

POLICY FOR PROVIDING MICROBIAL CULTURES TO R&D CENTRE FOR SCREENING AND RESEARCH

I. BACKGROUND AND INTRODUCTION

The Department of Biotechnology (DBT) had supported a major grand challenge mission project for microbial prospecting entitled “*Screening of Bio-Molecules from microbial diversity collected from different ecological niches for drug development*” for prospecting of drugs from microbes. The nine academic institutions namely- National Environmental Engineering Research Institute, Nagpur; National Centre for Cell Science, Pune; Institute of Genomics and Integrative Biology, New Delhi; Delhi University, New Delhi; Institute of Life Sciences, Bhubaneswar; Guru Nanak Dev University, Amritsar; M S Swaminathan Research Foundation, Chennai; Institute of Bioresources and Sustainable Development, Imphal and National Institute of Oceanography, Goa and Piramal Life Sciences Limited (PLSL), Mumbai are involved in this study with the support of Department of Biotechnology for screening microbes for drug development. Through this programme, nearly 250000 microbes from niche areas were screened on four different therapeutic areas namely Cancer, Diabetes, Inflammation and Anti-infectives. Based on the screening on four different therapeutic areas, nearly 16000 Hits have been identified. As part of the Microbial Mission programme, Department has established the country’s largest Microbial Repository (named as National Centre for Microbial Resources) at the National Centre for Cell Science, Pune, which is the custodian of all the microbes collected and deposited there under the microbial mission programme. This is the largest such facility in the country and gets ‘**International Depository Authority (IDA)**’ recognition which and also acquired the status of ‘**Designated Repository**’ under the BD Act, 2002.

II. PURPOSE

This policy document is issued by Department of Biotechnology (DBT), Government of India for the distribution of Microbial Cultures - to R&D Centres of private sector and to National Laboratories, Public Institutes, Universities etc,. Around 2 Lakh Microbial Cultures are currently preserved as a safe deposit at National Centre for Microbial Resources (NCMR) at the National Centre for Cell Science (NCCS), Pune, which serves as the focal point for storage of Microbial cultures collected under the Microbial Mission Programme. These guidelines serve as the basis for the distribution of cultures for non-commercial purposes.

III. DEFINITIONS OF TERMS

1. **NCMR (National Centre for Microbial Resources):** A National facility of DBT located in NCCS, Pune for handling and maintenance of microbial diversity of India isolated during the course of Project.

2. **Recipient R&D Centre:** National Laboratories, Public Institutes, Universities, Industries, etc., interested in receiving the Microbial Cultures from DBT-NCMR for screening them for bioactive compounds or other research activities.
3. **Third Party:** Secondary R&D centre(s) sought out by the Recipient R & D Centre for execution of the work.

IV. TERMS AND CONDITIONS

1. DBT-NCMR recommends users to follow standard microbiological practices and safety requirements for handling and disposal of these Cultures. DBT-NCMR will not be held responsible for any damage arising in future regarding the use of these microorganism(s). The Recipient R & D Centre accepts all liabilities for damage, which may arise from the use, storage and disposal of these Microbial Cultures.
2. The Recipient R & D Centre should follow the prevailing rules and regulations in the country for the use of these cultures including those of the Biodiversity Act.
3. DBT-NCMR will have the right to distribute the cultures simultaneously to more than one R&D Centre on non-exclusive basis.
4. Minimum number of Cultures to be procured from DBT-NCMR is 500 (five hundred). DBT-NCMR will supply a single copy of these cultures as stabs. DBT-NCMR will only be obligated to supply these cultures to the Recipient R&D Centre only once in either a batch-wise manner or a one-time shipment [if the number does not exceed 1000 (one thousand)] during the entire time-period of the agreement. In case, the Recipient R&D Centre requires a second shipment of cultures that have already been supplied to them once during the current agreement period, it will incur additional charges.

V. REQUEST FOR SHIPMENT

The request form for shipment of cultures is annexed here as *Annexure 1*.

VI. COST EVALUATION CRITERIA

Cost and modalities of supply of Cultures will be decided by DBT-NCMR as per prevailing rates and policies.

VII. SUB- LICENSE

The Recipient R&D Centre will not supply, share, lend, sub-lease or sell these cultures to any third-parties. Any such activities desired should be routed through DBT-NCMR only and will follow similar process.

VIII. OTHER TERMS AND CONDITIONS

1. Recipient R&D Centre will only screen for biomolecules / activities which are covered under the Agreement in the initial phase. Upon discovery of potentially commercializable product or IP of any product generated, from the supplied cultures or its derivatives based on DNA such as clones, plasmids, biomarkers or protocols will require signing of additional agreement according to then-prevailing terms and conditions.
2. The Cultures may not be preserved and maintained beyond the Agreement time frame by the Recipient R&D Centre or any Third parties. The Recipient R&D Centre must discard and dispose-off these Cultures by appropriate and safe method such as incineration with proper notification to Recipient R&D Centre's Biosafety committee if applicable, such as incineration, after completion of permissible time limit granted in the Agreement. A declaration to this effect must be sent to DBT-NCMR by the Recipient R&D Centre on expiry of the agreement.
3. At the time of submission of request form, the Recipient R&D Centre must disclose their interest, such as but not limited to the nature of study, type of Cultures required and duration of study. The Recipient R&D Centre should use the Cultures only for the activities specified in the request form. If it wishes to carry out any other assays/study using these Cultures, separate Agreement need to be signed.
4. Within ten years of receipt of Cultures from DBT-NCMR, if any Recipient R&D Centre comes out with any product of microbial origin, they will have to produce documentary and/or genetic evidence to prove that the said microbe is not from the DBT-NCMR collection. If required, the Microbial Culture (s) in question should be made available to DBT-NCMR and/or an independent authority for verification purpose.
5. Recipient R&D Centre must acknowledge in all the documentation including but not limited to publications / patents / reports that these Cultures were obtained from the DBT- NCMR collection supported by the Government of India, Ministry of Science and Technology, Department of Biotechnology.
6. Confidentiality and Protection of interest: Both, NCMR and the R&D Organization will maintain the full confidentiality of information and data exchanged between them and sign a non-disclosure agreement.

IX. INDEMNIFICATION

Recipient R & D Centre assumes all liabilities for any and all third party claims, losses, expenses and damage, including reasonable attorney's fees (collectively "Claims") arising out of or relating to R &D organization use, receipt, handling, storage, transfer, disposal and other activities relating to Biological Materials,

provided that Purchaser's liability shall be limited to the extent that any such claim arises out of DBT -NCMR gross negligence or willful misconduct.

X. LIMITATION OF LIABILITY

To the extent permitted by law, in no event will DBT-NCMR or its contributors be liable for any indirect, special, incidental or consequential damages of any kind of connection with or arising out of the cultures even if DBT-NCMR has advised of the possibility of such damages.

XI. INTELLECTUAL PROPERTY

DBT -NCMR retains ownership right, title and interest to the microbial cultures supplied to the R & D Organization and the activities, biomolecules modifications derived from them. The Recipient R&D Centre is required to inform DBT-NCMR before filing patent(s) and any other intellectual protection originating from screening/research/study using these Microbial Cultures.

XII. TERMINATION

If the Recipient R&D Centre wishes to terminate the Agreement prior to its stipulated end-date, then it must inform its intention to DBT -NCMR in writing at least three months in advance, and must discard and dispose off by appropriate and safe method(s) all the Cultures received from DBT-NCMR. In such a case, if the Recipient R&D Centre owes any financial charges to DBT-NCMR or DBT, they must clear all such charges prior to termination of the Agreement. In this case, if DBT-NCMR supplied only a partial supply of the agreed Cultures, DBT-NCMR will not be further obligated to supply the remaining Cultures either during the three-month notice period or upon the termination of the Agreement. At the same time there will be no refund of the advance fee paid to DBT-NCMR.

XIII. GOVERNING LAW AND JURISDICTION

In the event of any dispute or difference between the Parties, such dispute or difference, shall be resolved amicably and in good faith by mutual consultation. If such resolution is not possible, then the unresolved dispute or difference whatsoever arising between the Parties or the validity the breach thereof or in respect of any defined legal relationship associated therewith or derived therefrom dispute shall be submitted for arbitration to International Centre for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India. The Authority to appoint the arbitrator(s) shall be the ICADR. The Arbitration under this Clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996. The award made in pursuance thereof shall be binding on the Parties. The venue

of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language.

Annexure I

**REQUEST FORM
FOR THE PURCHASING OF MICROBIAL CULTURES**

1.	Full Name of the Organization Applying	
2.	Type of the Organization	
3.	Complete address (Registered)	
4.	Company/Organization's Details (Registration/Affiliation)	
5.	Relevant area	
6.	Purpose for applying (Only R&D institutes are applicable) (in brief)	
7.	Disclosure of interest	
8.	Quantity demanded	
9.	Duration of study/research	Minimum _____ Maximum _____