit.	
XI. [4] MOST RECENT SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION INDICATED IN CONNECTION WITH THE PREVIOUS DEPOSIT [5] ☐ [2]	
Scientific description: Proposed taxonomic designation:	
XII. DEPOSITOR	
Name: Address:	Signature [6]: Date:

[2] Mark with a cross if additional information is given on an attached sheet.

[4] Not to be filled in if neither a scientific description nor a proposed taxonomic designation has been indicated in connection with the previous deposit.

[5] Use form BP/7 if, when making the new deposit, it is desired to furnish for the first time or amend a scientific description or a taxonomic designation.

[6] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

Enclosures: Copy of the receipt of the previous deposit.

Copy of the most recent statement concerning the viability of the microorganism which was the subject of the previous deposit indicating that the microorganism is viable.

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: ☐ a scientific description ☐ a proposed taxonomic designation (Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism identified under I above, which was received by it on (date of the original deposit). [1]	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depositary Authority on (date of the original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion).	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Address:	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date:

[1] Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired.

Form BP/4 (sole page)

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

RECEIPT IN THE CASE OF A NEW DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:

II. REASON FOR MAKING THE NEW DEPOSIT AS STATED BY THE DEPOSITOR

☐ [1] The microorganism which was the subject of the previous deposit is no longer viable.

☐ [1] The sending or receipt of samples of the microorganism which was the subject of the previous deposit was prevented:

- ☐ [1] by export restrictions, or
- ☐ [1] by import restrictions.

☐ [1] The International Depositary Authority with which the previous deposit had been made has ceased to have the status of International Depositary Authority or has discontinued the performance of its functions, and the microorganism has not been transferred to another International Depositary Authority which is in a position to furnish samples thereof.

☐ [1] Other reason [2]:

☐ [1] Date of receipt of the notification referred to in Article 4(1)(a):

☐ [1] Date of the publication referred to in Article 4(1)(e):

[1] Mark with a cross the applicable box.

[2] Indicate the relevant reason.

III. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

In connection with the previous deposit, the depositor has indicated:

☐ a scientific description

☐ a proposed taxonomic designation

(Mark with a cross where applicable)

IV. INTERNATIONAL DEPOSITARY AUTHORITY WITH WHICH THE PREVIOUS DEPOSIT WAS MADE

Name:

Address:

V. ACCESSION NUMBER GIVEN TO THE PREVIOUS DEPOSIT

VI. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received by it on (date of the original deposit).

VII. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Address:	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date:

Enclosures: Copy of the receipt of the previous deposit.

Copy of the most recent statement concerning the viability of the microorganism which was the subject of the previous deposit indicating that the microorganism is viable.

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

RECEIPT IN THE CASE OF A TRANSFER
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
II. INTERNATIONAL DEPOSITARY AUTHORITY FROM WHICH THE TRANSFER WAS EFFECTED	
Name: Address:	
III. ACCESSION NUMBER GIVEN BY THE INTERNATIONAL DEPOSITARY AUTHORITY SPECIFIED UNDER II ABOVE	
IV. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The depositor has indicated to the International Depositary Authority specified under II above ☐ a scientific description ☐ a proposed taxonomic designation (Mark with a cross where applicable)	

<table>
<tr><td colspan="2">V. RECEIPT AND ACCEPTANCE</td></tr>
<tr><td colspan="2">A sample of the microorganism identified under I above has been transferred by the International Depositary Authority specified under II above and is accepted by this International Depositary Authority, which received it on (date of the transfer).</td></tr>
<tr><td colspan="2">VI. INTERNATIONAL DEPOSITARY AUTHORITY</td></tr>
<tr><td>Name:

Address:</td><td>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):

Date:</td></tr>
</table>

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

To be completed in duplicate

COMMUNICATION OF THE LATER INDICATION OR AN AMENDMENT OF THE SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION
pursuant to Rule 8.1

TO

NAME AND ADDRESS OF INTERNATIONAL DEPOSITARY AUTHORITY

I. IDENTIFICATION OF THE MICROORGANISM
Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION ☐ [1]
☐ [2] Scientific description: ☐ [2] Last preceding scientific description (if any): ☐ [2] Proposed taxonomic designation: ☐ [2] Last preceding proposed taxonomic designation (if any):

[1] Mark with a cross if additional information is given on an attached sheet.

[2] Mark with a cross the applicable box or boxes.

III. REQUEST FOR ATTESTATION	
The undersigned ☐ [3] requests ☐ [3] does not request the attestation referred to in Rule 8.2.	
IV. DEPOSITOR	
Name: Address:	Signature [4]: Date:

[3] Mark with a cross the applicable box.

[4] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

ATTESTATION CONCERNING THE LATER INDICATION OR
AN AMENDMENT OF THE SCIENTIFIC DESCRIPTION AND/OR
PROPOSED TAXONOMIC DESIGNATION
pursuant to Rule 8.2

TO

NAME AND ADDRESS
OF DEPOSITOR

The enclosed communication has been received by this International Depositary Authority on	
INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Address:	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date:

Enclosure: Communication of the later indication or an amendment of the scientific description and proposed taxonomic designation pursuant to Rule 8.1.

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

VIABILITY STATEMENT
issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS MADE

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: Address:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: Date of the deposit or of the transfer [1] :
III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on [2]. On that date, the said microorganism was ☐ [3] viable ☐ [3] no longer viable	

[1] Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

[2] In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.

[3] Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED [4]	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Address:	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date:

[4] Fill in if the information has been requested and if the results of the test were negative.

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

To be completed in duplicate

REQUEST
FOR THE FURNISHING OF SAMPLES
OF DEPOSITED MICROORGANISMS
pursuant to Rule 11.1

TO

NAME AND ADDRESS OF
INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED OFFICE HEREBY REQUESTS THE FURNISHING OF A SAMPLE OF THE MICROORGANISM IDENTIFIED HEREUNDER, IN ACCORDANCE WITH RULE 11.1 OF THE REGULATIONS UNDER THE BUDAPEST TREATY

I. IDENTIFICATION OF THE MICROORGANISM
Accession number of the deposit:

II. DECLARATION

It is hereby declared that:

(1) ☐ [1] patent application No. , filed on , referring to the deposit of the microorganism identified under I above has been filed with this Office for the grant of a patent [2] and that the subject matter of that application involves the said microorganism or the use thereof.

☐ [1] international application (PCT) No. , filed on , referring to the deposit of the microorganism identified under I above, designates for the grant of a patent [2] the State party to the Patent Cooperation Treaty (PCT) for which this Office is the "designated Office" for the purposes of the said Treaty, and that the subject matter of the international application involves the said microorganism or the use thereof.

(2) such application

☐ [1] is pending before this Office

☐ [1] has led to the grant of patent [2] No. , granted on

(3) the sample of the said microorganism is needed for the purposes of a patent procedure, in accordance with Rule 11.1(iii).

(4) the said sample and any information accompanying or resulting form it will be used only for the purposes of the said patent procedure.

III. REQUEST FOR INFORMATION

The undersigned Office

☐ [1] requests

☐ [1] does not request

an indication of the conditions which the International Depositary Authority employs for the cultivation and storage of the microorganism.

IV. INDUSTRIAL PROPERTY OFFICE

Industrial Property Office Street City (Country)	Signature: Date:

[1] Mark with a cross the applicable box.

[2] References to a "patent" shall be construed as references to patents for inventions, inventors' certificates, utility certificates, utility models, patents or certificates of addition, inventors' certificates of addition, and utility certificates of addition.

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

To be completed in duplicate

REQUEST FOR THE FURNISHING OF SAMPLES OF DEPOSITED MICROORGANISMS

pursuant to Rule 11.2(ii)

TO

NAME AND ADDRESS OF INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED AUTHORIZED PARTY HEREBY REQUESTS THE FURNISHING OF A SAMPLE OF THE MICROORGANISM IDENTIFIED HEREUNDER, IN ACCORDANCE WITH RULE 11.2(ii) OF THE REGULATIONS UNDER THE BUDAPEST TREATY

I. IDENTIFICATION OF THE MICROORGANISM	
Accession number of the deposit:	
II. DECLARATION OF THE DEPOSITOR	
The undersigned depositor of the microorganism identified under I above hereby authorizes the furnishing of a sample of the said microorganism to the party specified under IV below.	
Name of the depositor: Address of the depositor:	Signature of the depositor [1]: Date:
III. REQUEST FOR INFORMATION	
The undersigned authorized party ☐ [2] requests ☐ [2] does not request an indication of the conditions which the International Depositary Authority employs for the cultivation and storage of the microorganism.	
IV. AUTHORIZED PARTY	
Name of the authorized party: Address of the authorized party:	Signature of the authorized party [1]: Date:

[1] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

[2] Mark with a cross the applicable box.

Form BP/11 (sole page)

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

To be completed in duplicate

REQUEST [1]
FOR THE FURNISHING OF SAMPLES
OF DEPOSITED MICROORGANISMS
pursuant to Rule 11.3(a)

TO

NAME AND ADDRESS OF
INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED HEREBY REQUESTS THE FURNISHING OF A SAMPLE OF THE MICROORGANISM IDENTIFIED HEREUNDER, IN ACCORDANCE WITH RULE 11.3(a) OF THE REGULATIONS UNDER THE BUDAPEST TREATY

I. IDENTIFICATION OF THE MICROORGANISM
Accession number of the deposit:
II. PATENT APPLICATION OR PATENT REFERRING TO THE MICROORGANISM
☐ [2] Patent application No. filed on Filed by (name, address): ☐ [2] International Application (PCT) No. filed on Filed by (name, address): ☐ [2] Patent [3] No. granted on Granted to (name, address):

[1] The request must be sent to the competent industrial property office which, in conformity with its own applicable procedure, will either transmit it directly to the international depositary authority or send it back to the certified party for transmission to the international depositary authority.

[2] Mark with a cross the applicable box.

[3] References to a "patent" shall be construed as references to patents for inventions, inventors' certificates, utility certificates, utility models, patents or certificates of addition, inventions' certificates of addition and utility certificates of addition.

III. REQUEST FOR INFORMATION	
The undersigned ☐ [2] requests ☐ [2] does not request an indication of the conditions which the International Depositary Authority employs for the cultivation and storage of the microorganism.	
IV. CERTIFIED PARTY	
Name: Address:	Signature [4]: Date:

[2] Mark with a cross the applicable box.

[4] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

CERTIFICATION

It is hereby certified that:

(1) ☐ [2] the patent application specified under II above, referring to the deposit of the microorganism identified under I above, has been filed with this Office for the grant of a patent and its subject matter involves the said microorganism or the use thereof.

☐ [2] the international application specified under II above, referring to the deposit of the microorganism identified under I above, designates for the grant of a patent the State party to the Patent Cooperation Treaty (PCT) for which this Office is the "designated Office" within the meaning of the said Treaty, and the subject of that international application involves the said microorganism or the use thereof.

☐ [2] the patent specified under II above, referring to the deposit of the microorganism identified under I above, has been granted by this Office and its subject matter involves the said microorganism or its use thereof .

(2) ☐ [2] publication for the purposes of patent procedure has been effected:

☐ [5] by this Office.

☐ [5] by the International Bureau of the World Intellectual Property Organization as an international publication under the Patent Cooperation Treaty (PCT).

or

☐ [2] the certified party has a right to a sample before publication in accordance with [6]:

(3) ☐ [2] the certified party has a right to a sample of the microorganism identified under I above under the law governing patent procedure before this Office and this Office is satisfied that the conditions, if any, prescribed by the said law have actually been fulfilled.

or

☐ [2] the certified party has affixed his signature on a form before this Office and, as a consequence of the signature of the said form, the conditions for furnishing a sample of the microorganism identified under I above to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before this Office.

Industrial Property Office Street City (Country)	Signature: Date:

[2] Mark with a cross the applicable box.

[5] If only one box applies, mark with a cross that box; if both boxes apply, mark with a cross one of the two boxes (choose one).

[6] Cite the applicable provision of the law, including any court decision.

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

To be completed in duplicate

REQUEST
FOR THE FURNISHING OF SAMPLES
OF DEPOSITED MICROORGANISMS
pursuant to Rule 11.3(b)

TO

NAME AND ADDRESS OF
INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED HEREBY REQUESTS THE FURNISHING OF A SAMPLE OF THE MICROORGANISM IDENTIFIED HEREUNDER, IN ACCORDANCE WITH RULE 11.3(b) OF THE REGULATIONS UNDER THE BUDAPEST TREATY

I. IDENTIFICATION OF THE MICROORGANISM	
Accession number of the deposit: Name of the depositor [1]: Identification reference given by the depositor [1]: Taxonomic designation, if any, proposed by the depositor [1]:	
II. REQUEST FOR INFORMATION	
The undersigned ☐ [2] requests ☐ [2] does not request an indication of the conditions which the International Depositary Authority employs for the cultivation and storage of the microorganism.	
III. REQUESTING PARTY	
Name: Address:	Signature [3]: Date:

[1] To be indicated if known by the requesting party.

[2] Mark with a cross the applicable box.

[3] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

TO

NOTIFICATION OF THE FURNISHING OF SAMPLES OF DEPOSITED MICROORGANISMS
issued pursuant to Rule 11.4(g) by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

NAME AND ADDRESS OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM
Accession number of the deposit:
II. NOTIFICATION
The depositor is hereby notified that a sample of the microorganism identified under I above was furnished on to: Name [1]: Address [1]: This notification is accompanied by a copy of: ☐ [2] the request and the declaration under Rule 11.1 ☐ [2] the request and the declaration under Rule 11.2(ii) ☐ [2] the form containing the request and the certification under the Rule 11.3(a) ☐ [2] the request under Rule 11.3(b)
III. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Address:	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date:

[1] Write the name and address of the industrial property office, the authorized party, the certified party or the requesting party, as the case may be, to whom the sample was furnished.

[2] Mark with a cross the applicable box.

Form BP/14 (sole page)

[End of Appendix 3 and of Appendices]

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

To be completed in duplicate

REQUEST [1]
FOR THE FURNISHING OF SAMPLES OF DEPOSITED MICROORGANISMS
pursuant to Rule 11.3(a)

TO

NAME AND ADDRESS OF INTERNATIONAL DEPOSITARY AUTHORITY

THE UNDERSIGNED HEREBY REQUESTS THE FURNISHING OF A SAMPLE OF THE MICROORGANISM IDENTIFIED HEREUNDER, IN ACCORDANCE WITH RULE 11.3(a) OF THE REGULATIONS UNDER THE BUDAPEST TREATY

I. IDENTIFICATION OF THE MICROORGANISM
Accession number of the deposit:
II. PATENT APPLICATION OR PATENT REFERRING TO THE MICROORGANISM
☐ [2] Patent application No. filed on Filed by (name, address):
☐ [2] International Application (PCT) No. filed on Filed by (name, address):
☐ [2] Patent [3] No. granted on Granted to (name, address):

[1] The request must be sent to the competent industrial property office which, in conformity with its own applicable procedure, will either transmit it directly to the international depositary authority or send it back to the certified party for transmission to the international depositary authority.

[2] Mark with a cross the applicable box.

[3] References to a "patent" shall be construed as references to patents for inventions, inventors' certificates, utility certificates, utility models, patents or certificates of addition, inventions' certificates of addition and utility certificates of addition.

III. REQUEST FOR INFORMATION	
The undersigned ☐ [2] requests ☐ [2] does not request an indication of the conditions which the International Depositary Authority employs for the cultivation and storage of the microorganism.	
IV. CERTIFIED PARTY	
Name: Address:	Signature [4]: Date:

[2] Mark with a cross the applicable box.

[4] Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s).

CERTIFICATION

It is hereby certified that:

(1) ☐ [2] the patent application specified under II above, referring to the deposit of the microorganism identified under I above, has been filed with this Office for the grant of a patent and its subject matter involves the said microorganism or the use thereof.

☐ [2] the international application specified under II above, referring to the deposit of the microorganism identified under I above, designates for the grant of a patent the State party to the Patent Cooperation Treaty (PCT) for which this Office is the "designated Office" within the meaning of the said Treaty, and the subject of that international application involves the said microorganism or the use thereof.

☐ [2] the patent specified under II above, referring to the deposit of the microorganism identified under I above, has been granted by this Office and its subject matter involves the said microorganism or its use thereof .

(2) ☐ [2] publication for the purposes of patent procedure has been effected:

☐ [5] by this Office.

☐ [5] by the International Bureau of the World Intellectual Property Organization as an international publication under the Patent Cooperation Treaty (PCT).

or

☐ [2] the certified party has a right to a sample before publication in accordance with [6]:

(3) ☐ [2] the certified party has a right to a sample of the microorganism identified under I above under the law governing patent procedure before this Office and this Office is satisfied that the conditions, if any, prescribed by the said law have actually been fulfilled.

or

☐ [2] the certified party has affixed his signature on a form before this Office and, as a consequence of the signature of the said form, the conditions for furnishing a sample of the microorganism identified under I above to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before this Office.

Industrial Property Office Street City (Country)	Signature: Date:

[2] Mark with a cross the applicable box.

[5] If only one box applies, mark with a cross that box; if both boxes apply, mark with a cross one of the two boxes (choose one).

[6] Cite the applicable provision of the law, including any court decision.