US – UNITED STATES OF AMERICA

AGRICULTURAL RESEARCH SERVICE CULTURE COLLECTION (NRRL)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

1. All strains of agriculturally and industrially important bacteria, yeasts, molds and *Actinomycetales*, EXCEPT:

(a) *Actinobacillus* (all species); *Actinomyces* (anaerobic/microaerophilic, all species); *Afrizona* (all species); *Bacillus anthracis*; *Bartonella* (all species); *Bordetella* (all species); *Borrelia* (all species); *Brucella* (all species); *Clostridium botulinum*; *Clostridium chauvoei; Clostridium haemolyticum; Clostridium histolyticum; Clostridium novyi; Clostridium septicum; Clostridium tetani; Corynebacterium diphtheriae; Corynebacterium equi; Corynebacterium haemolyticum; Corynebacterium pseudotuberculosis; Corynebacterium pyogenes; Corynebacterium renale; Diplococcus* (all species); *Erysipelothrix* (all species); *Escherichia coli* (all enteropathogenic types); *Francisella* (all species); *Haemophilus* (all species); *Herellea* (all species); *Klebsiella* (all species); *Leptospira* (all species); *Listeria* (all species); *Mima* (all species); *Moraxella* (all species); *Mycobacterium avium*; *Mycobacterium bovis*; *Mycobacterium tuberculosis*; *Mycoplasma* (all species); *Neisseria* (all species); *Pasteurella* (all species); *Pseudomonas pseudomallei*; *Salmonella* (all species); *Shigella* (all species); *Sphaerophorus* (all species); *Streptobacillus* (all species); *Streptococcus* (all pathogenic species); *Treponema* (all species); *Vibrio* (all species); *Yersinia* (all species);

(b) *Blastomyces* (all species); *Coccidioides* (all species); *Cryptococcus neoformans; Cryptococcus uniguttulatus; Histoplasma* (all species); *Paracoccidioides* (all species);

(c) All viral, Rickettsial, and Chlamydial agents;

(d) Agents which may introduce or disseminate any contagious or infectious disease of animals, humans or poultry and which require a permit for entry and/or distribution within the United States of America;

(e) Agents which are classified as plant pests and which require a permit for entry and/or distribution within the United States of America;

(f) Mixtures of microorganisms;

(g) Fastidious microorganisms which require (in the view of the Curator) more than reasonable attention in handling and preparation of lyophilized material;

(h) Phages not inserted in microorganisms;

(i) Monoclonal antibodies;

(j) All cell lines;

(k) Plasmids not inserted in microorganisms.

2. Recombinant strains of microorganisms, strains containing recombinant DNA molecules, strains containing their own naturally occurring plasmid(s), strains containing inserted naturally occurring plasmid(s) from another host, strains containing inserted constructed plasmid(s), and strains containing viruses of any kind, excluding those already listed as nonacceptable, only if the deposit document accompanying the microbial preparation(s) includes a clear statement that progeny of the strain(s) can be processed at a Physical Containment Level of P1 or less and Biological Containment requirements meet all other criteria specified by the U.S. Department of Health and Human Services, National Institutes of Health *Guidelines for Research Involving Recombinant DNA Molecules*, December 1978 (*Federal Register*, Vol. 43, No. 247-Friday, December 22, 1978) and any subsequent revisions.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Bacteria, fungi and yeasts are accepted as slant, stab or broth cultures, or as lyophilized preparations. If the depositor wishes the NRRL to distribute his own lyophilized preparations, he must supply these preparations in tubes of overall dimensions no greater than 50mm in length and 6mm outside diameter. The minimum number of replicates that must be provided by the depositor when making his deposit is as follows: for bacteria, fungi and yeasts, the NRRL requires the deposit of one or more preparations (slants, stabs, or lyophilized preparations) if the NRRL is to distribute its own preparations. If the NRRL is to distribute depositor's preparations, 30 lyophilized preparations must be deposited.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the NRRL is given below, but depositors should realize that in some cases viability testing may take longer, as indicated by the figures in brackets:

Bacteria	3 days (or up to 15 days)
Fungi	10 days (or up to 15 days)
Yeasts	10 days (or up to 20 days)

(iii) Depositor Checks and Renewal of Stocks

The NRRL stores and distributes lyophilized material supplied by the depositor, if this is his wish, or it makes its own lyophilized preparations by subculture of, or directly from, active material supplied by the depositor. New batches are prepared as necessary for the renewal of diminishing stocks. The NRRL requires the depositor to check the authenticity of its lyophilized preparations. The viability statement issued by the NRRL contains a section in which the depositor can record the result of this test. If the depositor does not inform the NRRL of the results of this test within three months, the NRRL assumes that its preparations are equivalent to the depositor's original deposit.

The NRRL does not accept plasmids, except when they are contained in a living host microorganism.

Whichever method is used for preparing batches of samples for distribution, the NRRL stores a portion of the original prepared and deposited material.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the NRRL is English. Communications in any other language are not accepted.

Contract. The NRRL does not enter into any written contract with the depositor defining the liabilities of either party. However, by completing the NRRL deposition form, the depositor surrenders any right to withdraw his deposit during the required storage procedure, accepts NRRL policy on the handling and distribution of patent deposits, and accepts responsibility for the authenticity of NRRL preparations of his microorganism.

Import and/or Quarantine Regulations. Import and/or quarantine regulations do not apply to the kinds of microorganisms accepted by the NRRL for deposit.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete the NRRL Budapest Treaty Deposition Form. The NRRL does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that the NRRL has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively. (NRRL has modified the latter to include a section in which the depositor can record the result of his authenticity check of NRRL preparations of his deposit--see (iv), below.) Notification of furnishing of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, the NRRL will telephone or e-mail the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test is not so communicated.

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

(iii) Converting a Previous Deposit

The NRRL does not permit the conversion of deposits not originally made for patent purposes to Budapest Treaty deposits. The administrative requirements for converting a deposit previously made for patent purposes are the same as those to be met with respect to an original deposit made under the Treaty, except that no fee is payable.

(iv) Making a New Deposit

The NRRL does not require the depositor to complete a standard form when making a new deposit, but he is asked to supply an acknowledgment that the new deposit is the same as the original deposit (Article 4), and to send copies of the relevant documents (Rule 6.2).

2. Furnishing of Samples

(a) Requests for Samples

The NRRL does not advise third parties of the correct procedures to follow in order to make a valid request for samples. In the case of requests requiring proof of entitlement, third parties requesting a sample under European Patent Office regulations are supplied with the relevant EPO form, but otherwise the NRRL does not supply copies of model request form BP/12 or request forms used by other individual industrial property offices; these must be obtained from the appropriate industrial property office.

Although the NRRL does not knowingly maintain hazardous microorganisms or those requiring a permit to be worked with in the United States of America, the requesting party must be "skilled in the art" (of microbiological practice) before any microorganisms are shipped. If a microorganism being requested is a known producer of a restricted substance, e.g., a hallucinogen, the requesting party must furnish his drug registration number before he can be supplied with a sample. When responding to requests from overseas, the NRRL assumes that the requesting party has met the import requirements of his own country.

Samples of bacteria, fungi and yeasts furnished by the NRRL may be from batches of its own lyophilized preparations or from lyophilized preparations supplied by the depositor, depending on the wishes expressed by the latter at the time of deposit (see 1(b), above).

(b) Notification of the Depositor

Unless he has waived his right to be so notified, the NRRL notifies the depositor on form BP/14 each time a sample of his deposit is furnished to a third party.

(c) Cataloguing of Budapest Treaty Deposits

The NRRL does not publish any catalog.

3. Schedule of Fees

Applicable to all patent cultures deposited with the ARS Culture Collection (NRRL).

		USD
(a)	Deposit of each strain (payable at the time of deposit)	670
(b)	Furnishing of a sample	40

Checks, in US dollars, should be made payable to the Agricultural Research Service, United States Department of Agriculture.

4. Guidance for Depositors

The NRRL makes available a detailed statement on policies and procedures and a standard letter of explanation.