

Fostering and Nurturing Innovation Research

Promoting Affordable Product Development



Biotechnology Industry Research Assistance Council

(A Govt of India Enterprise)

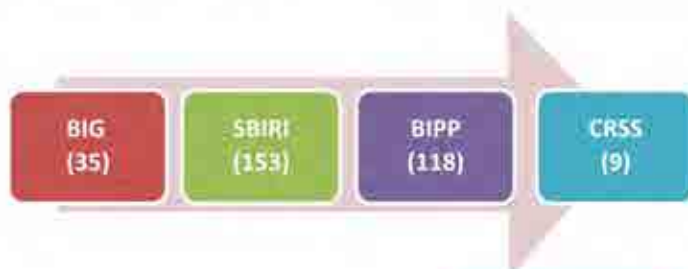


Biotechnology Industry Research Assistance Council (BIRAC) provides innovation funding to entrepreneurs and biotech firms especially start-ups and SMEs by combining a smart mix of grants and soft loans for affordable product development.

Fostering and Nurturing Innovation Research

BIRAC's innovation funding schemes cover all aspects of the discovery-development pipeline i.e. from idea generation to commercial scale production. BIRAC schemes encourage collaboration between the two important stakeholders of biotech ecosystem i.e. industry and academia.

Schemes & support System by BIRAC	Idea	Proof of concept	prototype	II prototype	validation	Pilot	Scale	Market
BIG	█							
SBIRI		█						
BIPP		█	█	█	█	█	█	█
CRS					█	█	█	█



BIG: Supports novel ideas evolving from start-ups or academic-spin offs and having commercialization potential.

SBIRI: Boosts early stage innovation focussed PPP initiative in the area of biotechnology.

BIPP: Government partnership with Industries for support on a cost sharing basis for path-breaking research in frontier futuristic technology areas having major economic potential.

CRSS: Supports academic institutes to take forward their research leads through validation and translation by an industry partner in the contract research mode

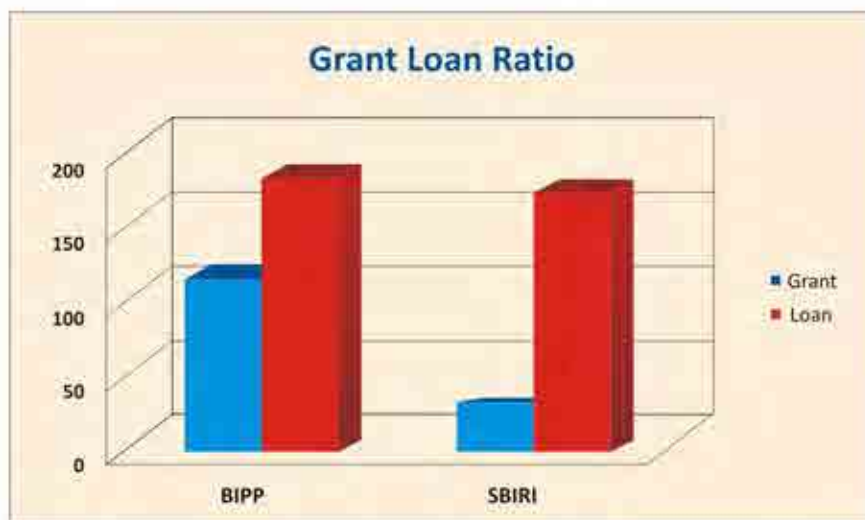
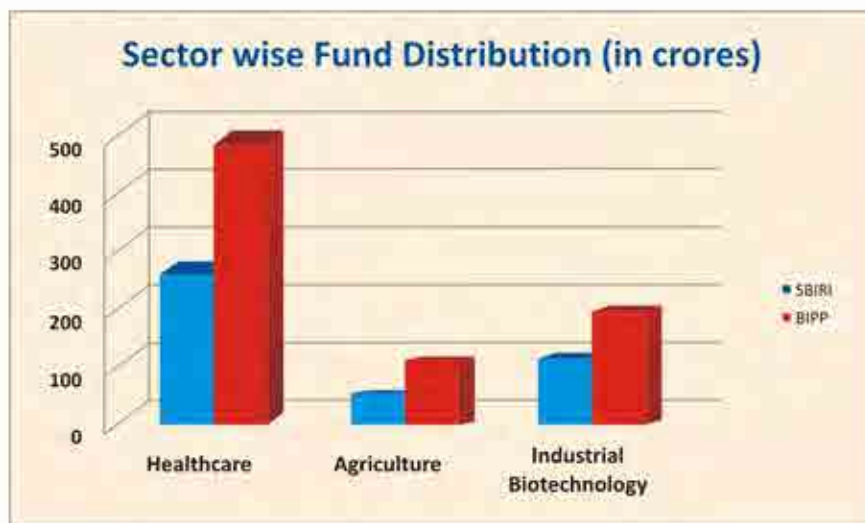
We Supported	We created	We delivered
<ul style="list-style-type: none"> ~ 210 Companies ~ 315 Projects ~ 40 Scientists & Entrepreneurs ~ 100 Incubatees ~ US \$ 230 million 	<ul style="list-style-type: none"> ~ Intellectual Property-23 ~ 70000 sq. ft. of incubation space ~ 5 University Innovation Clusters ~ 1 Regional Innovation Centre ~ 3 Bio-Industrial Facilities ~ 2 Contract Service Facilities 	<ul style="list-style-type: none"> ~ 15 Affordable products ~ 11 New technologies

BIRAC provides a conducive environment for collaborative R&D through its flagship programmes i.e. SBIRI and BIPP.

Areas of support,

- Healthcare
- Agriculture
- Industrial Biotechnology includes Industrial Products and Processes & Secondary Agriculture
- Infrastructure
- Bio- informatics/Systems Biology

Sector-wise fund distribution for three main sectors & Grant/Loan ratio for SBIRI and BIPP



- BIRAC's maximum funding support was given to Healthcare sector followed by industrial biotechnology and agriculture.

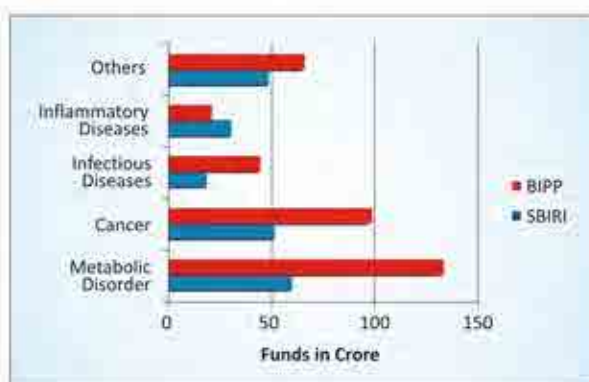
Healthcare

BIRAC's funding support to healthcare sector focusses on developing affordable technologies and products with a view to reduce their cost, increase their availability and accessibility to the society. The projects supported mainly address Cancer, Cardiac Disorders, Bone related abnormalities, Bacterial and Viral based infectious diseases, Diabetes, Inflammatory diseases, Tuberculosis and Aging related problems.

Disease Areas

- Cancer
- Metabolic disorders
- Infectious diseases
- Inflammatory diseases
- Others (bone-based abnormalities, neuro-disorders, animal bites, vector borne diseases & transplantation modalities)

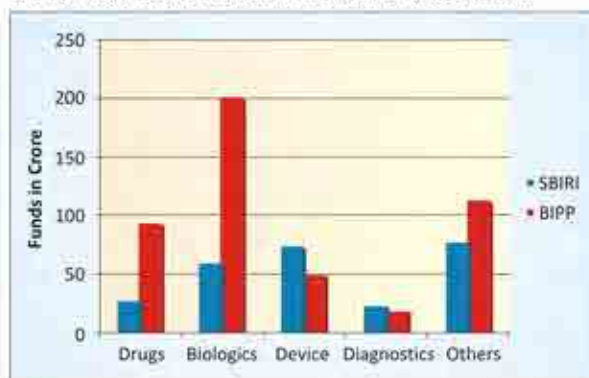
Disease area based Investment under BIRAC Schemes



Intervention Developments

- Drugs
- Biologics
- Devices/diagnostics
- Others (drug delivery, regenerative medicine, bio-manufacturing & platform technologies)

Intervention based Investment under BIRAC Scheme



- Metabolic disorders and cancer were funded maximum within disease areas and biologics (for infectious diseases) & bio-manufacturing (for vaccines and monoclonal antibodies) accounts maximum share within intervention developments.
- Most of the projects from cancer are in POC stage whereas projects from metabolic disorders are in scale-up followed by POC.
- Cancer projects attracted maximum number of academia/industry collaborations.

Products & Processes

Products

- **Foligrاف (Recombinant Follicle Stimulating Hormone) and Rasburicase (Recombinant Uricase)**

Foligrاف contains urofollitropin which is a purified form of follicle stimulating hormone (FSH) and is important in the development of follicles produced by the ovaries. This is the first recombinant FSH product developed, manufactured and sold by an Indian company.



Rasburicase is a recombinant uricase to control hyperuricemia in cancer patients undergoing chemotherapy. An innovative and economical production process was developed and the technology was out licensed to MNCs also.



- **A rapid cost-effective point-of-care diagnostic with micro PCR device diagnoses multiple diseases (presently Malaria, Dengue & Typhoid)- Ready for market.**

This development allows healthcare authorities to use PCR in resource limited settings at a fraction of the cost of commercially available PCR tests.

- **Multi deck shaker-Affordable clinical chemistry analyzer - Autochem ingenious**

This product will help early diagnosis thereby reducing the overall expenditure on healthcare. Robust design to withstand large power fluctuations.



- **Device for execution procedure for tumor ablation using Maxico (The Integrated planning navigation and Training Platform for Tumor Abaltion) launched in the market**

This system offers several features to help clinicians to target tumor and plan for accurate tool placement for diagnosis or therapy.

- **Development of novel microfluidics based flow analyzer**

This can be used broadly for immune health monitoring before anti-retroviral therapy. The novelty lies in the integration of novel microfluidics and optics for affordability.



- **Affordable fluorescence reader for point-of-care diagnostics**

This technology will help to detect multiple infections simultaneously in remote settings and ensures less medical waste in blood banks. This can be adapted for inexpensive tests for detection of HIV, HCV, HBV, Syphilis and Tuberculosis infections.

- **Single tube nested PCR kit for White Spot Syndrome Virus (WSSV), Infectious hypodermal and hematopoietic necrosis virus (IHHNV) and Yellow Head Virus (YHV)**

These kits will help in control of killer viral diseases of the shrimp.



- **Development of Fast-PCR kit for detection of tuberculosis**

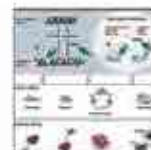
A novel primer design technology to achieve 100% sensitivity and specificity



- **Oncoscan-Digital oncopathology slide scanner-**
Facilitates early disease diagnosis and prevention

- **PAT-1102: HDAC inhibitor for cancer treatment**

The present HDAC inhibitor is expected to offer safe and affordable therapy to cancer patients in India. Pre-clinical studies completed.



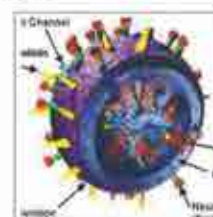
Vaccines/Drugs in Clinical Trials

- **Phase III trials of oral Rotavirus Vaccine successfully completed. Market Surveillance started. Manufacturing and Marketing License obtained**

A robust manufacturing process for production of clinical grade -20°C stabilized formulation of the Live Oral Rotavirus Vaccine 116E with a 2-year shelf life was developed using rotavirus strain 116E isolated from an asymptomatic neonate at AIIMS, New Delhi for the prevention of deaths in infants from severe rotavirus gastroenteritis.

- **Clinical development of Influenza vaccine**

Provides indigenous capability to produce vaccine



- **Clinical trials of novel anticancer drug cocrystal**

A hydrolytically stable formulation of Temozolomide will be relevant for tropical zone IV region countries

- **Silk protein blend film for wound management**

Market demand is there for healing of auto graft wounds & diabetic wounds



- **Development of affordable, Asia specific 15 valent pneumococcal polysaccharide-CRM 197 protein conjugate vaccine**

- **Novel molecules to address cardio metabolic risk reduction**

An indigenous NCE developed for the treatment of CMR associated with non-traditional risk factors such as obesity, IR and elevated triglycerides.





- **Clinical investigation of Galnobax[®] for the treatment of diabetic foot ulcer**
Galnobax is affordable, easily administrable and available

- **Japanese Encephalitis vaccine: Market license obtained in India for the age group of 1-3 years and 18-40 years.**

Support was provided to the clinical trials of 1-3 years age group and Phase III trials were successfully concluded.



Platform Technologies

- **SanGenix:** A comprehensive Next Generation Sequence (NGS) data analysis solution
Application is in re-sequencing of human genomes to enhance understanding of genetic differences in health and diseases

- **Hepatotoxicity Prediction Platform**

This platform is capable of providing insights into drug induced liver injury and will help in replacing/reducing the use of animals and increase efficiency of drug development by predicting hepatotoxicity.



Agriculture

Agriculture is one of the major focus areas of funding at BIRAC as it supports projects which are not only looking at the immediate urgency of farming community but also promotes projects which encourage technology leapfrogging in sync with the global trends. In the context of the BIRAC's agricultural investment funding, innovative ideas for cutting edge technologies are being promoted and pursued in a public and private partnership mode and there has been significant growth in numbers. Moreover, the growing attractiveness of agricultural investment projects as profitable business ventures is now evident from the industry committed funds.

The two major schemes of BIRAC i.e. BIPP and SBIRI which encourage public private partnerships have together funded close to sixty projects in agriculture. Major areas supported are

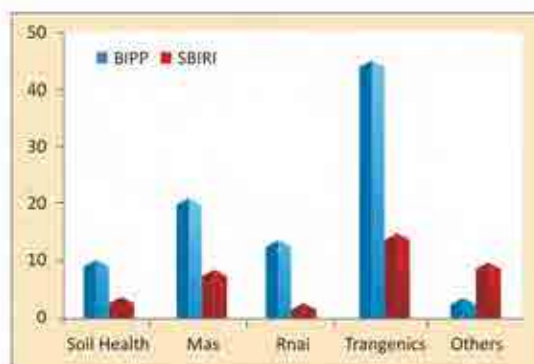
- Marker Assisted Selection
- RNAi
- Transgenics
- Soil health management

Within the technologies, a pipeline of the projects have been funded which are falling into various stages of development like proof of concept, validation and product development.

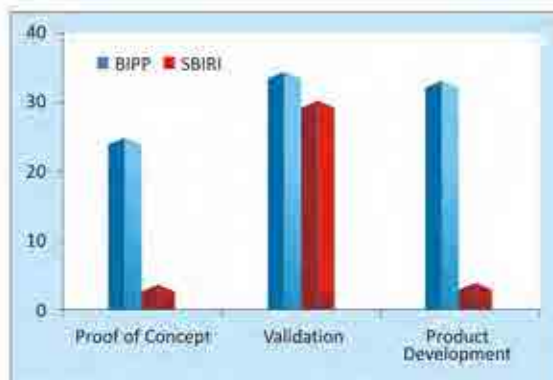
Stage Vs Category supported for crop development

Stage of Development / Category of Technique	Proof of concept	Validation	Product Development
Marker Assisted Selection	Abiotic Stress Tolerance and Identification of Elite Traits for micro-propagation	Yield Improvement under stress (Abiotic - Drought and Moisture)	Development of Elite varieties for nutrition, Abiotic and biotic stress.
	Crops : Rice and Banana	Biotic- viral and fungal) Crops: Rice , Maize, Tomato and Okra	Crops: Mustard, Rice and Pigeon Pea
RNAi	Development of resistance to insect and viruses	A nascent technology yet to reach validation and product development stage	
	Crops: Brinjal, Tomato and Okra		
Transgenics	Abiotic Stress Tolerance Crop : Rice	Development of stress tolerance (Abiotic -Drought, Salinity, Biotic- Insect pest, Viruses) Crops: Onion, Rice , Cotton, Maize, Cassava and Brinjal and Okra	Deregulation trails for Insect Pest and Herbicide Resistance Crops: Rice, Maize, Mustard
Soil Health Management	Synthesis of Nanopesticides and Actinomycetes Test Crop : Rice	Pilot scale Production of Biopesticides Nanopesticides and Nanofungicides	Commercial Scale Production biopesticides for weed management

- Traits covered are abiotic (drought, salinity and moisture stress) and biotic (virus, Insect and fungal) stress resistance, nutritional quality, herbicide tolerance, male sterility for hybrid seed production
- Crops covered are rice, maize, mustard, tomato, brinjal, okra and pigeon pea and finally cotton
- Transgenics have the commitment for maximum share of funding. Many of the projects are in validation/product development stages and so is the funding
- Many projects have taken advantage of genomics information and MAS based approach for crop improvement by combining classical breeding methods as in the case of integration of BLB resistance and salinity tolerance into rice



Area-wise Fund distribution (in crores)



Developmental stage fund distribution (in crores)

- BIRAC encourages crop improvement through RNAi although the technique is in its nascent stage in India
- Soil health management related projects are also supported through new and classical interventions like nano-fungicides, nano-pesticides and bio-pesticides
- Industry/academia collaborations were evident in this sector. Academic collaborations were found to be a major factor for progress in the projects towards product development.

Products & Processes Under Development

1. Marker Assisted Breeding

- **Rice-enhanced drought and multiple diseases and pest resistance**

Bacterial Blight, Blast and Brown Plant Hopper resistance into recurrent parents of the popular rice hybrid

- **Herbicide Resistant Mustard**

BRL-I second year trials have been completed along with a set of environmental safety studies and food and feed safety studies.

- **Improved yield potential of maize under abiotic stress. Development of Abiotic Stress Resilient Maize:**

This project aims to improve maize productivity under abiotic stress through an integrated approach of deploying molecular markers with conventional breeding process: Crossing 75 GEO inbred lines and 325 CIMMYT inbred lines

- **High yielding pigeonpea**

The innovative element of the project is deploying cutting edge molecular assisted breeding strategies to embark on accelerated product development of high yielding pigeonpea hybrids.

- Utilization of marker assisted selection for development of salt tolerant hybrids in rice
- Marker Assisted Introgression of yellow vein mosaic virus (YVMV) resistance trait in high yielding varieties of okra



Crop advancement through marker assisted breeding

2. RNAi

- Product Development of transgenic Tomato
Tomato resistant against leaf curl virus and Ground nut bud necrosis virus by using artificial microRNA construct.

- Virus resistant Okra

The project aims to develop RNAi constructs designed to provide resistance against Gemini viruses infecting okra.

3. Improved productivity and production

- Herbicide & Stress tolerant transgenic Onion

Usage of Rye grass EPSPS and Helicase PDH45 gene for drought and salinity stress tolerance in onion which was validated in rice & groundnut is the innovative element of this project.

- Brinjal resistant to fruit and shoot borer

The developed insect resistant brinjal without fruit damage is preferred for human consumption and the farmer's community will benefit economically. The pesticide residues on the harvest are expected to reduce heavily.

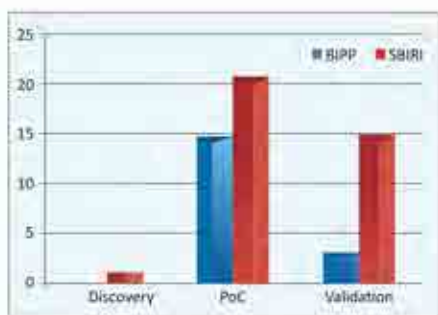


Industrial Biotechnology including Secondary Agriculture

Industrial Biotechnology sector involves the use and application of biotechnology for the sustainable production of materials, chemicals and fuels. It is a highly diverse area and can result in improved sustainability of industrial processes. The use of biotechnological approach for partial or complete removal of a chemical process is a paradigm shift.

Under the umbrella of viability gap funding for promoting this sector, BIRAC has supported a total of 60 projects. The total amount of funds that has been



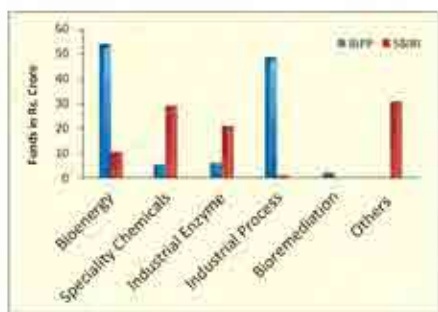


Stage of Development

invested for promoting innovative research in the sector is Rs. 245 crore (USD 40 million) with BIRAC contributing 40% of the total amount. The highest number of proposals (15) has been supported in the secondary agriculture sector. This is an upcoming area within the country and includes various sectors such as value added products, herbal drugs and nutraceuticals to name a few. This is closely followed by the industrial enzyme sector (12) and the speciality chemicals (9). Contrary to the number of proposals, it can be seen that highest amount of funds have been given in the bioenergy

sector (26%) followed by industrial processes (20%). This is because the both of these sectors demands facilities to be build up at a large scale which would require huge investment in funds.

The funding schemes cover all aspects of innovation pipeline.

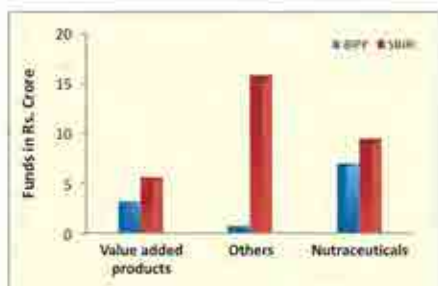


Funds Distribution (in Crores)

- Many projects from this sector are in POC followed by validation and discovery
- 25% of projects were supported in PPP mode and in-house research within industry is instrumental in developing products for rest of the proposals.

Industrial products and processes is a highly diverse area and includes

- Bioenergy
- Speciality chemicals
- Industrial enzymes
- Industrial processes
- Bioremediation
- Nutraceuticals
- Others (fine chemicals)
- Highest amount of funds are for the bioenergy sector (31%) followed by industrial processes (23%).
- Disbursement of funds for the development of high oil yielding petro-crops to address the issue of sustainable biomass availability.
- Support for technology development for import substitutes and products having a very high market demand like hyaluronic acid, lactic acid, rare sugars, docosahexaenoic acid, 2,3-butanediol and 1,3 propanediol.
- Support for the development of an anaerobic membrane bioreactor and thermophilic anaerobic bioreactor in the area of bioremediation.



Funds Distribution (in Crores)

- Support for fermentative production of several Industrial enzymes such as amylase, lipase, nitrilase, keto reductase and dextranase.
- Funding to establishment of single stage cottonseed extraction process.
- Support to twelve projects to develop technologies for the production of amino acids, platform technology for growth of adherent cells on micro-carriers, animal feed, secondary metabolites and antibiotics.

Secondary agriculture is an upcoming area in India. It can aid in adding value to the waste from agricultural industry in order to achieve a high degree of sustainability. BIRAC has supported

- Nutraceuticals
- Value added products
- Others (herbal drugs)
- Technology development for production of lipid lowering formulations and novel molecular drugs.
- Production of value added products from rice, Mycochitin- Bio-control agent, Chitosan derivatives, Bio-rakshak pesticide and astaxanthin.
- Demonstration and validation of a process to convert corn steep liquor into free flowing powder with increased nutritional values at lab scale.

Products & processes

Products:

- **Solid state fermentation process for production of Dextranase enzyme at 30 L**

Dextranase has been produced for the first time in the world using solid state fermentation. This has application in sugar industry and has enormous export potential

- **Nitrifying bioreactor for the establishment of organic recirculation prawn seed production system**

This indigenous technology helps the aquaculture industry in attaining stability and sustainability by establishing re-circulating aquaculture systems especially for seed production and maturation.

- **Value addition to crustacean exoskeleton and coir pith in a zero discharge process yielding a variety of products such as Pelrich Mycochitin- Bio-control agent, Chitosan derivatives, Pelrich Bio-rakshak pesticide, Pelrich Bio-boost and Pelrich Biocoat.**
- **Systems to cultivate macroalgae in rough ocean conditions (50 square meters prototypes at two locations) and subsequently convert the biomass into ethanol completely in a salt water environment.**

This project has the possibility to bring about energy independence for the nation while creating a new source of livelihood for coastal community.





Facilities Created

- **Bioprocess facility for large-scale production of microbial antigens and MAbs under cGMP conditions**

Import substitution and self-reliance.

Commercial scale production:

- Single stage cottonseed extraction process followed by online miscella refinery technology having a capacity of 600 MTPD

This process produces better oil with enhanced recoveries. Alternate protein sources can be fed to animals so that soya bean meal will be available for humans.



Pilot scale/Demonstration:

- **Pilot plant for production of 3000 litre ethanol/day using Lignocellulosic biomass technology from DBT-ICT Centre for Energy sciences**

Setting up of decentralized commercial lignocellulosic ethanol plants is a requirement considering the need for ethanol free from vagaries of sugarcane production and with the availability of more than 250 million tonnes of surplus agricultural residue available in the country.

- **Pilot scale production technology for generating Biological Hydrogen from sweet sorghum using 15 tonne biomass**

Biological hydrogen production is the vehicle to embark upon hydrogen economy and may also play a role for chemical industries in replacing their petroleum feedstock.



- **Proof of concept and validation of an anaerobic membrane bioreactor (2000 L)**

This reactor is expected to create a major impact in developing countries by providing sustainable solutions towards energy demand and waste water management issues.





Way Forward

BIRAC will continue to energise the biotechnology sector by supporting innovation and encouraging industry-academia collaborations for affordable product development. BIRAC remains committed to provide the right eco system and policy support to take the novel products to market.



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