

# BioE3 Policy

**(Biotechnology for Economy,  
Environment and Employment) 2024**



**Department of Biotechnology  
Ministry of Science & Technology  
Government of India**

***“Fostering High-Performance  
Biomanufacturing”***

**August, 2024**



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## 1. PREAMBLE :

Bharat has demonstrated a strong economic growth in the past decade and is poised to be amongst the global leaders in the next industrial revolution by leveraging emerging technologies and new innovative solutions. The crisis of climate change resulting in large-scale wildfires, melting of glaciers and decline in biodiversity along with the unsustainable pattern of material consumption and waste generation are global threats that require concerted sustainable interventions.

Biomanufacturing holds immense potential to offer solutions to these challenges by harnessing regenerative and sustainable potential of biological systems. Biomanufacturing refers to the use of engineered microbial, plant, and animal (including human) cells with increasing precision and control to produce commercially important products on scale. These are versatile processes that have the potential to create bio-based products allowing efficient utilization of resources, in a scalable and cost-effective manner with reduced environmental impact.

Keeping in view the national priority of steering Bharat on the path of accelerated '**Green Growth**', an integrated **BioE3 (Biotechnology for Economy, Environment and Employment) Policy for "Fostering High-Performance Biomanufacturing"** is proposed for a green, clean, prosperous, and self-reliant Bharat.

The Policy provides a framework to empower Indian institutions, universities, startups and industries to engage in transformative innovations by:

- **Intensifying research and innovation** to address challenges such as mitigation of climate change and achieving de-carbonization
- **Boosting domestic biomanufacturing capability** by enabling synergy between science, technology, engineering and manufacturing
- **Accelerating transition to biomanufacturing** by promoting integrated use of artificial intelligence (AI) and digitalization with '*omics*' and upstream biotechnology innovations
- **Setting up the facilities (Biomanufacturing Hubs/ Biofoundry/ Bio-AIs) for scaling-up and pre-commercial manufacturing**, co-located with resources and infrastructure for fostering high- performance biomanufacturing
- **Nurturing cohort** of highly skilled workforce

This Policy will place Bharat to realize the full potential of bioeconomic growth with sustainable resource management with inclusivity.

## 2. NEED FOR THE POLICY:

2.1 To address the intertwined challenges of 21<sup>st</sup> Century, there is a need to formulate a **robust policy framework** to create a convergence between biotechnology, engineering, and digitalization for building a more equitable and sustainable future.

- 2.2 To ensure the benefits of bioeconomy accrue to all, it is imperative to device and implement strategy roadmap with facilitative incentives.
- 2.3 Globally, biomanufacturing across diverse sectors is likely to create \$2-4 trillion (~₹ 167-335 trillion) of direct annual economic impact over the next decade. Accomplishing that requires objective strategy, technology platforms, and risk assessments.
- 2.4 Transition to biomanufacturing represents **a transformative shift towards more sustainable, efficient, and tailored production processes** across diverse sectors and thus requires government, academia, industry, and society to work with synergy in an enabling environment with supportive regulations.

## 2.5 The BioE3 Policy would be essential to:

- 2.5.1 **Strengthen and align science, technology innovation ecosystem** by fostering public-private partnerships, inter-ministerial collaborations, and international cooperation
- 2.5.2 **Accelerate technology development and commercialization** by setting up Bio-Enabler Hubs with access to technology platforms and infrastructure
- 2.5.3 **Foster surge in employment and intensify entrepreneurial momentum**
- 2.5.4 **Harmonize regulatory reforms** with global standards
- 2.5.5 **Effective and transparent patent system** for use of genetic resources
- 2.5.6 **Promote sustainability** in diverse ecosystems utilizing valuable knowledge of local communities
- 2.5.7 **Harness regenerative bioeconomy** with ethical and biosafety considerations
- 2.6 This Policy will further strengthen government's initiatives of '*Green Growth*', '*Net Zero*' economy and '*Lifestyle for the Environment*'.

## 3. GLOBAL SCENARIO:

The world is at the cusp of a new industrial revolution driven by bio-innovation. Given that biotechnology will strongly influence future bio-based manufacturing, many nations like the United States of America, Japan, Australia, Finland and European countries, have put forward their policies, strategies and roadmaps to set up a robust framework for biomanufacturing.

In all major countries, national governments are taking initiatives to expand R&D investments, building necessary infrastructure, housing biofoundry and pre-commercial capabilities for fostering high-performance biomanufacturing by switching to renewable feedstock for synthesis of low-carbon intensity chemicals and recyclable materials. Collaboration and partnerships among industries, research institutions, and governments are common in the biomanufacturing sector.

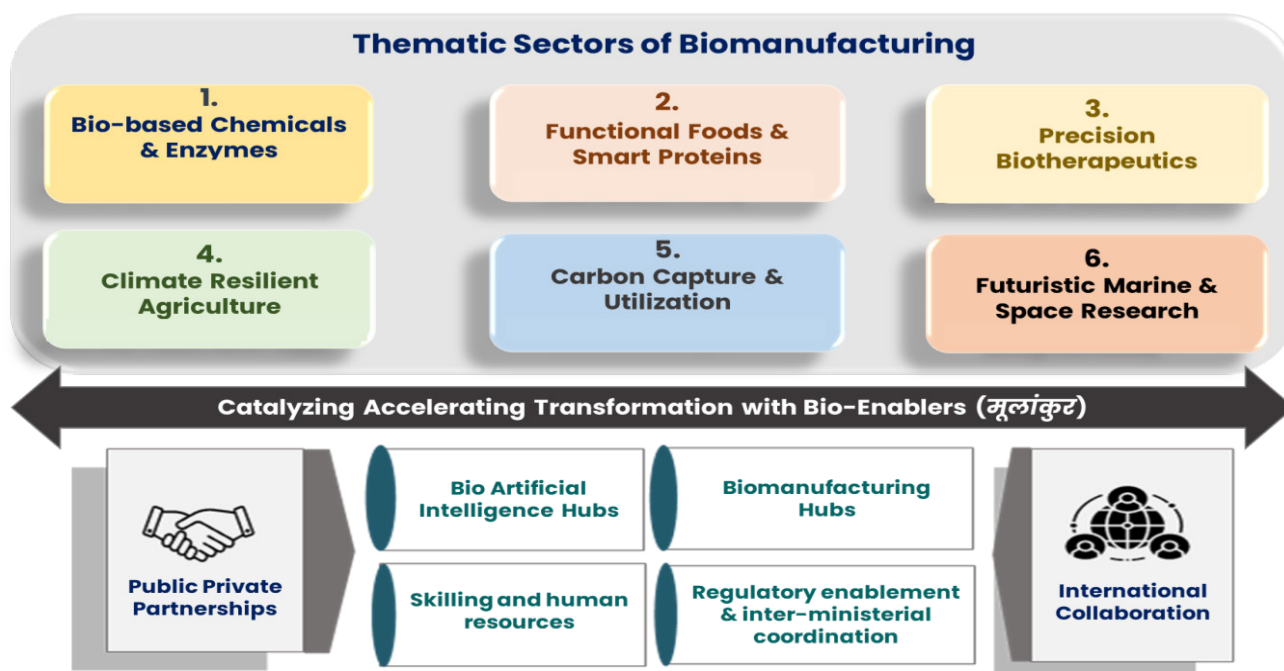
This collaboration helps to facilitate knowledge exchange, access to resources, and the development of innovative solutions. The biomanufacturing landscape is thus expanding globally, with emerging markets playing an increasingly important role.

## 4. POLICY FRAMEWORK- Vision, Goal and Objective:

- 4.1 **To set Bharat at the forefront of the future that is more sustainable, and responsive** to global challenges by accelerating and harnessing biomanufacturing solutions that encompass diverse bioeconomic activities, while safeguarding environmental and climate impacts.
- 4.2 The 'Goal' of the Policy is **to fast-track innovation-to-technology** in a sustainable manner by weaving together fragmented activities under the umbrella of biomanufacturing and to incentivize concrete options to build a sustainable future.
- 4.3 The overall objective is **to set forth a framework that ensures the adoption of cutting-edge advanced technologies**, align innovative research aimed at revolutionizing biomanufacturing processes for enhanced efficiency, sustainability, quality, and accelerate the development and production of bio-based high-value products.

## 5. POLICY OVERVIEW:

Through this Policy, the government will delineate an ambitious vision to achieve technology leadership and tackle major challenges with focused mission in six thematic sectors. The research and translational activities under these verticals will be catalyzed by Bio-Enablers.



## 6. ENABLING MECHANISMS:

### 6.1 Cross-cutting Enablers (मूलांकुर Bio-Enablers)

The मूलांकुर Bio-Enablers will augment discovery and translation research to enable biomanufacturing across the six sectoral prioritized verticals.

### **6.1.1 Bio-Artificial Intelligence (AI) Hubs:**

The Bio-AI Hubs will bring together experts from both biological and computational disciplines to address complex challenges and advance our understanding of living systems. The integration of artificial intelligence (AI) with biological data, such as genomics, proteomics, and medical imaging, holds great potential for advancing our understanding of biological systems, disease diagnosis and treatment, drug discovery and personalized medicine. The 'omics' data on microbial, fungal, and algal strains can identify novel metabolic modules with predictive molecular design principles guiding synthetic biology approaches to biomanufacture high-value chemicals and biomaterials. These hubs in agriculture sector can provide data analytics to improve farming practices, soil conditioning etc., thereby increasing productivity, hence reducing costs.

### **6.1.2 Biomanufacturing Hubs:**

The limited capacity to transform research leads into commercial products is one of the critical barriers in translational research. The translation of bio-based products from 'lab-to-market' is being hampered by lack of facilities for scale-up to pilot and pre-commercial manufacturing scale. The biomanufacturing hubs will comprise common usage of pilot and pre-commercial manufacturing facilities for researchers, startups and SMEs to support early-stage manufacturing. These hubs will be accessible to all strategic central agencies on need basis for providing technological and upscaling support on targeted products and applications. The shared infrastructure will enable development and demonstration of applications and the learnings can be leveraged across other emerging applications. Such industry hubs will attract and retain high-skilled workers, generate jobs, and provide a positive economic ripple effect to the surrounding community. These hubs may also act as training centres to ensure generation of skilled manpower in the evolving field of biomanufacturing in partnership with relevant institutions.

## **6.2 Regulations and Global Standards:**

Regulations and global standards are the key to create an enabling environment for promoting research & innovation, scaling up and manufacturing. Strategic reforms, harmonized with regulatory reforms and global standards, need to be defined for facilitating production and commercialization of novel bio-based products. Regulatory reforms should maintain the same stringency but ensure an increase in the pace at which these products can reach the market. The convergent and multi-disciplinary research for biomanufacturing at scale entails multiple elements of regulatory interface and approvals.

Proactively engaging with all stakeholders to identify such challenges and facilitating stakeholder interactions to pursue potential solutions will be crucial. This Policy will enhance inter-ministerial co-ordination to ensure fostering of an enabling environment with seamless integration of biosafety and biosecurity considerations. Appropriate cyber



security principles will be followed during implementation of the BioE3 Policy and as per extant rules and guidelines of the Government of India, to protect the national and economic security interests of the country.

### 6.3 Data Governance Framework:

This Policy will enable the building of a data governance framework to promote AI-based discovery and ensure that the data are utilized in a way that maximize benefit. The principles of the framework will ensure public benefit, not constrained by commercial or individual interests.

Discoveries, inventions, and other knowledge arising thereof, will be made freely available to the wider scientific community, while allowing for protection of intellectual property. Plans for data storage, management and access will be key components.

While ensuring equitable access to data, fail-safe mechanisms will be included for due acknowledgment of data sources and adherence to the terms and conditions under which data is sourced.

## 7. STRATEGIES TO PROMOTE BIOMANUFACTURING IN THE COUNTRY:

- 7.1 To foster pioneering biomanufacturing research, develop and improve cutting-edge technologies, and improving the production of biopharmaceuticals and bio-based products.
- 7.2 Developing and implementing new strategies for scaling-up biomanufacturing processes and commercializing new bio-based products. This will be achieved by:
  - 7.2.1 Undertaking **Discovery & Application-oriented Integrated Network Research** for developing advanced biosynthetic platforms through combination of biological sciences and artificial intelligence
  - 7.2.2 **Bridging the gaps for scale-up, between lab and market**, through effective industry-academia collaborations
  - 7.2.3 **Reducing costs, time, and complexity in the biomanufacturing innovation ecosystem** by co-locating in the vicinity of resources and existing infrastructure
  - 7.2.4 **Setting up 'मूलानुगत Bio-Enabler Hubs'** to augment discovery and translational research across the six sectoral verticals prioritized under this initiative. The 'Bio-AI Hubs' will enable discovery research across the sectors, while the 'Biofoundries \ Biomanufacturing Hubs' will support facilities for pilot scale and pre-commercial scale research
  - 7.2.5 **Addressing regulatory roadblocks** for biomanufacturing of genetically modified organism-based processes
  - 7.2.6 **Creating a large skill-set pool of trained manpower** in domestic biomanufacturing

### **7.3 Partnerships and Collaborations:**

Encourage a collaborative approach and active engagement with potential partners and stakeholders to synergize ongoing investments in biomanufacturing. This will be achieved through collaborations with international partners, research institutions, universities, government agencies, and public-private partnerships with startups and Indian industries.

### **7.4 Public-private co-creation model:**

Implementation of this biomanufacturing initiative will be through a public-private co-creation model that combines expertise in academia, startups, and industry through inter-ministerial coordination.

Biomanufacturing Hubs will engage private sector partners to ensure sustainability in investments and for leveraging private sector operating capabilities. This will enable growth of an economically and environmentally sustainable bioeconomy and contribute for making Bharat self-reliant.

### **7.5 International Collaborations:**

The green transition is a global focus with several countries across the world trying to develop enabling technologies to meet sustainability goals. India will actively engage across the world to collectively accelerate this journey of biotransformation for green growth. Scope for collaboration is extensive; and spans platform technologies, early-stage innovation, as well as late-stage translational research. In addition to upstream technology enablement, actualization of collective global goals also depends on delivering affordable solutions at scale for equitable access with economic viability. Leveraging India's current strengths in biologics manufacturing, the BioE3 Policy will further enhance capacity for India to serve as biomanufacturing hub for global innovation by promoting the advance to key milestones on the path to commercial scale operations.

### **7.6 Inter-Ministerial Coordination:**

Mutual collaborations will lead to synergistic combination of the expertise and services of multiple organizations for addressing relevant questions in the identified sectors of biomanufacturing. Inter-ministerial collaboration with various Ministries and Departments concerned such as Department of Science and Technology, Council of Scientific and Industrial Research, Indian Council of Medical Research, Indian Council of Agricultural Research, Ministry of Earth Sciences, Ministry of Electronics and Information Technology, Indian Space Research Organization, Ministry of Environment, Forest and Climate Change, Defence Research and Development Organization and Ministry of External Affairs will be explored for research in the identified sectors as well as establishment of enablers.

## 7.7 Skilling and Human Resources:

The biomanufacturing revolution will change the traditional hierarchy of biotechnology workforce. The development and deployment of biomanufacturing processes from upstream biological engineering, through manufacturing and downstream processing will require a diverse set of interdisciplinary, cross functional skill sets. The aim is to focus on building human resources to foster biomanufacturing with the required technical skills.

## 8. INTERVENTIONS:

Biomanufacturing can fundamentally transform the global economy from today's consumptive manufacturing paradigm to the one based on regenerative principles.

The BioE3 Policy will facilitate sustainable and efficient utilization of biological resources through scientific knowledge for innovation, scaling-up and biomanufacturing of specialty chemicals, enzymes, biopolymers, functional foods, smart proteins, veterinary products, precision biotherapeutics and services. The carbon capture storage to biomass and utilization thereof by converting it to fuels and chemicals through biological systems are essential in meeting the Net Zero targets.

- 8.1 The Indian chemical industry contributes significantly to the country's economy. The specialty chemicals segment comprises 22% of India's chemical industry. With an increasing global push towards developing sustainable manufacturing processes to minimize climate change, there is a need for innovation in biotransformation of chemical processes critical for achieving sustainability goals. This policy will play a catalytic role to drive industrial biotransformation in the country and to ensure sustainable bio-based production of high-value specialty chemicals, enzymes and biopolymers through synthetic biology and genetic engineering.
- 8.2 There is a growing demand for food as Bharat will likely comprise of around 1.67 billion citizens in 2050 for whom adequate and nutritional food intake would be a key concern. Globally, alternative/smart proteins which include proteins from new sources (like plants, algae, fungi, insects) and from new approaches (like fermentation, plant-based meat or dairy, cultured meat etc.), are receiving a growing interest due to lower environmental impact, animal welfare and food safety considerations. Accordingly, this Policy will facilitate production of smart proteins and functional foods with low carbon footprint using synthetic biology, and metabolic engineering tools.
- 8.3 Cell and Gene therapy, a new therapeutic modality, is considered "*one of the most phenomenal advances in research in Medical Science*". By 2027, the cell and gene therapy market is forecasted to be over \$22 billion (~₹1846 billion). This will be led by cell therapies, \$10.8 billion (~₹906 billion), followed by gene-modified cell therapies, \$6.5 billion (~₹545 billion). Similarly, global mRNA therapeutics market is expected to reach \$10 billion (~₹839 billion) by 2026. This Policy will intensify engagement of

Bharat in futuristic biotherapeutics technologies and personalized medicine such as cell and gene therapy, mRNA therapeutics, and monoclonal antibodies to position the country as a global development and manufacturing hub for equitable access at scale to a wider population.

- 8.4 There is a need to enhance agricultural productivity from reduced land mass, amidst climate change impact. There is a need to promote soil microbiome-based research in India including soil microbiome/genome analysis, selection process for superior microbial phenotypes, process for shifting the microbial community composition towards the desired/most beneficial microbial consortia, developing crop specific products for crop nutrition & protection, and product formulation for enhanced stability. This Policy will enable fundamental goal of food security through innovations for climate smart agriculture for production of improved crop varieties to address agrarian and nutritional challenges and traits for climate adaptation and mitigation.
- 8.5 Bharat is aiming for 45% reduction in emission intensity by 2030 and is taking steps towards achieving Net Zero by 2070. The Policy will facilitate to have focus on achieving de-carbonization from the hard-to-abate industry sectors. This also includes microbial conversion of captured CO<sub>2</sub> into industrially relevant compounds.
- 8.6 Our country has an extensive coastline and thereby access to marine resources which could be tapped to power its bioeconomy. The blue economy i.e., use of marine resources can also ease pressure on terrestrial land required for food production and also as a source of bioactive compounds, enzymes, and functional ingredients. These efforts could be dovetailed with country's '*Deep Ocean Mission*' launched with themes on climate resilience, exploration and conservation of deep-sea biodiversity, technologies for harnessing ocean resources and capacity building.
- 8.7 Globally, the focus is on studying the impact of space flights and conditions on astronauts' microbiomes to assess the potential health risks and develop probiotic based interventions. There is a need for development of safe, nutritious meals for future long-duration space missions, considering the challenges in product quality & safety, shelf life, and packaging waste. Microbial biomanufacturing has the potential to provide integrated solutions for remote or austere locations.

## 9. ROLE OF MINISTRIES AND DEPARTMENTS:

The role of various Ministries and Departments including sharing of resources, for effective implementation of BioE3 Policy is tabulated below:

S. No	Ministries/ Departments	Proposed Inter-Ministerial Collaborations
1.	Ministry of Electronics and Information Technology	<ul style="list-style-type: none"> <li>To provide computational and AI support for modelling of the biomanufacturing process</li> <li>Setting up of Bio-AI Hubs to support process innovation for rapid design, testing and engineering of microorganisms needed for scaling-up of bioprocesses</li> </ul>
2.	Indian Council of Agricultural Research	<ul style="list-style-type: none"> <li>Collaboration projects for the development, field trials and regulatory approval of emerging Agribiologicals including Biofertilizers, Biostimulants and Biopesticides</li> </ul>
3.	Ministry of New and Renewable Energy	<ul style="list-style-type: none"> <li>To ensure biomass supply chain, its management, and resource availability forecasting for future, using AI/ML/GIS/RS tools.</li> <li>Initiate collaborative projects on Carbon Capture and its Utilization</li> </ul>
4.	Department of Space/Indian Space Research Organization	<ul style="list-style-type: none"> <li>Collaborative experiments and studies under Joint ISRO-NASA Mission to International Space Station</li> <li>Collaborative experiments and studies in human space flight missions under "Gaganyaan" program and proposed Bharathiya Anthariksha Station</li> </ul>
5.	Department for Promotion of Industry and Internal Trade	<ul style="list-style-type: none"> <li>Startup India under DPIIT has a wide incubator network and over 160 seed-funded incubators. DBT will collaborate with Startup India for building the operationalization and business workflow for the hubs, along with building industry networks.</li> </ul>
6.	Department of Chemicals and Petrochemicals	<ul style="list-style-type: none"> <li>DBT will collaborate with this Department for shortlisting of high-value Chemicals /APIs/ Enzymes to be biomanufactured</li> </ul>
7.	Ministry of Health and Family Welfare (Food Safety and Standards Authority of India)	<ul style="list-style-type: none"> <li>Working with FSSAI, MoH&amp;FW to streamline regulatory approvals for Smart Proteins and Functional Foods.</li> </ul>
8.	Ministry of Health and Family Welfare (Central Drugs Standard Control Organization)	<ul style="list-style-type: none"> <li>Setting up of GMP grade facilities for Precision Biotherapeutics including Monoclonal Antibodies, mRNA Therapy and Cell &amp; Gene Therapy</li> </ul>

<b>S. No</b>	<b>Ministries/ Departments</b>	<b>Proposed Inter-Ministerial Collaborations</b>
9.	Department of Pharmaceuticals	<ul style="list-style-type: none"> <li>• Specific collaboration with NIPERs for the development of APIs</li> <li>• Fermentation-based bulk drugs under Production Linked Incentive (PLI) Scheme for Bulk Drugs implemented by the DoP will be taken up</li> <li>• Scheme for Biotherapies like Cell &amp; Gene therapy, Immune Therapy, etc.</li> </ul>
10.	Ministry of Earth Sciences	<ul style="list-style-type: none"> <li>• Dovetailing of DBT's Marine Biomanufacturing initiatives with MoES 'Deep Ocean Mission' and 'Blue Economy'</li> </ul>
11.	Department of Science and Technology	<ul style="list-style-type: none"> <li>• Collaboration with DST under its programme on 'Advanced Manufacturing Technologies'</li> </ul>
12.	Council of Scientific and Industrial Research	<ul style="list-style-type: none"> <li>• Establishing collaborations with CSIR labs for biomanufacturing of Bio-based chemicals, APIs, Bioplastics and Enzymes</li> </ul>
13.	Indian Council of Medical Research	<ul style="list-style-type: none"> <li>• Precision Biotherapeutics including Monoclonal Antibodies, mRNA Therapy, Cell and Gene Therapy</li> </ul>
14.	Ministry of External Affairs (NEST Division)	<ul style="list-style-type: none"> <li>• Fostering international cooperation, collaboration and knowledge exchange with foreign countries and in multilateral institutions to advance India's national interests</li> </ul>
15.	Defence Research Development Organization	<ul style="list-style-type: none"> <li>• Biopolymers, and space food research</li> </ul>

## 10. IMPACT:

Bharat is competitively positioned to be amongst the global leaders in futuristic manufacturing that leverages living systems. Biomanufacturing can fundamentally transform the global economy from today's consumptive manufacturing paradigm to the one based on regenerative principles. This Policy document will galvanize research and technological skills within the country, attract startups and industries and thus effectively steer this transition to build a robust bioeconomy.

The technology convergence will advance innovations in medical treatments, address farming and food challenges, and promote bio-based products. Appropriate regulatory reforms and compelling incentives will reduce timelines of development and commercialization. Biomanufacturing approaches will thus build a more prosperous, equitable, and sustainable development for current and future generations and achieve the target of Viksit Bharat by 2047.





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