Biotechnology Industry Research Assistance Council (BIRAC)
A Government of India Enterprise

Announces a Request for proposals
In the area of

Synthetic biology
With a focus on

"Synthetic biology approach for transition towards a Bio-based economy"

Biotechnology Industry Research Assistance Council (BIRAC)

Request for Proposal (RFP) document

INTRODUCTION

With mounting concerns on global warming, climate change and the looming threat of fossil resource scarcity, the world is increasingly looking to bio-based resources for a variety of applications and end products. Increasing pressure to reduce carbon emissions is an additional factor in searching for alternate route for production of chemicals from renewable sources. There is a need to replace chemical processes and allow the production of new products by environmental friendly technologies. Therefore, to achieve a long term sustainable development there is an urgent need for a fundamental shift towards bio-based clean technology. Bio-based economy can favourably impact several areas such as fine chemicals, terpene based materials, vitamins, food ingredients, flavours and fragrances, sweeteners, bulk chemicals, detergents and bioplastics to name some.

Synthetic biology is an interdisciplinary area that involves the application of engineering principles to biology. It aims at the (re-)design and fabrication of biological components and systems that do not already exist in the natural world. The production of chemicals was attainable previously only through expensive extractions or through the use of petrochemicals and other non-renewable resources. However, through the design and construction of biological systems it is now possible to turn organisms into living factories thereby forwarding towards a bio-based economy. Synthetic biology, at the heart of a bio-industrial revolution, has an impact on multiple industrial sectors ranging from production of chemicals, biofuels, food ingredients and supplements, and pharmaceuticals. By improving the productivity of bio-manufacturing processes, synthetic biology can help generate more sustainable materials, chemicals and energy.

SYNTHETIC BIOLOGY – STATUS INDIA

Synthetic biology is in infancy and much needs to be done for moving towards commercialization. It is gaining increasing attention because of the potentials and the opportunities it creates in solving some important problems.

Though, research in synthetic biology and its application are on high priority globally, India is lagging behind in this field of research and an urgent need arises to promote and accelerate the synthetic biology research in India. Given the fact that India has a dynamic biotechnology industry and lot of research and teaching activities are happening in biotechnology, the situation is ripe for growth of synthetic biology

To promote this initiative in India, BIRAC intends to generate joint research, development and commercialization activities and co-ordinate a national mission on the application of synthetic biology for promoting bio-based economy in India. The main aim will be to call for proposals so as to stimulate and promote translational research in the area. In addition, it will also focus to develop complete pathway for synthetic production of high commercial value.

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A. PROGRAM GOAL

The theme of the current RFP is:

"Synthetic Biology Approach for Transition towards a Bio-Based Economy"

Primary scope of the RFP: *is to (re-) design and fabricate biological components and systems that do not already exist naturally but should exclude simple recombinant production systems.*

Definition -*"synthetic biology is defined as a new interdisciplinary area that involves the application of engineering principles to biology."*

Projects applied must take into account the criteria for affordability, wide-spread adoption and have a realistic possibility for scale-up. The scope of the RFP is inclusive of and not exhaustive of the following areas:

a. Pathway engineering/genome engineering for affordable and/or sustainable routes for production of useful chemicals in microorganisms, mammalian cells and algae:
    i. Fine chemicals (active pharmaceutical ingredients, amino acids, vitamins, proteins, peptides, oligonucleotides, organic acid)
    ii. Speciality chemicals (adhesives, surfactants, oleochemicals, catalysts, dyestuffs and pigments, enzymes, flavors and fragrances, food and feed additives, pharmaceuticals)
    iii. Polymers (Polyhydroxyalkanoates, cellulose, alginate, chitin, chitosan, hyaluronan, Isoprene monomer and polymer)
    iv. Biolubricant range esters
    v. Aromatic and aliphatic hydrocarbons
    vi. Enzyme production
b. Development of synthetic genetic parts (including engineered proteins) and synthetic circuits for production of above mentioned products.

B. Key requirements for the proposed technologies/ products that will be considered:

a. Projects with a well-established proof of principle
b. Projects that propose a process/product innovation with significant commercial potential
c. Developed process should be sustainable from an economic and environmental

point of view

d. Projects on establishing proof of concept for technology idea
e. Should be scalable

C. EXCLUSIONS- Examples of areas that will not be considered:

a. Exploratory research ideas not leading to a product
b. Simple recombinant production systems will not be considered.
c. Projects with no element of novelty
d. Projects not having product development component
e. The proposed concept not having commercialization potential
f. Funding cannot be used to support PhD student research or any other academic research. The grant is not a research fellowship.

D. APPLICATION OPENING

Important dates for RFP:
Publication on - 15th May 2019 and
End date on- 1st July 2019

E. ELIGIBILITY: The proposals can be submitted by:

a. Company (Start-up, Small, Medium or Large) incorporated under the Companies Act, 2013 having a minimum of 51% of the shares of the Company to be held by Indian Citizens (Indian passport holders).
b. Limited liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum half of the persons who have subscribed their names to the LLP document as its Partners should be Indian citizens

NOTE: *The applicant Company/LLP should have adequate in-house facility to address the project implementation (which shall be evaluated during the site visit) or incubated with any of the recognized incubation facility. DSIR certificate is not mandatory.*

c. Academia (Public or Private Research Institute, University) having a well-established support system for research. The institute should have been established in India and have NAAC/ UGC/ AICTE or any equivalent recognition certificate or any other Public/Government supported organization

NOTE: *Academia (with or without enabling industry partners) will be considered as primary applicant as per the conditions mentioned in the next section as the objective of the first category is to enable early stage research/product development efforts for further translation.*

d. Non-academic Individuals (NAI)

Application can be submitted by any of the above entities (a - d) jointly or severally in accordance with the criteria of specific Category.

NOTE: *Applicants and Co- applicants should not have any other legal disqualification that will prohibit them from participating in the scheme process and execution of necessary agreements thereafter.*

F. FUNDING MODALITIES

a. **Category I:** Development of proof of concept (project to reach TRL - 3 at the end)
   i. **Funding Support:** Grant-in-aid assistance up to Rs. 50 lakhs (The non-recurring cost should not be more than 10% of the total project cost)
   ii. **Eligibility**: This category is open to:
      1. Company: Start-up company only (the incorporation date of the Company should not be earlier than 3 years from the date of Publication of the RFP)
      2. Limited Liability Partnership (LLP)
      3. Indian Academic institutes/universities with or without industry partner
      4. Non-academic Individuals (NAI are defined as persons other than scientists working in academic institutes/universities (applicant has to be physically incubated in an incubator))
   iii. **Duration**: Project duration can be up to 18 months

Note: *Feasibility of the technology for further validation should be demonstrated. Reactor studies atleast till 10 L scale would have to be demonstrated as the final outcome*

b. **Category II:** Early Transition /Validation of existing R & D hypothesis in simulated environment (project to reach TRL-6 at the end)
   i. **Funding Support:** Grant-in-aid assistance on a cost sharing basis up to Rs. 100 lakhs
   ii. **Eligibility:** This category is open to:
      1. Company entity/LLP as the primary applicant with or without Academia or other companies as collaborators
      2. Academic institute with one or more validating partners of which at least one is a company
   iii. **Duration**: Project duration can be up to 24 months

Note: *Robustness of the engineered organism should be demonstrated by producing commercially viable amounts of the product*

c. **Category III:** Scale up of technology to be demonstrated in operational environmental conditions (Project to reach TRL 7 and above)
   i. **Funding support:** Grant-in-aid assistance on a cost sharing basis
   ii. **Eligibility:**
      1. Company entity/LLP as the primary applicant with or without Academia or other companies as collaborators
      2. Academic institute with one or more validating partners of which at least one is a company
   iii. **Duration**: Project duration can be up to 36 months
   iv. **Payment of Royalty:** Royalty payment obligations (5% of Net Sales) shall become applicable for funding assistance under this Category.

Note: *Readiness of the technology for commercial uptake should be demonstrated*

Note: *For Category II and III, when academia applies as primary applicant, the project should be for validating or scale-up of the PoC developed in their laboratory. In such cases, there has to be one or more validating partners of which at least one is a company. The guidelines of the CRS scheme of BIRAC will be followed for such an approach.*

G. APPLICATION PROCESS

a. **Process of application submission**
   i. Proposals are required to be submitted online only. Online proposal submission can be done by registered users. The RFP will be open for a period of 45 days. Process for submitting the proposals online is detailed below:
   ii. Log on the BIRAC website (www.birac.nic.in)
   iii. Registered users may log-in using the credentials and new users need to register the institution with by clicking on New User Registration.
   iv. In case of new user registration, a computer generated password is sent to the email-id provided at the time of registration.
   v. Upon login, the user is navigated to the page displaying the specific scheme link.
   vi. Click on the link under Programmes and the active call would be highlighted.

vii. Click on the active call against which the proposal needs to be submitted.
viii. Further details on How to submit a proposal are available in the specific program User Guide available on the website.

b. **Process for selection of the proposals**
   i. The process of evaluation broadly comprises the following steps:
   ii. Eligibility check of mandatory legal parameters
   iii. Online review by experts for RFP suitability and scope of the project
   iv. Peer Review by a Panel of area-specific experts called as Area Review Panels (ARPs) created for evaluation of sectoral relevance and other parameters
   v. Presentation of proposals shortlisted by the ARP to the Technical Screening and Expert Committee (TSEC) comprising eminent scientists from all over the country
   vi. Site Visit for the projects shortlisted by the committee (if required) after presentation by the applicant including financial due diligence.
   vii. Expert Review, wherever required
   viii. Final review by TSEC and scrutiny and decision by the Apex Committee comprising Senior Technical Experts of members from various ministries and Government departments.
   ix. Final recommendations and execution of funding agreement
   x. The proposals will be evaluated based on following criteria:
      1. Scientific Merit
      2. Technical strength of PoC
      3. Clarity of technical strategy
      4. Innovation level
      5. Level of Risk
      6. National / Social Relevance
      7. Commercial Potential
      8. Investigators Credentials and/or collaborative team's expertise.

H. SCOPE OF INTELLECTUAL PROPERTY GENERATED DURING THE DURATION OF THE PROJECT

a. The New Intellectual Property (IP) rights belong to the recipient of funds, in a joint manner unless mutually agreed otherwise.
b. It is the responsibility of the Fund Recipients to protect the New Intellectual Property (New IP).
c. Applicants with collaborators shall have MoUs in place.

d. Project having the final deliverable as TRL-7 and above shall have royalty payment obligations

NOTE: *For the purpose of this GLA, New IP means intellectual property generated during the conduct of the Project by the Fund Recipient(s), but excluding the intellectual property generated by the Fund Recipient(s) before execution of this GLA and any IP generated outside the scope of this GLA even during the term of this GLA.*

I. PROJECT MONITORING & MENTORING

a. **Project Monitoring Committee (PMC)**

The projects shall be monitored/and mentored regularly by an Expert Committee constituted by BIRAC for each project. Site visits shall be conducted by specially constituted Expert Committees comprising two to three Technical experts and one financial expert. The Project Monitoring Committee (PMC) is responsible to;

i. Monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives is contained in the Agreement.
ii. Based on the foregoing, to assess and recommend:
iii. The release of next instalment or part release thereof by the BIRAC.
iv. revision of project duration
v. closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
vi. inclusion of additional industrial/institutional partner(s), if the applicant requests involvement of such partner(s), in the overall interest of the Project,
vii. mentor(s) to overcome any technological problem faced in the Project implementation; and
viii. Revision of the financial assistance.
ix. To advise on issues related to securing of IPR; and
x. To advise on any other matter as referred to it by BIRAC and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of proposed Scheme.

b. **Reporting of Progress**

i. On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.
ii. The MCR will be assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget is released.

iii. The Applicant will have to submit a duly certified Statement of Expenditure for the every 30th September and 31st March.
iv. Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure will be made available as per requirement.

J. TERMS & CONDITIONS AND REQUISITES FOR FUND DISBURSEMENT

a. **Agreement of funding**
On announcement of Award, all concerned applicants need to sign the Grant-in-aid Letter Agreement (GLA) with BIRAC.

K. OTHER REQUISITES FOR FUNDS DISBURSEMENTS TO COMPANY

a. In addition to signing of agreement between all the concerned parties, following requirement needs to be completed before the first instalment can be released:
b. A Board Resolution needs to be passed for acceptance of the Grant-in-aid offer by the BIRAC
c. Opening up a No-Lien Account with a scheduled/nationalized Bank in case of a Company
d. Letter of Authorization in case of Institute in the prescribed format of BIRAC
e. MoUs related to IP arrangements/collaborations/outsourcing, etc needs to be in place.

L. ROYALTY GUIDELINES- Payment of Royalty

a. The Company shall pay royalty to BIRAC at the rate of 5 (five) per cent on annual Net Sales of the product(s) developed with BIRAC's assistance. Payment of royalty shall fall due beginning with the first sale of the product(s) and the liability to pay royalty will be as per BIRAC norms.
b. Royalty for each financial year shall be payable to BIRAC within 60 (sixty) days of close of corresponding financial year.
c. If the Company gets grant-in-aid assistance for more than one Project that will culminate into the same Product(s), then the Company shall pay royalty to BIRAC at a cumulative rate of 7 (seven) per cent on annual Net Sales of the product(s) developed with BIRAC"s assistance in the same manner as provided above under sub section (i).
d. If the Company gets grant-in-aid assistance for more than one Project that will culminate into the distinct Product(s), then the Company shall pay royalty to BIRAC at the rate of 5 (five) per cent on annual Net Sales of each such distinct

Product(s) developed with BIRAC‟s assistance in the same manner as provided above under sub section (i).

e. If the Company intends to transfer or sell the Product, it shall take prior written permission from BIRAC and BIRAC will recover the Royalty amount or 5% of the resultant income excluding excise duty

M. ACKNOWLEDGEMENT OF BIRAC SUPPORT

Acknowledge the assistance of BIRAC while publishing, marketing the resultant Product or presenting in any manner the details of the Project, its progress or its success along with the "Disclaimer" that reference therein to any specific commercial product, process, views or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or assuming liability of any sort by the BIRAC. Use of BIRAC logo is not permitted without written approval.

N. CONTACT INFORMATION

Further information can be obtained at

BIRAC Website: www.birac.nic.in

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