



Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini"

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ITALY

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VIRUS

BOX TO BE COMPLETED BY THE DEPOSITARY AUTHORITY

SERIAL NUMBER

Date of RECEPTION

Date of ACCEPTANCE

- Transmission
- Name
- Shape
- Labelling

INTERNATIONAL DEPOSITARY AUTHORITY

- **STATEMENT** *in the case of an original deposit pursuant to Rule 6.1*
n the case of a con version pursuant to Rule 6.4.d
in the case of an associated contract (component)

- **TYPE OF MICROORGANISM** **Virus**

- **SINGLE MICROORGANISM**

MIXTURE OF MICROORGANISM

GIVE THE NUMBER OF MICROORGANISMS AND THEIR TYPES WHERE APPLICABLE

The undersigned hereby deposits the microbial material identified hereunder and undertakes not to withdraw the deposit for the period specified in rule 9.1

1. **IDENTIFICATION REFERENCE** NUMBER SYMBOLS etc GIVEN TO THE MATERIAL BY THE DEPOSITOR

2. **DEPOSITOR(S) Name(s) and address (es)**

3.

SCIENTIFIC DESCRIPTION

MARK WITH A CROSS IF ADDITIONAL INFORMATION IS GIVEN ON AN ATTACHED SHEET

Taxonomy

Family - Genus – Species:

Common virus name:

Serological type , etc:

Natural host

Natural vector

Characteristics

MARK WITH A CROSS WHERE APPLICABLE AND GIVE ADDITIONAL INFORMATION

New isolate

Recombinant

Modified characters

Further or other particularities

Details

CRITERIA OF THE PROPOSED CLASSIFICATION; DESCRIPTION OF THE VECTOR AND THE INSERTED NUCLEIC ACID FRAGMENT IN THE CASE OF A RECOMBINANT VIRUS; ETC

Literature references

THE SUPPLYING OF SUCH INFORMATION IS OPTIONAL. BUT STRONGLY RECOMMENDED IN ACCORDANCE WITH RULE 6.1 b

MARK WITH A CROSS IF ADDITIONAL INFORMATION IS GIVEN ON AN ATTACHED SHEET

PROPERTIES DANGEROUS TO HEALTH OR ENVIRONMENT

4.

MARK WITH A CROSS THE APPLICABLE BOX

The microorganism or the mixture identified under 1 above has the following properties which are or may be dangerous to health or/and the environment

The undersigned is not aware of such properties

ANY DIRECT OR INDIRECT, KNOWN OR LIKELY TO BE EXPECTED EFFECT ON ANY ANIMAL, VEGETAL OR OTHER ORGANISM MUST BE INDICATED

5.

BIOSAFETY MEASURES REQUIRED TO MANIPULATE THE MICROBIAL MATERIAL

L1/P1

L2/ P2

Others

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6a.

REQUIREMENTS FOR PROPAGATING THE VIRUS

CELL TYPE

IF THE SUGGESTED CELL TYPE IS NOT AVAILABLE AT IZSLER A FORM FOR THE DEPOSITION OF THE ABOVE-NAMED CELL LINE SHOULD BE FILLED IN WITH A VIEW TO ESTABLISHING AN ASSOCIATED SERVICING CONTRACT

MEDIUM *(give full details if special formulation)*

Serum type - %

Sodium bicarbonate

pH

TEMPERATURE

Gaseous phase

Further details

6b. **METHOD USED FOR OBTAINING A VIRUS SUSPENSION**

Details for propagating the virus

Criteria for evidence of infection

Details for preparing the virus suspension

6c. **METHOD USED FOR TITRATION**

Technique

Suggested host cells and media (if not the same as given under 6a above)

Further comments (give full details if special proceeding)

Time for reading the results

Expected titer

MINIMAL TITER REQUIRED FOR DEPOSITION: AT LEAST 100 TIMES THE MINIMAL DETECTION LEVEL

7.

FURTHER CHARACTERISTICS TO BE CHECKED CONFIRMING THE VIABILITY OF THE VIRUS

Where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence should be given in accordance with Rule 6.1.a.iii.

8.

CONDITIONS FOR STORAGE

Long-term maintenance by freeze-drying and storage at °C by freezing at °C

or prepared as follows

Particularities in suspension preparation as far as conservation is concerned

Suspending fluid

Further comments

xx.

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DETAILS ON THE TRANSMITTED SUBCULTURE REQUIRED

References of the proteic substrate (supplier; code, batch, date, country or origin)

9a.

MARK WITH A CROSS IF ADDITIONAL INFORMATION IS GIVEN ON AN ATTACHED SHEET

FURTHER DETAILS ON THE TRANSMITTED SUBCULTURE

Passage level of the transmitted subculture

Date of preparing

Titer of the transmitted subculture

MINIMAL TITER REQUIRED FOR DEPOSITION: AT LEAST 100 TIMES THE MINIMAL DETECTION LEVEL

Last viability check (date)

Date / Passage level Results

LAST PURITY CHECKS Bacteria - Fungi
 Mycoplasma
 Virus

FURTHER COMMENTS

WHERE A DEPOSIT IS CONTAMINATED. IT SHOULD BE DENOTED AS A 'MIXTURE OF MICROORGANISMES' (SEE INSTRUCTIONS GIVEN UNDER 7 ABOVE)

SUCH INFORMATION IS NEITHER LINKED TO THE PROVISIONS OF RULE 6.1.b. RULE 6.2.a.iii, RULE 7.6. AND RULE 8, NOR TO THE PROVISIONS OF RULE 6.1.a.iii, AND RULE 11.4.f. ITS FURNISHING IS OPTIONAL.

THIS FORM SHOULD BE DULY COMPLETED WITHDUT DELETIONS OR ALTERATIONS

9b.

ADDITIONAL INFORMATION

MARK WITH A CROSS IF ADDITIONAL INFORMATION IS GIVEN ON AN ATTACHED SHEET

Source of the microorganism (as far as not given under 3 above)

Strain isolated or established by institution (Names, dates, references, etc)

Date

Registration in other any other depository

Further comments

SUCH INFORMATION IS NEITHER LINKED TO THE PROVISIONS OF RULE 6.1.b. RULE 6.2.a.iii, RULE 7.6. AND RULE 8, NOR TO THE PROVISIONS OF RULE 6.1.a.iii. AND RULE 11.4.f. ITS FURNISHING IS OPTIONAL.

* *Name, address, phone and/or fax number of the scientist responsible for the microbial material transmitted*

The microbial material released for the purpose of deposition will be transmitted at as 12 °C samples from the same batch, in airtight vials, marked as requested, and

prepared by freeze-drying for freezing by addition of a cryoprotector

or as follows

* **DATE**

SIGNATURE(S)

THE TYPEWRITTEN NAMES OF THE NATURAL PERSONS SIGNING ON BEHALF OF THE LEGAL ENTITY SHOULD ACCOMPANY THE SIGNATURES.



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ADDENDUM TO THE APPLICATION FORM

IDENTIFICATION REFERENCE

NUMBER, SYMBOLS, etc, GIVEN TO THE MATERIAL BY THE DEPOSITOR

GENETICALLY MODIFIED ORGANISM

Yes No

HAZARD GROUP

1

2

E(*)

(*) ENVIRONMENTAL RISK

The undersigned declares that he has proceeded to the notifications required by his own national regulations in force concerning the use and the release of the above-mentioned microorganism and all the associated components, and that he has got from the competent authorities the relevant permits.

The Depositor(s)

The scientist(s) responsible for the biological materials transmitted

Date

Date

Signature(s)

Signature(s)

CONTRACT

according to Rule 6.3.a.(v) of the Budapest Treaty

binding the following parties



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DEPOSITARY AUTHORITY

DEPOSITOR(S) Name(s) and address(es)

Concerning the microorganism identified hereunder (*)

IDENTIFICATION REFERENCE

NUMBER, SYMBOLS, etc, GIVEN TO THE MICROORGANISM BY THE DEPOSITOR

1.- The depositor recognizes being aware of the requirements and recommendations concerning the deposit of microorganisms under the Budapest Treaty.

2.- The IZSLER shall accept the above-identified microorganism provided

all the requirements for validity of the deposit are fulfilled pursuant to Rule 6.1.(a) or 6.2.(a) and to Rule 6.3.(a) of the Budapest Treaty, implying that:

the IZSLER has received twelve samples from a same subculture of the above-identified microorganism, prepared with a view to a long-term storage in accordance with the given instructions (#), marked legibly and indelibly with the identification reference and the date of preparation;

and a preliminary examination of one of the samples received by the IZSLER has shown that the pieces of information given in compliance with Rule 6.1.a.(iii) of the Budapest Treaty are valid and the material transmitted by the depositor is acceptable with regard to Rule 6.4.(a) of the Budapest Treaty.

(*) 'MICROORGANISM' means any biological material the IZSLER is liable to accept for deposit under the Budapest Treaty

(#) The vials must agree with the storage equipments of the IZSLER; they must be airtight, without any risk of cracking, breaking or explosion for the period provided for in Rule 9.1. of the Budapest Treaty.

- 3.- As soon as the microorganism is received, the IZSLER may pass a registration number on to the depositor. The receipt and registration of a microorganism will not imply its acceptance.
- 4.- A refusal to accept the microorganism may be notified in the circumstances laid down in Rule 6.4.(a) of the Budapest Treaty.
- 5.- If any of the requirements for validation of the deposit are not met, a procedure of deferment of the acceptance shall be applied: the IZSLER shall notify the depositor in writing of such postponement and of the reasons there for; it shall allow the depositor an one-month time limit for compliance with all his obligations. If the depositor does not comply with the requirements in the time allotted to, the IZSLER shall cancel the request of deposition and destroy the transmitted biological material.

This procedure may imply a replacement deposit (\$) where any irregularity concerning the state, quantity or presentation of the transmitted biological material is noted by the IZSLER in the case of an original or of a new deposit. A replacement shall be regarded as another original deposit as long as the viability of the deposit waiting for acceptance is not established.
- 6.- Each time a biological material is transmitted to the IZSLER by the depositor, the IZSLER shall charge the fee for storage provided for in Rule 12.1.a.(i) of the Budapest Treaty.
- 7.- If the deposit is accepted, the accession number assigned to by the IZSLER shall be identical to the registration number and the date of deposit shall be the date the IZSLER has received the above-identified microorganism.
- 8.- The notification of the acceptance, the refusal or the cancellation of a request for deposit shall be done by the IZSLER within a six-months time limit after receiving the microorganism. Acceptance shall be attested by the receipt.
- 9.- Once the depositor has complied with all the requirements of the applicable regulations, the IZSLER shall carry out the first viability testing.
- 10.- The first viability statement shall attest the validation or the cancellation of the deposit: if the microorganism is viable the deposit shall be validated; if the microorganism is not viable the deposit shall be cancelled.
- 11.- In the case of a refusal, a cancellation of the request for deposit or a cancellation of the deposit, the samples of the transmitted biological material shall be destroyed. If the depositor disagrees with the reasons of the refusal or cancellation, the samples may be maintained by the IZSLER; they shall not be sent back to the depositor except in the case of a particular agreement made after receipt of the notification of the refusal or cancellation by the depositor; the samples never can be deposited with the IZSLER for other purposes.
- 12.- The fee for storage provided for in Rule 12.1.a.(i) of the Budapest Treaty shall be charged in all cases whatever the circumstances, either acceptance or refusal or cancellation of the deposit.
- 13.- The depositor undertakes to deposit under an associated agreement any not or hardly available living biological material necessary for the controls and/or the storage of the above-identified microorganism.
- 14.- The depositor undertakes to supply the IZSLER with any not or hardly available substrate necessary for the controls and/or the storage of the above-identified microorganism in a quantity allowing twelve tests or passages.
- 15.- The depositor recognizes having communicated all indications he is aware regarding any known or foreseeable action of the above-identified microorganism on humans or any animal, plant or other organism, in a direct or in an indirect way.

He undertakes to notify immediately the IZSLER of any further information relating to this.
- 16.- Once the microorganism is accepted, the IZSLER shall store it, perform the viability controls, issue any relevant declaration, certification or notification and release samples of the deposit to any authorized, certified or requesting party pursuant to the applicable regulations.

($\$$) 'REPLACEMENT DEPOSIT' means a supplementary series of samples of the microorganism subject of an original or of a new deposit waiting for acceptance, transmitted to the IZSLER on its request within the time limit allotted to and in one release; the samples shall be prepared in accordance with the given instructions; they shall be accompanied by a declaration similar to that referred to in Rule 6.2.(a) of the Budapest Treaty.

17.-Each time the IZSLER considers advisable to send a sample of a subculture from the above-identified microorganism to the depositor (***) with a view to an authenticity check, the depositor (***) shall verify the expression of the relevant properties by the microorganism in the said subculture; the form included in the sending shall be duly completed, signed and returned to the IZSLER within a three-months time limit after the sample has been received.

The depositor (***) recognizes, where the above-referred form is not returned to the IZSLER in the time allotted to, the properties of the said subculture are to be considered identical to the properties of the subculture transmitted to the IZSLER at the date of deposit.

18.-The depositor cannot withdraw, cancel or modify the deposit during the storage period provided for in Rule 9.1 of the Budapest Treaty.

The above-identified microorganism shall in any case be stored by the IZSLER for a period of 35 years.

19.-When the storage period expires, the whole biological material shall be destroyed, except in the case of a particular agreement made at the request of the depositor during the thirty fifth year of storage.

20.-If for any reason the IZSLER cannot furnish samples of the above-identified microorganism once accepted and its viability stated, the depositor shall proceed to a new deposit of the microorganism which was originally deposited, in compliance with the applicable regulations, within a three-months time limit after he has received the relevant notification by the IZSLER.

The reasons based on good practice as for Depositary Authorities that lead to refuse the release of samples are entirely left to the assessment of the IZSLER.

21.-If a variation in the characteristics, a loss of viability, a contamination or an accidental destruction of the deposited biological material is noted despite the application of the precautions complied with for its preservation, the IZSLER will bear no responsibility.

22.-If by the fault or the negligence of the depositor damage is caused to the IZSLER at the time of receipt or during handling or storage of the above-identified microorganism, the depositor shall compensate the IZSLER for the said damage.

23.-The depositor guarantees that no action will be undertaken against the IZSLER for the compensation of damage relating to the release of a sample of the above-identified microorganism, unless the fact of damage can be imputed to the fault or negligence of the IZSLER.

24.- In the case of dispute the Italian law shall be applied and the competent court shall be the Italian Court.

THE DEPOSITOR(S) (*)**

Date and signature(s)

**THE SCIENTIST(S)
in charge of the microorganism**

Date and signature(s)

(**) The obligations indicated in Point 17 may be ensured either by the depositor or equally by the scientist designated by the depositor.

(***) when a deposit is requested by several depositors, the signature of each co-depositor is required on the relevant form and contract. In this case one of the depositors shall be designated as unique representative acting for the others. This latter will receive all the original documents issued by the IZSLER during the whole storage period.