

## **Regulations for the Deposit of Biological Material for Patent Application**

1. Promulgated and entered into force on June 21, 2002.
2. Revised and promulgated on December 10, 2003; entered into force on July 1, 2004.
3. Revised and promulgated on December 4, 2012; entered into force on January 1, 2013.
4. Revised and promulgated on June 4, 2015; entered into force on June 18, 2015.

Article 1            These regulations are formulated pursuant to Paragraph 6, Article 27 of the Patent Act (hereinafter referred to as “the Act”).

Article 2            A request for deposit of biological material may be filed by providing the following items to the depository institution (hereinafter referred to as “the Depository”) designated by the Specific Patent Agency:

1. a request form (Appendix II) indicating the name, domicile, residence of the depositor; in case of a juristic person or an organization with a representative, indicating the name thereof, representative’s name, and business establishment;
2. basic information of the biological material (Appendix III);
3. the biological material with required quantity; and
4. deposit fees.

In case the biological material referred to in the preceding paragraph is imported, the import permit shall also be provided.

In case a request referred to in Paragraph 1 is filed by an appointed agent, the document specifying the power of attorney shall also be provided along with the request.

Article 3            The biological materials accepted for deposit include bacteria, actinobacteria, yeasts, molds, mushrooms, plasmids,

bacteriophages, viruses, animal cell lines, plant cell lines, hybridoma, and other biological materials requiring deposit.

Article 4 The deposited biological materials shall be preserved in freeze-dried or frozen form, and the container requirements for depositing biological materials are set forth in Appendix I. However, the biological materials that cannot be preserved in freeze-dried or frozen form may be preserved by other appropriate preservation methods determined by the Depository.

The biological materials referred to in the preceding paragraph shall be transported under an appropriate temperature and in an appropriate way to maintain their viability and properties, and to prevent them from being released to the environment during transport.

Article 5 The “biological material with required quantity” referred to in Subparagraph 3, Paragraph 1 of Article 2 is set forth below:

1. for bacteria, actinobacteria, yeasts, molds, mushrooms, bacteriophages, and plasmids in transformed host, 6 vials of culture samples shall be deposited and each shall contain the amount necessary for performing viability test;
2. for viruses, animal cell lines, plant cell lines, hybridoma, and biological materials with special cultivation conditions, 25 vials of culture samples shall be deposited and each shall contain the amount necessary for performing viability test;
3. for plasmids deposited in nucleic acid form, at least 10 micrograms shall be deposited and be evenly distributed in 25 vials of culture samples; each vial of sample shall contain the amount necessary for performing viability test; and
4. for other biological materials requiring deposit, the amount to be deposited shall be determined by the

Depository.

In case the plasmids referred to in Subparagraph 3 of the preceding paragraph are deposited in nucleic acid form, the Depository, if it deems necessary, may notify the depositor to provide 6 vials of hosts in an appropriate preservation form and each vial of culture samples shall contain the amount necessary for performing viability test.

Article 6        The Depository shall reject a request for deposit under any of the following circumstances:

1. the request for deposit is not filed pursuant to Article 2;
2. the biological material is not provided in an appropriate form and with necessary quantity pursuant to the provisions from Article 4 to the preceding article;
3. the biological material is under restriction by laws, except for the one having obtained the permit; or
4. the biological material obviously has been contaminated, or cannot be accepted for deposit due to scientific reasons.

The Depository shall notify the depositor in advance of the reasons for rejection and allow the depositor to respond within a time limit.

Article 7        The Depository shall perform viability tests within 1 month after the date that all the required items of a request for deposit referred to in Article 2 have been submitted in full, and issue a certificate of deposit to the depositor whose biological material has been proven to be viable.

The certificate of deposit referred to in the preceding paragraph shall indicate the following items:

1. the name and address of the Depository;
2. the name and residence, domicile, or business establishment of the depositor;
3. the date of the deposit accepted by the Depository;
4. the accession number given by the Depository;
5. the identification number or symbol given by the

depositor to the biological material;

6. the scientific name of the biological material shown in the request form; and
7. the date of the viability test.

In case the biological material cannot be proven to be viable after performing the viability test referred to in Paragraph 1, the depositor shall provide the relevant information of the biological material or its culture medium within the time limit specified by the Depository.

Article 8 After performing the viability test referred to in the preceding article, the Depository may perform additional viability tests to the deposited biological material, when necessary for reasons of storing the biological material, or upon request by the depositor.

In case a culture medium with special components is required for the viability test referred to in the preceding article or preceding paragraph, the Depository may inform the depositor to provide such medium when necessary.

Article 9 The Depository shall issue a viability statement under the following circumstances:

1. after performing the viability test referred to in Paragraph 1 of Article 7, the biological material cannot be proven to be viable;
2. upon request by the depositor; and
3. upon request from one who is not the depositor but is entitled to be furnished with the biological material pursuant to Article 13.

The viability statement referred to in the preceding paragraph shall indicate the following items:

1. the name and address of the Depository;
2. the name and the residence, domicile, or business establishment of the depositor;
3. the date of deposit accepted by the Depository;
4. the accession number given by the Depository;

5. the date of the viability test; and
6. the viability test result that indicates whether the biological material is viable or not.

In case the viability test shows the biological material is not viable, the viability statement shall additionally indicate the conditions under which the viability test has been performed and the relevant information.

Article 10        The duration of deposit of a biological material deposited in the Depository is 30 years.

The Depository shall preserve the biological material for at least five years additionally after the date a request for furnishing the biological material is made prior to the end of the duration referred to in the preceding paragraph.

After the end of the duration referred to in the preceding two paragraphs, the Depository may destroy the deposited biological material.

Article 11        The depositor may not withdraw the deposit in the time period prescribed in the preceding article; however, this shall not apply where the withdrawal is made prior to the issuance of the certificate of deposit by the Depository in accordance with Paragraph 1 of Article 7.

The depositor withdrawing the deposit pursuant to the proviso of the preceding paragraph (Appendix V) may request a refund of the paid deposit fee; however, the cost occurred from the performed viability test should be deducted therefrom.

For the deposit withdrawn pursuant to the proviso of Paragraph 1, the Depository shall return the deposited biological material or destroy it and inform the depositor.

Article 12        The Depository is under the obligation to keep confidential the deposited biological materials and relevant information. With the exception of the situation set forth in Article 13, the Depository shall not release deposited biological materials and relevant information to any third party.

Article 13        The Depository shall furnish the deposited biological materials to the following requesters:

1. the Specific Patent Agency;
2. the depositors or one with the consent of the depositor;  
and
3. one eligible for such request under Article 14.

After furnishing the biological materials pursuant to the preceding paragraph, the Depository shall notify the depositor in writing for the fact of furnishing, except for furnishing to the depositor.

When furnishing the biological materials pursuant to Paragraph 1, the Depository shall at the same time provide the scientific names of the biological materials given by the depositor.

Upon request by the requester, the Depository shall provide the cultivation or preservation conditions performed by the Depository.

Article 14        To practice an invention involving the deposited biological materials for research and experimental purposes, one may request the Depository for furnishing the biological materials under any of the following circumstances:

1. the patent application for invention involving a biological material has been allowed and published;
2. the one who has received a written notification from the invention patent applicant referred to in Paragraph 1, Article 41 of the Act; or
3. the one who has requested a re-examination referred to in Article 48 of the Act after the patent application was rejected.

The biological materials acquired pursuant to the preceding paragraph shall not be provided to others for use.

For a request for furnishing the biological materials pursuant to Paragraph 1, the following documents shall be provided:

1. a request form(Appendix IV);
2. a photocopy of the publication of the allowed patent application, of the written notification from the invention patent applicant, or of the written decision of rejection from the Specific Patent Agency;
3. a declaration of utilizing the biological materials only for research and experimental purposes; and
4. a declaration that the biological materials are not to be provided to others.

Article 15 For a request for furnishing biological materials pursuant to Article 13, the Depository may refuse to furnish the biological materials on account that the requester does not possess the knowledge or the equipment for handling the biological materials and may damage or threaten the environment, plants, or the health of humans or animals.

Article 16 One who obtained the biological materials that are pathogenic or may damage the environment pursuant to Article 13, shall destroy the biological materials immediately after use, and shall notify the Depository of the destruction.

Article 17 Where the Depository cannot continue furnishing the deposited biological materials because the deposited biological materials that had originally been found viable were no longer nonviable, or due to other circumstances, the date of re-deposit may be deemed the original deposit date if the requester replaces the biological materials within 3 months after having received the notification of non-viability from the Depository.

Where the depositor cannot replace the biological materials within the time period prescribed in the preceding paragraph due to the properties of the biological materials or other legitimate reasons, the period referred to in the preceding paragraph may be extended once such extension has been approved by the Depository.

For replacing the biological materials pursuant to the preceding two paragraphs, the depositor shall provide an

affidavit alleging that the replacement is the same as the original deposit.

Where the replaced biological materials are not received by the Depository within the specified time limit referred to in the preceding paragraphs, the date of deposit shall be the date on which the Depository receives a replacement of biological materials.

Where the depositor does not replace the biological materials pursuant to Paragraph 1 to 3, the Depository shall notify the Specific Patent Agency.

Article 18       Where the Depository has performed a viability test or preservation using the method provided or agreed by the depositor, the Depository has no obligation for compensation if the biological materials cannot be preserved properly or are no longer available for furnishing.

Article 19       Any person requesting for a deposit shall pay the deposit fee according to the following:

1. NT\$38,400 per request for bacteria, actinobacteria, yeasts, molds, mushrooms, plasmids, and bacteriophages;
2. NT\$52,800 per request for animal cell lines, plant cell lines, hybridoma, viruses, and other biological materials; and
3. for the biological materials referred to in the preceding two subparagraphs with special preservation condition, the deposit fee pertaining to properties of the biological materials, preservation materials, and equipment required is to be determined based upon the agreement between the depositor and Depository.

In case the biological materials referred to in the preceding paragraph cannot be proven to be viable, the depositor may request for a refund of the paid deposit fee of which the viability test fee referred to in Article 20 should be deducted therefrom.



Article 20 Any person requesting to the Depository for issuance of a viability statement pursuant to Paragraph 1 of Article 9 shall pay the deposit fee according to the following:

1. NT\$2,400 per request for bacteria, actinobacteria, yeasts, molds, mushrooms, and plasmids transformed in hosts;
2. NT\$4,800 per request for plasmids and bacteriophages in nucleic acid form, animal cell lines, plant cell lines, hybridoma, bacteriophages, viruses, and other biological materials; and
3. for the biological materials referred to in the preceding two subparagraphs with special cultivation condition, the deposit fee, up to NT\$120,000, is to be determined by the Depository based on properties of the biological materials, cultivation materials, and equipment required.

Article 21 Any person requesting to the Depository for furnishing the biological materials pursuant to Paragraph 1 of Article 13 shall pay the deposit fee according to the following:

1. NT\$2,400 per request for bacteria, actinobacteria, yeasts, molds, mushrooms, plasmids, and bacteriophages;
2. NT\$4,800 per request for animal cell lines, plant cell lines, hybridoma, viruses, and other biological materials; and
3. for the biological materials referred to in the preceding two subparagraphs with special cultivation condition, the deposit fee, up to NT\$120,000, is to be determined by the Depository based on properties of the biological materials, cultivation materials, and equipment required.

Article 22 A request to the Depository for providing cultivation or preservation condition of a biological material pursuant to Paragraph 4 of Article 13 shall cost NT\$360.

A request for issuance of replacement or a substitution of the certificate of deposit shall cost NT\$360.

Article 23        The appendixes referred to in these Regulations may be amended and promulgated by the Specific Patent Agency when necessary.

Article 24        For a patent application for invention involving a biological material or the utilization of a biological material filed after the implementation of the amended Act, in the event that the request for deposit of biological material has been filed prior to the implementation of the amended Act and the certificate of deposit submitted by the patent applicant pursuant to Paragraph 2 or 3, Article 27 of the Act does not contain the viability test report, the applicant for invention patent shall submit the viability test report within the time period set by the Specific Patent Agency. If the report is not submitted within the specified time period, the deposit shall be deemed not to have been made.

Article 25        These Regulations shall enter into force on January 1, 2013.

                      The amendment of these Regulations shall enter into force on June 18, 2015.