

CA – CANADA

INTERNATIONAL DEPOSITARY AUTHORITY OF CANADA (IDAC)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The IDAC will accept for deposit: animal viruses of Risk Group Levels 1, 2 and 3, which can be propagated in cell culture, Risk Group Levels 1, 2 and 3 bacteria, all bacteriophages, all mammalian cell lines, and all cloned genes. Fungi, hybridomas, yeasts, plasmid and phage vectors, libraries and other rDNA material will also be accepted.

The IDAC will only accept deposits which can be preserved without significant change to their properties by freezing or lyophilization. Deposits which cannot be so preserved or can only be maintained in active culture, may be accepted on an individual basis, with prior negotiation and determination of associated fees.

(b) Technical Requirements and Procedures

(i) Form and Quantity

The IDAC will only accept deposits which can be preserved without significant change to their properties by freezing or lyophilization. Deposits which cannot be preserved in this manner or can only be maintained in active culture may be accepted on an individual basis, with prior negotiation and determination of associated fees.

Depositors are encouraged to supply frozen or freeze-dried material. However, when possible, the IDAC will accept actively growing material, and preserve it by freezing or freeze-drying at an additional cost. In these cases a sample of the preserved material will be returned to the depositor for verification of properties. However, if the preserved material is viable but not acceptable (e.g., properties altered), a new deposit must be made, and the original deposit date will be void. Depositors are therefore urged to supply frozen or freeze-dried material prepared in their laboratory in order to avoid the possibility of this occurring.

The quantity of material required for the various types of deposits is as follows:

Microorganisms (including bacteria (either containing a plasmid or not containing a plasmid), bacteriophages, fungi and yeast)	10 frozen (0.5 ml each) or freeze-dried samples
Plasmids and Vectors not in host (e.g., purified DNA, libraries and associated rDNA material)	25 vials (min. 100 ng each)
Animal Viruses	25 frozen (1 ml each) or freeze-dried samples
Cell Lines and Hybridomas	25 frozen samples (2 – 6 million cells each)

(ii) Time Required for Viability Testing

The time required for testing the viability of the different types of deposits is indicated below. However, depositors should be aware that in certain cases viability testing may take longer.

Bacteria	3 – 7 days
Fungi and yeasts	7 – 10 days
Cell lines, hybridomas and bacteriophages	7 – 10 days
Plasmid, phages and other rDNA ¹	7 – 10 days
Animal viruses	30 or more days

(iii) Depositor Checks and Renewal of Stocks

It is the responsibility of the depositor to furnish a sufficient quantity of the material for the specified period of time. If a culture or other biological material should become non-viable or be destroyed during the effective term of the deposit, it is the responsibility of the depositor to replace it with viable material. The IDAC may consider, for a fee, to replenish the material on behalf of the depositor, however, it is the responsibility of the depositor to authenticate the material prepared and to inform the IDAC of the results. Whichever method is used for renewal of stocks the IDAC will maintain a portion of the material originally submitted for deposit.

¹ If applicable “viability” of the deposit is determined by the ability of the material to successfully transform, infect or otherwise alter a host cell.

(c) Administrative Requirements and Procedures

(i) General

Language. The official languages of Canada and the IDAC are English and French. Communications in any other language are not accepted.

Contract. The IDAC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by completing the IDAC BP/1 deposit form, the depositor foregoes any right to withdraw his deposit during the required storage period and accepts that the material will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The IDAC is subject to Canadian and international regulations governing the importation, exportation and transportation of infectious substances. Information relating to the importation and safe handling of infectious substances affecting humans can be obtained through the Health Canada web site (<http://www.hc-sc.gc.ca/hpb/lcdc/biosafety/index.html>), or by contacting the Director, Office of Biosafety, Laboratory Centre for Disease Control, Ottawa, Ontario, K1A 0L2, tel: (613) 957-1779. Information regarding veterinary pathogens and permits may be obtained from Agriculture and Agri-Food Canada, 59 Camelot Drive, Nepean, Ontario K1A 0Y9, tel.: (613) 952-8000. Inquiries regarding the transportation of regulated material should be directed to the Director General of the Transport of Dangerous Goods Directorate of Transport Canada, Canada Building, 344 Slater Street, 14th Floor, Ottawa, Ontario K1A 0N5, tel.: (613) 998-0517. These agencies may also be able to assist with information relating to the relevant regulations in countries other than Canada however it is advised that the appropriate agencies for the country in question be contacted.

It is essential that the depositor contact the IDAC in advance of submitting a deposit which may be subject to these regulations to ensure that the appropriate documentation is obtained. This is particularly important for deposits made from outside of Canada. Failure to do so could result in the deposit being refused entry into the country.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. The IDAC requires that depositors complete the Statement In The Case Of An Original Deposit (form BP/1) in order to meet the requirements of the Budapest Treaty. In the event of later amendments to the scientific description and/or proposed taxonomic designation the depositor must complete the IDAC form BP/7. In the case of a new deposit made under Article 4 of the Budapest Treaty the depositor must complete form BP/2.

Official Notifications to the Depositor. Notifications of receipt and viability are issued on the mandatory international forms (BP/4 and BP/9, respectively). Attestation of receipt of an amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/8. If requested, notification of furnishing of a sample to a third party is issued on form BP/14.

Unofficial Notifications to the Depositor. If requested, the IDAC will convey the date of deposit and accession number after the submission has been received but before the official receipt is issued. Notification of the result of the viability testing is only communicated through official correspondence.

Supply of Information to a Patent Agent. If requested, the IDAC will supply copies of the receipt and viability statement to the depositor's patent agent.

(iii) Converting a Previous Deposit

The IDAC does not permit the conversion of deposits not originally made for patent purposes for Budapest Treaty deposits. The procedures outlined above for making a deposit must be followed in all cases.

(iv) Making a New Deposit

In the event that a new deposit is submitted the IDAC requires that the Statement In The Case Of A New Deposit (form BP/2) be completed. The deposit will retain its initial deposit number and date as long as the replacement deposit is viable, the deposit is made within three months of receiving notification from the IDAC and the IDAC receives a statement signed by the depositor alleging that the newly deposited material is the same as that originally deposited. Charges for viability testing are required for new deposits.

2. Furnishing of Samples

(a) Requests for Samples

The IDAC makes available samples of deposited material only to parties who are so entitled under the terms of the Budapest Treaty and its Regulations. The IDAC will provide requesting parties with request forms (as appropriate) or assist with obtaining the necessary forms required for their request.

The IDAC accepts deposits of organisms which are potentially hazardous and may be subject to health and safety regulations. When such organisms are requested the IDAC will withhold issuing samples until it has confirmed that the requesting party can comply with such regulations. In certain cases, the IDAC may also require that the requesting party sign an assurance of acceptance of responsibility before agreeing to release a sample. In order to expedite the release of such samples it is therefore advisable that all requests be accompanied by documentation attesting to the fact that the requesting party has the facilities required for, and agrees to the regulations governing the handling of the requested material.

The IDAC attempts to ensure that the correct documentation is obtained prior to the shipping of the material requested. However, it is the responsibility of the requesting party to obtain all of the necessary permits which may be required.

(b) Notification of the Depositor

Unless the right to be so notified has been waived, the IDAC will notify the depositor on form BP/14 each time a sample of the deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

At this time the IDAC does not publish a catalog of its culture collection.

3. Schedule of Fees

	<u>CAD</u>
(a) Issuance of a viability statement	200
(b) Storage (30 years)	800
(c) 30 years of notification of requesting parties	500
(d) Furnishing of a sample (plus expedition cost)	50
(e) Attestation of receipt of revised scientific description	50
(f) Communication of scientific description to 3 rd party	50
(g) Amount for additional five years of storage beyond 30 years	125

This list is of base prices. Deposits requiring special conditions or care are subject to surcharges. All charges are subject to the Canadian Goods and Services Tax at the current rate.

4. Guidance for Depositors

The IDAC is in the process of preparing a detailed information package for depositors. Until this is available all inquiries should be directed to the main office.