

**IT – ITALY**

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E DELL'EMILIA ROMAGNA "BRUNO UBERTINI" (IZSLER)

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Entity in charge of handling Deposits under the Budapest Treaty

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1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

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

Except: microorganisms and plasmids having properties which are or may be dangerous to human/animal health or to the environment.

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

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

No mixed microbiological cultures will be accepted. They will be accepted if sent separately. Microorganisms and plasmids having properties which are or may be dangerous to human/animal health or to the environment will not be accepted.

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

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

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IZSLER BVR has the following requirements for the form of the microorganisms and plasmids that are submitted for deposit:

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

- Bacteriophages                      12 frozen vials (1 ml each with a titre of at least  $10^8$  pfu/ml)

- Plasmids (in hosts)                12 lyophilized vials plus 3 agar cultures

Plasmids (purified DNA)       12 frozen vials (25 micrograms each of isolated and purified DNA preparations).

Suitable host of the plasmid also need to be deposited in an active form (2 slants).

(ii) Time Required for Viability Testing

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

Bacteria	average time 14 days (up to 3 weeks)
Human and Animal Viruses	average time 20 days
Bacteriophages	average time 14 days
Plasmids in hosts or purified DNA*	average time 8 or up to 10 days (longer in slow growing hosts)

\* A "viability test" for plasmids consists of transforming a suitable host with the plasmid. If the host is transformed, the "viability test" is regarded as positive.

(iii) Depositor Checks and Renewal of Stocks

In general, IZSLER does not prepare batches of bacteria and viruses and when the batches are exhausted it requests the depositor to make a new deposit. Only in particular case and following previous written consent of the depositor, IZSLER can prepare a new batch of the material. However, the depositor has to control the quality characteristics of the material.

A portion of each original material supplied by the depositor is stored as *master* deposit.

(c) Administrative Requirements and Procedures

(i) General

*Language.* The official language of IZSLER is Italian. Communications and correspondence are accepted in Italian and in English.

*Contract.* A contract between IZSLER and the depositor must be prepared. It has to be signed by both parties and the depositor acknowledges the conditions of the deposit under the Budapest Treaty, the rules and requirements to be observed and the relative liability in the event of an incident.

In particular, the depositor has to declare the following:

- quantity and form of the material to be deposited;
- characteristics and biological risk of the material;
- payment of the fees charged;
- to comply with the requirements of the Budapest Treaty and with those of IZSLER notified to WIPO.

*Import and/or Quarantine Regulations.* IZSLER requests an import authorization from Italian Ministry of Health.

No quarantine regulation must be followed for microorganisms that are accepted by IZSLER.

Transport of infectious material in Italy is subjected to the package conforming to international regulations of the transport of hazardous materials.

(ii) Making the Original Deposit

*Requirements to be Met by the Depositor.* Depositors have to complete and sign the contract and deposit forms for the Budapest Treaty deposits. Each form is specific for each type of Biological Resource.

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

Sending of Biological Resource to be deposited must be previously agreed between two parties.

Original deposit documents have to be sent together with the biological resource; however, it is advised to send them before sending by e-mail.

*Official Notifications to the Depositor.* The receipt and the viability statement are communicated by transmission of “international forms” BP/4 and BP9, respectively. Other notifications are sent by individual letters.

Any attestation concerning a change of the technical description and/or the proposed taxonomic designation will be delivered on form BP/8.

Furthermore, any notification on the furnishing of samples to third parties will be sent to the Depositor on form BP/14.

Official forms will be sent to the depositor only after the results of viability testing and when deposit is accepted. Accession number will be the same of the registration number.

*Unofficial Notifications to the Depositor.* IZSLER will communicate by e-mail the date of deposit and number of deposit before the official statement of receipt and viability testing are made.

*Supply of Information to a Patent Agent.* IZSLER will provide, if requested, information to the patent agent.

(iii) Converting a Previous Deposit

Deposit of other types (open deposit, safe deposit) can be converted by the depositor into deposit under the Budapest Treaty. In this event the depositor has to indicate the date on which the original deposit was received, the accession number of the biological resource, the name and address of the depositor and the request of conversion of the deposit and to maintain deposit and distribution of the microorganism for research purposes during the period specified in rule 9.1. In this event the batch has to be moved from the previous to the new deposit. In alternative, the depositor prepares a new batch to be deposited under the Budapest Treaty. The new deposit is subjected to the rules and administrative requirements of the Budapest Treaty.

(iv) Making a New Deposit

The depositor has to complete the BP/2 model form in order to make a new deposit and to send copies of the documents mentioned in Rule 6.2. Statements of the receipt and viability testing are sent on mandatory international forms BP/5 and BP/9.

## 2. Furnishing of Samples

### (a) Requests for Samples

IZSLER notifies third parties of the correct procedures to order patent microorganisms. In the case of requests of proof of entitlement, IZSLER will send to requesting party copies of the model request form BP/12.

Third parties will receive a microorganism under patent regulations following providing evidence that they are allowed to work with such a microorganism.

Moreover, all documents, including permit importations, are requested by IZSLER to respond to requests from overseas, or a declaration stating that no authorization is necessary for the proper shipping of the microorganism.

### (b) Notification to the Depositor

Depositors are informed by form BP/14 on the distribution of a patent microorganism to third parties.

### (c) Cataloguing of Budapest Treaty Deposits

IZSLER does not publish list of deposits under the Budapest Treaty in any published catalogue.

## 3. Schedule of Fees

Human and animal bacteria	
Freeze dried	€ 608.80
Frozen at -80°C	€ 701.27
Frozen liquid nitrogen	€ 1448.27
Human and animal viruses	
From embryonated chicken embryos	€ 788.92
From cell cultures	€ 1086.96
Bacteriophages	
Frozen at -80°C	€ 701.27
Frozen liquid nitrogen	€ 1448.27
Plasmids (in hosts or as an isolated DNA)	
Freeze dried	€ 608.80
Frozen at -80°C	€ 701.27
Viability	
Issuance of viability statement based on last test	€ 60.00
Viability test (bacteria)	€ 100.00
Viability test (virus)	€ 150.00
Viability test (bacteriophage)	€ 100.00
Viability test (plasmid in hosts or as an isolated DNA)	€ 110.00
Distribution	
Furnishing of a sample (bacteriophage) (plus shipping costs)	€ 400.00

Furnishing of a sample (virus) (plus shipping costs)	€ 400.00
Furnishing of a sample (bacteriophage) (plus shipping costs)	€ 400.00
Furnishing of a sample (plasmid) (plus shipping costs)	€ 105.00
Communication of information or issuance of an attestation	€ 50.00

Value Added TAX (VAT) is added according to Italian regulations

#### 4. Guidance for Depositors

IZSLER provides a written note for the request of deposit under the Budapest Treaty. It is at the home page of IZSLER ([www.ibvr.org](http://www.ibvr.org)). Further information can be requested by e-mail.