

March 1996

**PROCEDURES AND POLICIES
FOR DEPOSITION OF STRAINS OF MICROORGANISMS FOR PATENT PURPOSES
IN THE AGRICULTURAL RESEARCH SERVICE CULTURE COLLECTION (NRRL)**

The Agricultural Research Service Culture Collection (NRRL) serves as a depository for strains of microorganisms which are involved in patents and, therefore, will be glad to receive such materials in connection with patent applications. On January 31, 1981, this depository achieved the status of International Depository Authority under the Budapest Treaty. Therefore, microorganisms can be deposited either under the Treaty or not under the Treaty, as the depositor wishes.

A user fee of \$500 is charged for each strain deposited with the Agricultural Research Service Patent Culture Collection. Payment must be made at the time of culture deposit. Checks for user fees must be for the exact amount in U.S. dollars and should be made payable to: Agricultural Research Service, U.S. Department of Agriculture. This is a one-time fee and includes preservation, storage, viability testing, and all required correspondence.

As soon as the microorganism has been received and proven viable, an NRRL number will be assigned and will be communicated verbally to the depositor on his request. The depositor should allow sufficient time for viability testing by the depository before the NRRL number can be received.

BUDAPEST TREATY DEPOSITS

In order for strains to be deposited under the Budapest Treaty, a special Budapest Treaty Deposition Form must accompany each deposit. Forms can be obtained from the Curator of the Patent Collection.

When strains are to be deposited under the Budapest Treaty, the International Receipt Form (BP/4) will be issued and sent once the following are received: (1) a viable microorganism, (2) the completed Deposition Form, and (3) the correct fee. The Viability Statement will be sent as soon as the depository's preparation is also determined viable. At the same time, the depository's preparation will be sent to the depositor so that he can determine its equivalency to his original deposit. The depositor then completes the Viability Statement and returns it to the Agricultural Research Service Patent Culture Collection.

If the depositor elects not to confirm the equivalency of the ARS Patent Culture Collection's preparation to his deposit (this is permitted under the Budapest Treaty), this information will be communicated to authorized requestors at the time the microorganism is distributed.

If the depository's preparation is found not equivalent (does not correspond to, or function as, the microorganism described in the patent application), a replacement culture must be sent accompanied with the form "Statement in the Case of a New Deposit." A new set of preparations will be made and a "Receipt in the Case of a New Deposit" will be issued by the depository and sent.

The Agricultural Research Service Culture Collection (NRRL) does not issue a catalog or list of its complete holdings. It has no regulations imposing restrictions on the use of progeny of strains deposited for patent purposes. Such materials are distributed according to the depositor's wishes so long as there is no adverse effect on Agricultural Research Service Culture Collection (NRRL) policies. The depositor's

wishes generally are based on his interpretation of patent office requirements. Use of such materials, once distributed, is the responsibility of the requestor. Strains are automatically removed from any restriction category once a U.S. Patent issues wherein the particular microorganism is disclosed. The requestor is advised, at the time the material is sent, that any commercial or other unauthorized use of these strains without the consent of the depositor could involve patent infringements.

NON-BUDAPEST TREATY DEPOSITS

When all fees have been paid, a letter of receipt will be sent advising the depositor of the NRRL designation and date of deposit. Also one of the following statements will be included (if the depositor does not indicate which statement he requires, number two will be used).

1. "As of this date, progeny of the subject strain(s) will be made available to any *bona fide* requester in the international public who requests the same."
2. "With reference to 886 O.G. 638, progeny of this (these) strain(s) will be available during pendency of the U.S. Patent application to one determined by the Commissioner of Patents to be entitled thereto under 37 CFR 1.14 of the Rules of Practice in Patent Cases and 35 U.S.C. 122. Also, access to progeny of this (these) strain(s) by other parties will be granted upon receipt of written authorization from your organization specifying the name and the Agricultural Research Service Culture Collection (NRRL) designation (NRRL number) of the strain and identifying the party who is to receive it. All other distribution will be withheld pending its (their) disclosure in a U.S. Patent. All restrictions on the availability of progeny of the strain(s) to *bona fide* requesters in the international public will be irrevocably removed upon the granting of the U.S. Patent(s) of which the strain(s) is (are) the subject.

Supplementary paragraph to be included in each letter

Strains of microorganisms deposited in the Agricultural Research Service Culture Collection will be maintained with all the care necessary to keep them viable and uncontaminated for a period of not less than 30 years from the date of deposit. In addition thereto, the strain will be stored for a period of at least 5 years after the most recent request for the release of a sample.

It is suggested that you seek advice from your attorney as to which type of statement you should use. The Agricultural Research Service Culture Collection (NRRL) letter then can be attached to the patent application for the Patent Examiner.

The depositary's preparation will be returned to the depositor in order that he can determine its equivalency to his original deposit. He is requested to return a statement within 3 months to the depositary concerning the equivalency. If the acknowledgment is not received, at the end of the 3-month time, the deposit will be considered as equivalent but requestors will be notified that the equivalency was not confirmed. If the depositary's preparation is found not equivalent, a replacement culture must be sent to the depositary within 3 months.

**KINDS OF MICROORGANISMS ACCEPTED FOR DEPOSIT
FOR THE PURPOSES OF PATENT PROCEDURE**

1. The Agricultural Research Service Culture Collection (NRRL) is willing to accept for deposit, in connection with patent applications, progeny of strains of agriculturally and industrially important bacteria, yeast, molds, and *Actinomycetales*, **EXCEPT**:
 - a.

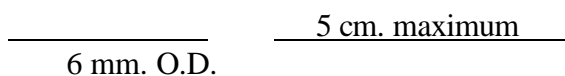
<i>Actinobacillus</i> (all species)	<i>Haemophilus</i> (all species)
<i>Actinomyces</i> (anaerobic/microaerophilic-- all species)	<i>Francisella</i> (all species)
<i>Arizona</i> (all species)	<i>Herellea</i> (all species)
<i>Bacillus anthracis</i>	<i>Klebsiella</i> (all species)
<i>Bartonella</i> (all species)	<i>Leptospira</i> (all species)
<i>Bordetella</i> (all species)	<i>Listeria</i> (all species)
<i>Borrelia</i> (all species)	<i>Mima</i> (all species)
<i>Brucella</i> (all species)	<i>Moraxella</i> (all species)
<i>Clostridium botulinum</i>	<i>Mycobacterium avium</i>
<i>Clostridium chauvoei</i>	<i>Mycobacterium bovis</i>
<i>Clostridium haemolyticum</i>	<i>Mycobacterium tuberculosis</i>
<i>Clostridium histolyticum</i>	<i>Mycoplasma</i> (all species)
<i>Clostridium novyi</i>	<i>Neisseria</i> (all species)
<i>Clostridium septicum</i>	<i>Pasteurella</i> (all species)
<i>Clostridium tetani</i>	<i>Pseudomonas pseudomallei</i>
<i>Corynebacterium diphtheriae</i>	<i>Salmonella</i> (all species)
<i>Corynebacterium equi</i>	<i>Shigella</i> (all species)
<i>Corynebacterium haemolyticum</i>	<i>Sphaerophorus</i> (all species)
<i>Corynebacterium pseudotuberculosis</i>	<i>Streptobacillus</i> (all species)
<i>Corynebacterium pyogenes</i>	<i>Streptococcus</i> (all pathogenic species)
<i>Corynebacterium renale</i>	<i>Treponema</i> (all species)
<i>Diplococcus</i> (all species)	<i>Vibrio</i> (all species)
<i>Erysipelothrix</i> (all species)	<i>Yersinia</i> (all species)
<i>Escherichia coli</i> (all enteropathogenic types)	
 - 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 would require a permit for entry and/or distribution within the United States of America.
 - e. Agents which are classified as Plant Pests and which would require a permit for entry and/or distribution within the United States of America.

- f. Mixtures of microorganisms.
 - g. Fastidious microorganisms which would 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) will be accepted 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 no greater than P1 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.

Curators in the Agricultural Research Service Culture Collection (NRRL) do not attempt to make identification or to name any organism which has been deposited in connection with a patent application, nor do they carry out research work with such deposits until a U.S. Patent issues or cultures are otherwise released to other requesters. It is not necessary, of course, to provide a precise identification but the depositor should state to which genus the microorganism belongs. Also, if special media or conditions are required for growth and maintenance, such information should be supplied. We now recommend that two agar slant cultures or two lyophilized preparations for each strain be received from depositors. **Depositors also are responsible for resupplying material should the need ever arise and this responsibility extends beyond the life of the patent.**

The depositor has the option of sending materials for deposit to the Agricultural Research Service Culture Collection (NRRL) in three ways:

- 1. Thirty lyophilized preparations, clearly labeled with the depositor's original strain designation and date the tubes were sealed (month, day, year) and in tubes of **no greater dimensions than indicated in the drawings below:**



One of these is checked for viability, the NRRL number is placed on each tube, and the supply of tubes stored at 3EC to 5EC. *Bona fide* letter requests for progeny would be shipped from this stock.

Larger sized tubes greatly complicate storage. If these specifications cannot be met,

are sent.

2. Two lyophilized preparations, clearly labeled with the depositor's original strain designation. On receipt, the microorganism is cultivated on appropriate agar media and 30 lyophilized preparations are made. One of these is checked for viability, the remainder handled as in option 1. This option, and option 3, below, is acceptable provided cultures submitted are not fastidious and do not require more than usual normal operating procedures.
3. Two agar slant cultures of the microorganism(s) growing on an appropriate medium. Sufficient material is prepared by our curators to make 30 lyophilized preparations, check one for viability and distribute the remainder as in options 1 and 2. If initial agar slant cultures deposited appear suitable, lyophilizations often are made from that material.

ADDITIONAL COMMENTS

1. The Agricultural Research Service Culture Collection (NRRL) reserves the right to refuse to accept for deposit any microorganism which, in its opinion, is dangerous or impossible to maintain in its collection.
2. The Agricultural Research Service Culture Collection (NRRL) accepts no responsibility for violation of any import, export, or other laws, rules, or regulations governing shipment of progeny of strains of microorganisms to or from any location in the world. Every effort is made to comply with known existing laws, rules, and regulations.
3. Progeny of strains deposited in, and accepted by, the Agricultural Research Service Patent Culture Collection (NRRL) cannot be returned in toto or completely destroyed except for very good reason, e.g., the receipt and accessioning of a virulent pathogen by mistake. In addition, under the Budapest Treaty, the depositor must sign the Budapest Treaty Deposition Form in which he agrees that the strain will not be withdrawn for the period specified by Rule 9 of the Budapest Treaty (at least 30 years from the date of accessioning).
4. Progeny (agar slant cultures or lyophilized preparations) of strains of microorganisms deposited in connection with patent applications may be obtained (when restrictions, if any, are removed), by a letter of request stating the name of the microorganism and its strain number (our NRRL number) or by providing an otherwise satisfactory reference to the strain(s) in question. A \$20 fee is charged for all patent strains deposited after November 30, 1983 (strains with a number of 15723 or higher). Strains deposited before this date are distributed free of charge.
5. The depositary will notify the depositor when strains are distributed to third parties only when the strain has been deposited under the Budapest Treaty. The depositor will receive a copy of the request and the International Form BP/14 " Notification of the Furnishing of Samples of Deposited Microorganisms." **No notification** will be sent to depositors of strains not deposited under the Budapest Treaty. If the depositor requires information on who has received his strain, he may, from time to time, request it, as is necessary.
6. The Agricultural Research Service Culture Collection (NRRL) has been recognized as an International Depositary by the European Patent Organization. A letter of instructions stating that the deposit(s) is (are) subject to Rule 28 of the European Patent Organization must

distribution of the strain(s). If the strain is deposited under the Budapest Treaty, this statement is not necessary.

7. The Agricultural Research Service Culture Collection (NRRL) has been recognized by the German Patent Office as a Patent Culture Depository. The Curator of the Agricultural Research Service Patent Culture Collection is authorized to sign the form "Declaration of Release, II Acknowledgment" for submission to the West German Patent Office.

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