

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

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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.

AM - ARMENIA

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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.

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1. Requirements for Deposit

The deposit of a culture of a microorganism is required: a) if the invention is a microorganism, or b) 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(1A), 41(1) - (3) and 43(2B); Patents Regulations, Regulations 1.5(1) - (4) and 3.12(5))

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 (6), 3.13B(5), 3.13C(4) and 3.13D(5) and 3.32(1), (2))

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) and 42(1); Budapest Treaty Regulations Rule 9.1)

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 (OPI).

The commissioner must grant the certification: a) if the request is in respect of an application that has lapsed, been refused or been withdrawn, b) if the request is in respect of a patent that has expired, ceased, or been revoked, or c) in certain other prescribed circumstances as defined in the Act and Regulations.

(Patents Regulations, Regulation 1.5(5), 3.24(1), 3.25, 3.25B, 3.25C, 3.25D, 3.25E and 3.25F)

(ii) Restrictions Concerning the Furnishing of Samples

If a request is made in respect of an application that has not lapsed, been refused or been withdrawn, or in respect of a granted patent that has not expired, ceased or been revoked, 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 the following specified proceedings:

- opposition proceedings under Chapter 5 of the Patents Act in relation to the grant of a standard patent on the application; or
- opposition proceedings under section 101M of the Patents Act in relation to an innovation patent; or
- relevant proceedings in relation to the patent.

(Patents Regulations, Regulation 3.25C, Form P/00/031)

The Commissioner may 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 3.25G)

The Commissioner must not grant the certification if the request relates to a microorganism (or its use, modification or cultivation) that is the subject of a PCT application, and the applicant of the PCT application has not complied with subsection 29A(5) of the Patents Act.

(Patents Regulations, Regulation 3.25B(5))

The applicant may, at any time before the specification relating to the application is OPI, notify the Commissioner that a sample of the deposited microorganisms is only to be provided during the period;

(a) only once the application is OPI, and

(b) only to a person who is skilled addressee without an interest in the invention; and is nominated by the person who made the request.

The above conditions only apply until the application has lapsed, been withdrawn or been refused, or until a patent is granted on that application.

(Patent Regulations, Regulation 3.25(A))

AT – AUSTRIA

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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)

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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.

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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

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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).

(Paragraphs 109, 120 and 430 of the Regulations on the procedure of drawing up an application for an invention patent, on examination and a decision making procedure on the results of the examination (hereinafter – Regulations)).

2. Time of Deposit

The deposit of a microorganism must be made before or on the priority date of an application.

(Paragraphs 109, 120 and 430 of the Regulations)

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.

(Paragraph 430 of the Regulations)

4. Conditions for the Furnishing of Samples

No provision.

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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).

(Paragraphs 109, 120 and 430 of the Regulations on the procedure of drawing up an application for an invention patent, on examination and a decision making procedure on the results of the examination (hereinafter – Regulations)).

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(Paragraph 430 of the Regulations)

4. Conditions for the Furnishing of Samples

No provision.

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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 10bis 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

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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.

BN – BRUNEI DARUSSALAM

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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 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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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

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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 1996¹, 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

Telephone: (56) 2 2887 0550, 2887 0551
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

China National Intellectual Property Administration (CNIPA)
6 Xituchenglu
Haidian District
100088 Beijing

Mailing address:
P.O. Box 8020
100088 Beijing

Telephone: (86-10) 62 35 66 55
Telefax: (86-10) 62 01 96 15
E-mail: sipo@sipo.gov.cn
Internet: <http://www.cnipa.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 be given, 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 biological material 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 9; 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)

CO - COLOMBIA

Superintendencia de Industria y Comercio
Ministerio de Comercio, Industria y Turismo
Carrera 13 No. 27-00
Pisos Mezanine, 1, 3, 4, 5, 6, 7 y 10
Bogotá

Telephone: (571) 587 0051 (Superintendente) - (571) 587 0000
Facsimile: (571) 587 0054 (Superintendente) - (571) 587 0054
E-mail: contactenos@sic.gov.co

1. Requirements for Deposit

2. Time of Deposit

3. Duration of Storage

4. Conditions for the Furnishing of Samples

CR – COSTA RICA

Registry of Industrial Property
Ministry of Justice
Apartado postal 523
2010 Zapote
San Jose

Telephone: (506) 2234 1537, (506) 2202 0885

Telefax: (506) 2234 1537

E-mail: cmena@rnp.go.cr, kquesada@rnp.go.cr, ljimenezs@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

Telephone: (385-1) 610 61 00
Telefax: (385-1) 611 20 17
E-mail: info@dziv.hr
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) 862 43 79, 862 43 95, 866 05 57, 866 05 59
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 the 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.org>

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 2012, 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 of Business and Growth. 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

National Office of Industrial Property
State Secretariat for Industry and Commerce
Avenida Los Próceres No. 11
Jardines del Norte
Santo Domingo

Telephone: (809) 567 74 74
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

National Center of Registries (CNR) (El Salvador)
1ª Calle Poniente y 43 Avenida Norte N° 2310
San Salvador

Telephone: (503) 2593 5151, 2593 5444
E-mail: patentes@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)
Sörnäisten rantatie 13 C
00100 Helsinki

Mailing address:
00091 PRH

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 Finnish Patent and Registration Office 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 17(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 16 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 Finnish Patent and Registration Office. 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 Finnish Patent and Registration Office 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 (INPI)
15, rue des Minimes, CS50001
92677 Courbevoie Cedex

Telephone: (33) 1 71 08 71 63 (international calls) - (33) 0820 210 211 (national calls)
Telefax: (33) 1 56 65 86 00
Email : contact@inpi.fr
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
5, Antioch Str.
3300 Mtskheta

Telephone: (995-32) 225 25 33
Telefax: (995-32) 298 84 26
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) 2195-0; (49-89) 2195-1000 (Customer Care and Services)
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- BGBl*) 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

Telephone: (30-210) 618 35 48, 618 35 08

Telefax: (30-210) 681 92 31

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)
II. János Pál pápa tér 7
1081 Budapest

Mailing address:
P.O. Box 415
1438 Budapest

Telephone: (36-1) 312 44 00
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
Engjateigi 3
105 Reykjavík

Telephone: (354) 580 94 00
E-mail: postur@els.is
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: delhi-patent@nic.in
Internet: <http://www.ipindia.nic.in>

Indian Patent Office Kolkata
Intellectual Property Office Building
CP-2, Sector-V
Salt Lake City
Kolkata 700 091

Telephone: (91-33) 23 67 19 87 – 23 67 50 91
Telefax: (91-33) 23 67 19 88
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 9695101

Mailing address:
P.O. Box 53420
Jerusalem 91533

Telephone: (972-73) 392 73 13, 392 73 20
E-mail: OritR@justice.gov.il
Internet: <http://www.justice.gov.il/En/Units/ILPO/Pages/default.aspx>

1. Requirements for Deposit

Where 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 where the biological material has been deposited in a deposit institution, then part of the description of the invention or of the manner of its performance thereof may consist of referral to such deposit, all in accordance with the term and conditions as mentioned below.

For purposes of this paragraph, a biological material is a biological material that is not available to the public, and which cannot be described in a manner that will enable a skilled person to carry out the invention, provided that the biological material has the capability of replication or transcription either by itself or in an animal or plant host cell.

Article 12(b) to the Israel Patents Law, 5727-1967

If the applicant chose to refer to a deposit of a biological material in a depository institution under section 12(b) of the law, then the reference shall be conducted as follows:

- (1) When submitting the patent application, the institution and deposit number as well as the date in which the deposit was made shall be noted in the description of the invention. A certification from the depository institution attesting to the reception of the biological material (certification of reception) shall be attached to the application in accordance with the rules of the Budapest Treaty as published in the WIPO website.
- (2) The owner of an application or patent, as appropriate, shall notify the Office of the number of a new deposit and will attach the certification of reception within 3 months of the date given in case of a new deposit (as referred to under article 4 of the Budapest Treaty) subsisting of a biological material previously deposited. The provisions under sections 22, 29 and 65 of the Law shall apply to amendments of the application or patent, as appropriate.

Regulation 20(al) of the Israel Patents Regulations (Office Practice, Rules of Procedure, Documents and Fees) 5728-1968

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 depository 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 depository 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 depository 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, 18 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
3-4-3 Kasumigaseki
Chiyoda-ku
Tokyo 100-8915

Telephone: (81-3) 35 92 13 08
Telefax: (81-3) 35 81 06 59, 35 01 06 59
E-mail: PA1A31@jpo.go.jp
Internet: <http://www.jpo.go.jp/e/index.html>

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 depository authority designated by the Commissioner of the Japan Patent Office or with an international depository authority under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as the “Treaty”). The International Patent Organism Depository National Institute of Technology and Evaluation (IPOD, NITE) and the National Institute of Technology and Evaluation, Patent Microorganisms Depository (NPMD) are designated as official depository authorities.
(Regulations under the Patent Law, Rule *27bis*)

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 Treaty for the deposit of the microorganism issued by the international depository 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 Japan Patent Office or by the non-contracting states of the Treaty, as designated by the Commissioner of the Japan Patent Office, and which allows Japanese nationals to conduct the patent process with respect to the deposit of microorganisms under the same conditions as in Japan, 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 *27bis*)

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 Japan Patent Office, in which case the applicant must reply to such notice.

(Regulations under the Patent Law, Rule *27ter*)

(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 *27ter*)

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 (NIIP)
Korgalzhyn Highway
Building 3B
010000 Nur-Sultan

Telephone: (7-7172) 62 15 15, 62 15 16, 62 15 91
Telefax: (7-7172) 74 96 21
E-mail: kazpatent@kazpatent.kz
Internet: www.kazpatent.kz, www.adilet.gov.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

Kyrgyz Respublikasynyn Okmotunun karashtuu Intellektualdyk
Menchik jana Innovacialar Mamlekettik Kyzmaty
State Service of Intellectual Property and Innovation under
the Government of the Kyrgyz Republic
62, Moskovskaya Street
Bishkek 720021

Telephone: (996-312) 68 08 19
Telefax: (996-312) 68 17 03
E-mail: info@patent.kg; inter@patent.kg
Internet: <http://patent.kg/index.php/en/>

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.lrv.lt>

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 depository 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 depository 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)
Ministère de l'économie
19-21, Boulevard Royal
Luxembourg-Ville

Mailing address:
2914 Luxembourg

Telephone: (352) 247 84113
Telefax: (352) 247 94113
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
Ciudad de Mexico

Telephone: (52-5) 334 07 24, 334 07 00 (ext. 10025, 10078, 10095)
Telefax: (52-5) 555 44 31
E-mail: dp@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.

The only institutions recognized for the deposit of microorganisms for patent purposes are the international authorities for the deposit of biological material established 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

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 Guide to the deposit of Microorganisms under the Budapest Treaty shall apply.

MC - MONACO

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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.

ME – MONTENEGRO

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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.

MA – MOROCCO

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E-mail : adil.elmaliki@ompic.org.ma - elmaliki@ompic.org.ma
Internet: www.ompic.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

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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

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General Directorate for Industry
Ministry for Economy and Development
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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 – NORTH 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 lose 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.

NO – NORWAY

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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, first paragraph, 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, first paragraph, no. 7)

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, first paragraph)

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, second paragraph)

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, fourth paragraph)

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, fifth paragraph)

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, first paragraph, 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, first paragraph, 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, second paragraph)

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, third paragraph)

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, fourth paragraph)

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, seventh paragraph, first and second sentences)

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, first paragraph)

(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, seventh paragraph)

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, eighth paragraph)

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, ninth paragraph)

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, first paragraph)

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, second paragraph)

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, third paragraph)

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, fourth paragraph)

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, fifth paragraph)

OM – OMAN

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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.

PA – PANAMA

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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

PE – PERU

National Institute for the Defense of Competition and Intellectual Property Protection
Ministry of Industry, Tourism, Integration and International Trade Negotiations
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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.

PH – PHILIPPINES

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1. 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

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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

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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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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

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Daejeon 35208

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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

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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 depository 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

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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 may be deemed to be disclosed, according to the provisions of Art 18 paragraph (1)¹ only if:

(a) a sample of biological material was deposited with an international depositary authority, prior to the date of filing the application or the date of the recognized priority;

(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, according to Art. 74.

(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 information is communicated until the end of the technical procedures with the view of publishing the patent application;

¹ As the current text of the Implementing Regulations, from which the quoted passages are taken, has not yet been updated, following the latest amendments of the Patent Law, the reference to Art. 18, para (1) should be replaced with Art. 17, para (1), according to the current version of the Law.

(b) up to the date of presenting the request for publication of the patent application, in compliance with Art. 23, paragraph (3)² of the Law;

(4) After the communication of these indications, the applicant shall be considered to consent unreservedly and irrevocably to render the deposited biological material, available to the public, according to Art. 74.

(Art. 17 (2), Patent Law 64/1991, as amended and republished in 2014; Art. 73, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991)

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.

Art. 73, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991.

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, according to Art. 73, 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 sample of deposited biological material to the interested person under the provision of Art. 75.

(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 expression “compulsory license” mentioned in paragraph (3) includes the

² As the current text of the Implementing Regulations, from which the quoted passages are taken, has not yet been updated, following the latest amendments of the Patent Law, the reference to Art. 23 para (3) should be replaced with Art. 22 para (3), according to the current version of the Law.

ex officio licenses and any right to use a patented invention for the interest of public.

(5) “Derived biological material” is, within the meaning of paragraph (2), any material having the essential features of the deposited material for carrying out the invention.

(6) 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 both the filing of a patent application referring to a biological material deposit and the fact that the interested person or the expert appointed by that person, in compliance with Art. 75, is entitled to deliver a sample of this material.

(7) The request provided for in paragraph (1) may be addressed to OSIM even after the grant of the patent.

(8) OSIM shall transmit a copy of the request referred to in paragraph (1), accompanied by the certification referred to in paragraph (6) both to the international depositary authority and to the applicant or patent owner.

(Art. 74, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991)

(ii) Appointment of an expert

(1) Up to the end of the technical preparations for the publication of the patent application, the applicant may communicate to OSIM that:

(a) up to the publication of the mention of the decision to grant the patent in compliance with Art. 23 paragraph (4)³ of the Law; or, where appropriate,

(b) for a 20-year period starting from the patent application filing date, if the patent application is rejected, withdrawn or considered to be withdrawn, the access provided for in Art. 74 can be allowed only by delivering a sample of biological material to an expert appointed by an interested person.

(2) The appointed expert may be:

(a) any natural person, provided that the interested person, according to paragraph (1), makes the evidence that on the date of filing the request for the delivery of the sample, the appointment of the expert was made with the agreement of the applicant;

(b) any natural person that is recognized to be an expert by OSIM.

(3) The appointment mentioned in paragraph (2) is accompanied by a statement made by the expert whereby this assumes the commitment to the applicant in compliance with Art. 74 and the fact that, either up to the date of the patent expiration or up to the date provided for in paragraph (1) letter b), the patent application may be rejected, withdrawn or deemed being withdrawn, the interested person being deemed to be a third party.

³ As the current text of the Implementing Regulations, from which the quoted passages are taken, has not yet been updated, following the latest amendments of the Patent Law, the reference to Art. 23, para (4) should be replaced with Art. 22, para (4), according to the current version of the Law.

(Art. 75, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991).

Besides the provisions presented above, under the entries indicated in your letter, the current version of the Implementing Regulations of the Patent Law 64/1991, as republished, also comprises the following provisions:

New deposit of biological material

(1) If the biological material deposited according to Art. 73 paragraph (1) ceases to be available with the international depositary authority, there shall not be considered a discontinuity of its availability if the following conditions are fulfilled cumulatively:

- (a) a new deposit is constituted in compliance with the Budapest Treaty;
- (b) a copy of the document issued by the international depositary authority, confirming the receiving of the new deposit and in which the application or patent number is mentioned, is sent to OSIM within four months from the date of the new deposit.

(Art. 76, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991).

Description of the invention relating to microorganisms

(1) If the subject-matter of the invention relates to a new microorganism strain, the description of the invention shall contain, within the embodiment of the invention, at least one process for obtaining said microorganism, besides the morphological and biochemical features of the microorganism; in the description there shall also be indicated the taxon integration of the microorganism, number of order and date of depositing the microorganism with the international depositary authority where the microorganism was deposited.

(2) If the subject-matter of the invention related to a product containing a microorganism or obtained by means of a process involving a microorganism, or to a process in which a microorganism is involved, the description of the invention shall contain in the embodiment the taxon integration, the morphological and biochemical features of the microorganism, denomination of the microorganism, number of order and date of depositing the microorganism with the international depositary authority, as well as the denomination of the international depositary authority where the used microorganism has been deposited.

(Art. 78, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991).

RU – RUSSIAN FEDERATION

Federal Service for Intellectual Property (Rospatent)
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E-mail: rospatent@rupto.ru
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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

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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 depository 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 depository 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))

SG - SINGAPORE

Intellectual Property Office of Singapore
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Internet: www.ipos.gov.sg

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))

SK – SLOVAKIA

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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))

SI – SLOVENIA

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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))

ZA – SOUTH AFRICA

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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 8(a) 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 8(a), 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 18 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 25(a) 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).

CH - SWITZERLAND

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1. Requirements for Deposit

Article 50a(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 45b 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 50a 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 50a(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 45j 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 45e(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 45h, 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 45f).

(ii) Restrictions Concerning the Furnishing of Samples

Article 45g 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.

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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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

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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.

UA – UKRAINE

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Ministry of Economic Development and Trade of Ukraine
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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

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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

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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

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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.

**AP – AFRICAN REGIONAL INTELLECTUAL
PROPERTY ORGANIZATION (ARIPO)**

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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)

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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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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*).