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# COMMITTEE OF EXPERTS ON THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

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DRAFT REGULATIONS UNDER THE TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS

FOR THE PURPOSES OF PATENT PROCEDURE

prepared by the International Bureau

#### SUMMARY

This document contains a revised draft of the Regulations under the draft Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The text of the latter draft is contained in document DMO/IV/2, which also contains comments on some of the draft Rules of the draft Regulations. Both drafts have been prepared by the International Bureau in accordance with the recommendations adopted by the Committee of Experts on the Deposit of Microorganisms for the Purposes of Patent Procedure at its second session (April 1975) and taking into account the replies received to WIPO Circular No. 2256 of July 18, 1975, inviting comments on some of the provisions.

## DRAFT REGULATIONS UNDER THE TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

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#### Rule 1

#### ABBREVIATED EXPRESSIONS

#### 1.1 "Treaty"

In these Regulations, the word "Treaty" means the Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

#### 1.2 "Article"

In these Regulations, the word "Article" refers to the specified Article of the Treaty.

#### INTERNATIONALLY RECOGNIZED DEPOSITARY AUTHORITIES

#### 2.1 Legal Status

Any internationally recognized depositary authority may be a government agency, including public institutions attached to any public administration other than the central government, or a private entity.

#### 2.2 Staff, Equipment and Facilities

The requirements referred to in Article 6(1)(ii) shall include in particular the following:

- (i) the staff, equipment and facilities of any internationally recognized depositary authority must be such that they enable that authority adequately to perform its scientific and administrative tasks under the Treaty and these Regulations; they must, in particular, enable the said authority to store the deposited microorganisms in a manner which ensures that they are kept viable and uncontaminated;
- (ii) any internationally recognized depositary authority must, for the storage of microorganisms, provide for sufficient safety measures to minimize the risk of losing stored microorganisms.

#### Alternative A\*

GRANTING OF THE STATUS OF INTERNATIONALLY RECOGNIZED DEPOSITARY AUTHORITY

#### 3.1 Proposal

- (a) The proposal referred to in Article 7(1)(a) shall be transmitted to the Director General through diplomatic channels.
  - (b) The proposal shall:
- (i) indicate the name and address of the depositary institution to which it is proposed that the status of internationally recognized depositary authority be granted;
- (ii) contain detailed information on all facts relevant in appreciating the said institution's capacity to comply with the requirements referred to in Article 6(1)(ii) to (vii)[, including information on its legal status, scientific standing, staff, equipment and facilities];
- (iii) where the guarantee referred to in Article 6(1)(iv) relates to certain kinds of microorganisms only, specify the kinds of microorganisms in respect of which the depositary institution, in its capacity of internationally recognized depositary authority, will perform the tasks it is obliged to perform under the Treaty and these Regulations;

#### Alternative B\*

ACQUISITION OF THE STATUS OF INTERNATIONALLY RECOGNIZED DEPOSITARY AUTHORITY

#### 3.1 Communication

- (a) The communication referred to in Article 7(1)(a) shall be transmitted to the Director General through diplomatic channels.
  - (b) The communication shall:
- (i) indicate the name and address of the depositary institution to which the communication relates;
- (ii) contain detailed information on all facts relevant in appreciating the said institution's capacity to comply with the requirements
  referred to in Article 6(1)(ii) to
  (vii)[, including information on its
  legal status, scientific standing,
  staff, equipment and facilities];
- (iii) where the guarantee referred to in Article 6(1)(iv) relates to certain kinds of microorganisms only, specify the kinds of microorganisms in respect of which the depositary institution, in its capacity of internationally recognized depositary authority, will perform the tasks it is obliged to perform under the Treaty and these Regulations;

<sup>\*</sup> This Alternative applies if Alternative A of Article 7 is adopted.

<sup>\*</sup> This Alternative applies if Alternative B of Article 7 is adopted.

#### [Rule 3.1(b) (Alternative A), continued]

- (iv) indicate the amount of
  any fees that the said institution
  will, upon recognition, charge for
  storage, viability statements and
  release of samples of microorganisms;
- (v) where applicable, indicate the date before which the granting of the status of internationally recognized depositary authority shall not take effect in respect of that institution.

#### 3.2 Processing of the Proposal

- (a) If the proposal complies with Article 7(1)(a) and Rule 3.1, it shall be promptly notified by the Director General to all Contracting Parties.
- (b) Any Contracting Party may within four months from the notification of the proposal notify the Director General of its agreement with the proposal. If three-fourths of the members of the Assembly notify their agreement with the proposal, the Assembly shall be deemed to have decided to adopt the proposal and its decision shall take effect at the expiration of four months from the notification of the proposal or, where applicable, on the date indicated under Rule 3.1(b)(v).
- (c) Where no decision is taken under the procedure referred to in paragraph (b), the proposal shall be considered by the Assembly not earlier than four and not later than eight months from the notification of the proposal.

#### [Rule 3.1(b) (Alternative B), continued]

- (iv) indicate and amount of
  any fees that the said institution
  will, upon recognition, charge for
  storage, viability statements and
  release of samples of microorganisms;
- (v) where applicable, indicate the date before which the acquisition of the status of internationally recognized depositary authority shall not take effect in respect of that institution.

#### 3.2 Processing of the Communication

If the communication complies with Article 7(1)(a) and Rule 3.1, it shall be promptly notified by the Director General to all Contracting Parties and shall be promptly published in the Gazette.

#### [Rule 3.2 (Alternative A), continued]

- (d) If the Assembly decides to grant the status of internationally recognized depositary authority, the said decision shall specify the date on which the internationally recognized depositary authority will commence its functions in the capacity of such an authority. Such date may not precede any date indicated under Rule 3.1(b)(v).
  - (e) The Director General shall promptly notify all Contracting Parties of the decision under paragraph (b) or (d); the decision shall be promptly published in the Gazette.

### 3.3 Extension of the List of Kinds of Microorganisms Accepted

The Contracting State having made the proposal referred to in Article 7(1)(a) may, at any time thereafter, notify the Director General that its guarantee is extended to specified kinds of microorganisms to which, so far, the guarantee has not extended. In such a case, and as far as the additional kinds of microorganisms are concerned, Article 7(1) and Rules 3.1 and 3.2 shall apply, mutatis mutandis.

#### [Rule 3 (Alternative B), continued]

## 3.3 Extension of the List of Kinds of Microorganisms Accepted

The Contracting State having made the communication referred to in Article 7(1)(a) may, at any time thereafter, notify the Director General that its guarantee is extended to specified kinds of microorganisms to which, so far, the guarantee has not extended. In such a case, and as far as the additional kinds of microorganisms are concerned, Article 7(1) and Rules 3.1 and 3.2 shall apply, mutatis mutandis.

#### Alternative A\*

WITHDRAWAL OR LIMITATION OF THE STATUS OF INTERNATIONALLY RECOGNIZED DEPOSITARY AUTHORITY

#### 4.1 Request

- (a) The request referred to in Article 7(2)(a) shall be transmitted to the Director General as provided in Rule 3.1(a).
  - (b) The request shall:
- (i) indicate the name and address of the internationally recognized depositary authority concerned;
- (ii) where it concerns certain
  kinds of microorganisms only, indicate the kinds of microorganisms to
  which it relates;
- (iii) indicate in detail the facts on which it is based.

#### 4.2 Processing of the Request

- (a) Subject to paragraph (b),the procedure provided for in Rule3.2 shall apply, <u>mutatis</u> <u>mutandis</u>,to the request.
- (b) Where, in the opinion of the Assembly, respect of the time limit provided for in Rule 3.2(c) could endanger the interests of actual or potential depositors, the Assembly may shorten that time limit.

#### Alternative B\*

TERMINATION OR LIMITATION OF THE STATUS OF INTERNATIONALLY RECOGNIZED DEPOSITARY AUTHORITY

#### 4.1 Request

- (a) The request referred to in Article 7(2)(a) shall be transmitted to the Director General as provided in Rule 3.1(a).
  - (b) The request shall:
- (i) indicate the name and address of the internationally recognized depositary authority concerned;
- (ii) where it concerns certain
  kinds of microorganisms only, indicate the kinds of microorganisms to
  which it relates;
- (iii) indicate in detail the facts on which it is based.

#### 4.2 Processing of the Request

- (a) If the request complies with Rule 4.1, it shall be notified by the Director General to all Contracting Parties.
- (b) The Assembly shall consider the request not earlier than four and not later than eight months from the notification of the request.
- (c) Where, in the opinion of the Assembly, respect of the time limit provided for in Rule 4.2(b) could endanger the interests of actual or potential depositors, the Assembly may shorten that time limit.

<sup>\*</sup> This Alternative applies if Alternative A of Article 7 is adopted.

<sup>\*</sup> This Alternative applies if Alternative B of Article 7 is adopted.

#### [Rule 4.2 (Alternative A), continued]

(c) If the Assembly decides to withdraw, either entirely or in respect only of certain kinds of microorganisms, the status of internationally recognized depositary authority, the said decision shall become effective six months after the date on which it was made. However, the Assembly may shorten that time limit where, in its opinion, respect of the said time limit could endanger the interests of actual or potential depositors.

#### [Rule 4.2 (Alternative B), continued]

(d) If the Assembly decides to terminate, either entirely or in respect only of certain kinds of microorganisms, the status of internationally recognized depositary authority, the said decision shall become effective six months after the date on which it was made. However, the Assembly may shorten that time limit where, in its opinion, respect of the said time limit could endanger the interests of actual or potential depositors.

#### WITHDRAWAL OR LIMITATION OF THE GUARANTEE

#### 5.1 Communication

- (a) The communication referred to in Article 7(3)(a) shall be made to the Director General as provided in Rule 3.1(a).
  - (b) The communication shall:
- (i) indicate the name and address of the internationally recognized depositary authority concerned;
- (ii) where the withdrawal relates only to certain kinds of microorganisms, indicate the kinds of microorganisms to which it relates;
- (iii) where the Contracting State making the communication desires that the effects provided for in Article 7(3)(b) take place at a date later than at the expiration of a period of six months from the date of the communication, indicate that date.

#### 5.2 Effective Date of the Withdrawal or Limitation

Where Rule 5.1(b)(iii) applies, the effects provided for in Article 7(3)(b) shall take place on the date indicated under that Rule in the communication; otherwise, they shall take place at the expiration of six months from the date of the communication.

#### 5.3 Processing of the Communication

The Director General shall promptly notify all Contracting Parties of any communication received under Article 7(3) and of its effective date under Rule 5.2. A corresponding notice shall be promptly published in the Gazette.

## DEFAULTS BY THE INTERNATIONALLY RECOGNIZED DEPOSITARY AUTHORITY

#### 6.1 Interruption or Discontinuance of Functions in Respect of Accepted Deposits

- (a) If any internationally recognized depositary authority interrupts, other than incidentally, or discontinues the performance of any of the tasks it should perform under the Treaty and these Regulations in relation to any microorganisms deposited with it, the Contracting State which, in respect of that authority, has guaranteed the compliance with the requirements provided for in Article 6 shall:
- . (i) ensure that all such microorganisms are transferred promptly and in perfect condition, in particular without affecting their viability and without contamination, from the said ("the defaulting") authority to another ("the substitute") internationally recognized depositary authority;
- (ii) ensure that all mail or other communications addressed to the defaulting authority and all files and other relevant information in the possession of that authority in respect of the said microorganisms are promptly transferred to the substitute authority;
- (iii) ensure that the defaulting authority promptly notifies all interested depositors and all interested industrial property offices of the interruption or discontinuance of functions and the transfers effected;
- (iv) promptly notify the Director General of the fact and the extent of the interruption or discontinuance in question and of the measures which have been taken by the said Contracting State under (i) to (iii).
- (b) The Director General shall promptly notify the Contracting Parties of the notification received under paragraph (a)(iv) and shall promptly publish the same in the Gazette.
- (c) The depositor shall, upon receipt of any notification under paragraph (a)(iii), notify the new number of the deposit given by the internationally recognized depositary authority to which the microorganism was transferred to any industrial property office of a Contracting Party with which a patent application was filed with reference to the original deposit.

#### 6.2 Refusal To Accept Certain Kinds of Microorganisms

(a) If any internationally recognized depositary authority refuses to accept for deposit any of the kinds of microorganisms to which the guarantee referred to in Article 6(1)(iv) applies, the Contracting State which, in respect of that authority, has made the declaration referred to in Article 7(1) shall promptly notify the Director General of the relevant facts.

#### [Rule 6.2, continued]

(b) The Director General shall promptly notify the other Contracting Parties of the notification received under paragraph (a) and shall promptly publish the same in the Gazette.

## LOSS OF STATUS OF INTERNATIONALLY RECOGNIZED DEPOSITARY AUTHORITY

#### 7.1 Total Loss of Status

Where an internationally recognized depositary authority loses the status of such authority, the Contracting State which, in respect of that authority, has guaranteed the compliance with the requirements provided for in Article 6 shall ensure:

- (i) that all microorganisms deposited with it under the Treaty are transferred promptly and in perfect condition, in particular without affecting their viability and without contamination, from the said ("the former") authority to another ("the substitute") internationally recognized depositary authority;
- (ii) that all mail or other communications addressed to the former authority and all files and other relevant information in the possession of that authority in respect of the said microorganisms are promptly transferred to the substitute authority;
- (iii) that the former authority promptly notifies all interested depositors and all interested industrial property offices of the transfers effected.

#### 7.2 Loss of Status in Respect of Certain Kinds of Microorganisms

Where an internationally recognized depositary authority loses the status of such authority in respect of certain kinds of microorganisms, Rule 7.1 shall apply in respect of such kinds of microorganisms.

#### MAKING THE ORIGINAL DEPOSIT OR NEW DEPOSIT

#### 8.1 Original Deposit

- (a) The microorganism transmitted by the depositor to the internationally recognized depositary authority shall, except where Rule 8.2 applies, be accompanied by a written statement, signed by the depositor, containing:
  - (i) an indication that the deposit is made under the Treaty;
  - (ii) the name and address of the depositor;
- (iii) details of the conditions necessary for the cultivation of the microorganism and, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and methods for checking their presence and viability;
- (iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism.
- (b) The written statement referred to in paragraph (a) may contain the scientific description and/or proposed taxonomic designation of the deposited microorganism.

#### 8.2 New Deposit

In the case of a new deposit made under Article 3(2), the microorganism transmitted by the depositor to the internationally recognized depositary authority shall be accompanied by a copy of the receipt of the original deposit, a copy of the most recent statement concerning the viability of the microorganism originally deposited indicating that the microorganism is viable and a written statement, signed by the depositor, containing:

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- (i) the indications referred to in Rule 8.1(a)(i) to (iv);
- (ii) a declaration stating the reason relevant under Article 3(2) (a) for making the new deposit, the statement required under Article 3(2) (d), and, where applicable, an indication of the date relevant under Article 3(2) (f);
- (iii) any scientific description and/or proposed taxonomic designation indicated in connection with the original deposit as existing on the date relevant under Article 3(2)(f).

RECEIPT

#### 9.1 Issuance of Receipt

The internationally recognized depositary authority shall issue to the depositor, in respect of each deposit of a microorganism effected with it, a receipt in attestation of the fact that it has received and accepted such deposit.

#### 9.2 Form; Language; Signature

- (a) Any receipt referred to in Rule 9.1 shall be established on a form called an "international form," a model of which shall be established by the Director General.
- (b) Any text matter in the receipt shall be in English or French. It may be in both English and French. Any text matter appearing in the receipt in English or French may also appear therein in any other language.
- (c) The receipt shall be signed by the person or persons having the power to represent the internationally recognized depositary authority or by any other official of that authority duly authorized by the said person or persons and/or shall bear the seal of the internationally recognized depositary authority.

#### 9.3 Contents in the Case of the Original Deposit

Any receipt referred to in Rule 9.1 and issued in the case of an original deposit shall contain at least the following indications:

- (i) the name and address of the internationally recognized depositary authority:
  - (ii) the name and address of the depositor;
- (iii) the date of receipt of the microorganism by the internationally recognized depositary authority;
- (iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
- (v) the accession number given by the internationally recognized depositary authority to the microorganism;
- (vi) where the written statement referred to in Rule 8.1(a) contains the scientific description and/or proposed taxonomic designation of the microorganism, such description and/or designation.

#### [Rule 9, continued]

#### 9.4 Contents in the Case of the New Deposit

Any receipt referred to in Rule 9.1 and issued in the case of a new deposit effected under Article 3(2) shall be accompanied by a copy of the receipt of the original deposit and a copy of the most recent statement concerning the viability of the microorganism originally deposited indicating that the microorganism is viable, and shall at least contain:

- (i) the indications referred to in Rule 9.3(i) to (v);
- (ii) an indication of the relevant reason and, where applicable, the relevant date as stated by the depositor in the statement referred to in Rule 8.2(ii);
- (iii) where Rule 8.2(iii) applies, the scientific description and/or proposed taxonomic designation.

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## LATER INDICATION OR AMENDMENT OF THE SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

#### 10.1 Communication

- (a) Subject to Rule 8.2(iii), where, in connection with the deposit of a microorganism, the scientific description and/or taxonomic designation of the microorganism was/were not indicated, the depositor may later indicate or, where already indicated, may amend such description and/or designation.
- (b) Any such later indication or amendment shall be made in a written communication, signed by the depositor, addressed to the internationally recognized depositary authority and containing:
  - (i) the name and address of the depositor;
  - (ii) the relevant accession number given by the said authority;
- (iii) the scientific description and/or proposed taxonomic designation of the microorganism;
- (iv) in the case of an amendment, the last preceding scientific description and/or proposed taxonomic designation.

#### 10.2 Attestation

The internationally recognized depositary authority shall, on the request of the depositor having made the communication referred to in Rule 10.1, and without charging a fee, deliver to him an attestation showing the data referred to in Rule 10.1(b) (i) to (iv) and the date of receipt of such communication.

#### STORAGE OF MICROORGANISMS

#### 11.1 Duration of the Storage

Subject to Rule 11.2, any microorganism deposited with an internationally recognized depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the release of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

#### [11.2 Return or Destruction of the Deposited Microorganism

As long as no publication for the purposes of patent procedure has occurred, the depositor may request the internationally recognized depositary authority to return to him the deposited microorganism or to destroy it, and the said authority shall promptly comply with the request[, provided that a period of [three] years has elapsed from the date of receipt of such microorganism by the said authority]. The fact of such return or destruction of the deposited microorganism shall, together with the relevant indications, be promptly notified by the said authority to the Director General, who shall notify all Contracting Parties of the said notification.]

#### 11.3 Secrecy

As long as no publication for the purposes of patent procedure has occurred, the fact that the deposit has been made shall, subject to Rule 13.3, be kept secret by the internationally recognized depositary authority, and such authority shall not give any information concerning the deposit to any person, except with the written authorization of the depositor.

#### VIABILITY TEST AND STATEMENT

#### 12.1 Obligation To Test

The internationally recognized depositary authority shall test the viability of each microorganism deposited with it

- (i) promptly after the deposit;
- (ii) at regular intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary for technical reasons;
  - (iii) at any time, on the request of the depositor.

#### 12.2 Viability Statement

- (a) The internationally recognized depositary authority shall issue a statement concerning the viability of the deposited microorganism
  - (i) to the depositor, promptly after the deposit;
  - (ii) to the depositor, on his request, at any time after the deposit;
- (iii) to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were released in conformity with Rule 13, on his or its request, together with or at any time after such release.
- (b) The viability statement shall indicate whether or not the microorganism is or is no longer viable.
- (c) In the cases of paragraph (a)(ii) and (iii), the viability statement shall refer to the most recent viability test.
- (d) As to form, language and signature, Rule 9.2 shall apply, <u>mutatis</u> <u>mutandis</u>, to the viability statement.
  - (e) The viability statement shall contain:
- (i) the name and address of the internationally recognized depositary authority issuing it,
  - (ii) the name and address of the depositor,
  - (iii) the date of the deposit of the microorganism,
    - (iv) the accession number of the said authority,
- (v) the date of the test to which it refers and an indication of the results of that test,
- (vi) the latest scientific description and/or proposed taxonomic designation, if any, available to the internationally recognized depositary authority.
- (f) The issuance of the viability statement referred to in paragraph (a)(i) shall be free of charge. Any fee payable under Rule 14.1(a)(ii) in respect of any other viability statement shall be chargeable to the party requesting the statement and shall be paid before or at the time of making the request, provided that, where the request is made by an industrial property office of a Contracting Party, the fee shall be chargeable to the depositor.

#### RELEASE OF SAMPLES

#### 13.1 Release to Interested Industrial Property Offices

Any internationally recognized depositary authority shall release a sample of any deposited microorganism to the industrial property office of any Contracting Party, upon the request of the latter, provided that the request shall be accompanied by a declaration to the effect that

- (i) the depositor has filed an application with the said industrial property office for the grant of a patent for an invention involving the use of the microorganism;
- (ii) such application is pending before the said office or has led to the grant of a patent;
- (iii) the sample is needed for the purposes of patent procedure before a competent body of the said Contracting Party;
- (iv) the said competent body will use the sample and any information accompanying or resulting from it only for the purposes of its patent procedure.

#### 13.2 Release to or with the Authorization of the Depositor

Any internationally recognized depositary authority shall release a sample of any deposited microorganism

- (i) to the depositor, on his request,
- (ii) to any authority, natural person or legal entity (hereinafter referred to as "the authorized party"), on the request of such party, provided that the request is accompanied by a declaration, signed by the depositor, authorizing the requested release.

#### 13.3 Release to Parties Legally Entitled

- (a) Any internationally recognized depositary authority shall release a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as "the certified party"), on the request of such party, provided that the request is accompanied by a declaration, signed by the industrial property office of a Contracting Party, certifying that
- (i) the depositor has filed an application with that office for the grant of a patent for an invention involving the use of the microorganism,
- (ii) publication for the purposes of patent procedure has been effected by that office,

#### [Rule 13.3, continued]

- (iii) the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled.
- (b) Paragraph (a) shall apply with the exception of item (ii) thereof where the following conditions are fulfilled and where the industrial property office certifies, in the declaration referred to in paragraph (a), that they are fulfilled:
- (i) the need exists, for the purposes of a patent procedure pending before that office, to establish the date on which the invention involved in that procedure was made;
  - (ii) such need exists for the certified party;
- (iii) such need exists prior to the publication, in that patent procedure, of the patent application or patent which refers to the deposited microorganism.
- (c) The industrial property office of any Contracting Party may declare, through a notification addressed to the Director General, that, for the purposes of its patent procedure, paragraphs (a) and (b) shall not apply; in such a case,
- (i) the said office shall, for each patent application referring to the deposit of a microorganism, communicate to the internationally recognized depositary authority with which the deposit has been made the date on which the deposited microorganism becomes available for release to any third party requesting a sample thereof (hereinafter referred to as "the requesting party") under the law governing patent procedure before the said office; such date may not precede the date of publication by the said office for the purposes of patent procedure; the said office shall also communicate, where applicable, the conditions which any requesting party must fulfill; the communication shall be made by transmitting to the internationally recognized depositary authority a form, which shall be signed by any requesting party before the release is effected;
- (ii) any internationally recognized depositary authority which has received the communication referred to in (i) shall release a sample of the deposited microorganism, on or after the date indicated in the communication, to any requesting party having signed the form referred to in (i).
- (d) The declaration referred to in paragraph (c) may be withdrawn at any time through a notification addressed to the Director General.
- (e) The declaration referred to in paragraph (c) and any withdrawal referred to in paragraph (d) shall be published in the Gazette.

#### 13.4 Common Rules

(a) Any request and any declaration made under Rules 13.1, 13.2 or 13.3 shall be established at least in English or in French, shall be in writing, shall be signed, shall be dated and shall contain the following indications:

#### [Rule 13.4, continued]

- (i) the name and address of the industrial property office making the request, of the authorized party or of the requesting party;
  - (ii) the name and address of the depositor;
- (iii) in the case of Rule 13.1, the name of the original applicant for the relevant patent and the date and number of the application or, where a patent has been granted, the name of the original applicant and the date and number of the grant;
- (iv) in the case of Rule 13.3, the indications referred to in (iii) and the name and address of the industrial property office which has made the declaration referred to in Rule 13.3(a) or the communication referred to in Rule 13.3(c)(i).
- (b) Notwithstanding paragraph (a), any internationally recognized depositary authority may agree with any industrial property office that the request and the declaration referred to in Rule 13.1(a) shall or may be in a given language other than English or French.
- (c) Any release of a sample of a deposited microorganism shall be subject to compliance with the provisions of the applicable national law concerning health or the environment.
- (d) The internationally recognized depositary authority having effected the release of the sample shall promptly notify the depositor in writing of that fact, as well as of the date on which the release was effected, and of the name and address of the industrial property office and of the authorized party or of the requesting party, as the case may be, to which the sample was released.
- (e) The release of samples referred to in Rule 13.1 shall be free of charge. Where the release of samples is made under Rule 13.2 or 13.3, any fee payable under Rule 14.1(a)(iii) shall be chargeable to the depositor or to the authorized party or the requesting party, as the case may be, and shall be paid before or at the time of making the request for release.

#### FEES

#### 14.1 Kinds and Amounts

- (a) Any internationally recognized depositary authority may, with respect to the procedure under the Treaty and these Regulations, charge a fee:
  - (i) for storage,
  - (ii) subject to Rule 12.2(f), for the issuance of viability statements,
  - (iii) for the release of samples.
- (b) The fee for storage shall be for the whole duration of the storage of the microorganism as provided in Rule 11.1.
- (c) The amount of any fee shall not vary on account of the nationality or residence of the depositor or of any authority, natural person or legal entity requesting the issuance of a viability statement or release of samples.

#### 14.2 Change in the Amounts

- (a) Any change in the amount of the fees charged by any internationally recognized depositary authority shall be notified to the Director General by the Contracting State which, under Article 7(1)(a), made the declaration in respect of that authority. The notification may, subject to paragraph (c), contain an indication of the date from which the new fees will apply.
- (b) The Director General shall promptly notify all Contracting Parties of any notification received under paragraph (a) and of its effective date under paragraph (c). He shall promptly publish the said notification and date in the Gazette.
- (c) Any new fees shall apply as of the date indicated under paragraph (a), provided that, where the change consists of an increase in the amounts of the fees or where no date is so indicated, the new fees shall apply as from the thirtieth day following the publication of the change in the Gazette.

#### GAZETTE

#### 15.1 Frequency of Issue and Contents; Languages

- (a) Issues of the Gazette shall be published at least once every six months. The Director General may publish an extraordinary issue of the Gazette whenever information on internationally recognized depositary authorities requires urgent divulgation.
- (b) Each issue shall contain an up-to-date list of the internationally recognized depositary authorities, indicating in respect of each such authority the kinds of microorganisms that may be deposited with it and the amount of the fees charged by it.
- (c) Full information on the following facts shall be published in the Gazette once, in the first issue published after the occurrence of the fact:
- (i) [granting, withdrawal,] [acquisition, termination,] loss and limitation of the status of internationally recognized depositary authority,
- (ii) interruption or discontinuance of the functions of internationally recognized depositary authorities, refusal to accept certain kinds of microorganisms, and the measures taken in connection with such interruption, discontinuance and refusal,
- (iii) changes in the fees charged by the internationally recognized depositary authorities[,]
  - [(iv) return and destruction of deposited microoganisms].
  - (d) The Gazette shall be in English and French.

#### 15.2 Price

The subscription price and the price of any individual issue of the Gazette shall be fixed by the Director General.

<sup>1</sup> These words apply if Alternative A of Article 7 is adopted.

These words apply if Alternative B of Article 7 is adopted.

#### EXPENSES OF DELEGATIONS

#### 16.1 Coverage of Expenses

The expenses of each delegation participating in any session of the Assembly and in any committee, working group or other meeting dealing with matters of concern to the Union shall be borne by the Government or organization which has appointed it.

#### ABSENCE OF QUORUM IN THE ASSEMBLY

#### 17.1 Voting by Correspondence

- (a) In the case provided for in Article 8(5)(b), the Director General shall communicate any decision of the Assembly (other than decisions relating to the Assembly's own procedure) to the Contracting Parties which were not represented when the decision was made and shall invite them to express in writing their vote or abstention within a period of three months from the date of the communication.
- (b) If, at the expiration of the said period, the number of Contracting Parties having thus expressed their vote or abstention attains the number of Contracting Parties which was lacking for attaining the quorum when the decision was made, that decision shall take effect provided that at the same time the required majority still obtains.

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