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# **PREFACE**

The world is moving towards BioEconomy. This concept is getting increased attention from the governments and policy-makers of different countries. Countries see BioEconomy as a foundation to solve fossil fuels crisis, climate change, address food and nutrition problems, and push innovations to create a healthy world. Policy-makers are beginning to consider BioEconomy at the macro-economic level. The India BioEconomy Report 2019 is also an effort to bring the multi-pronged concept with appropriate definitions and dimensions to the forefront. The goal is to set up an appropriate Methodology to measure the national BioEconomy and monitor its performance over a period of time. The initial findings of the study suggest that India's BioEconomy for calendar year 2019 is valued at \$62.5 billion.

It may be recalled that the Department of Biotechnology (DBT) has been propelling India's BioEconomy by providing an enabling ecosystem to promote biotechnology research and improve capacity building across the country. The focus has been on fostering cutting edge-research and innovation alongside translational research. The initiatives are aimed towards boosting innovative research, empowering people, building world class infrastructure, and supporting public-private partnerships across all sectors like agriculture, healthcare, industry and environment.

India's National Biotechnology Development Strategy, announced in 2015, lays major emphasis on generation of biotech products, processes and technologies for enhanced efficiency, productivity and cost-effectiveness in the areas of agriculture, food and nutritional security; affordable health care and wellness; environmental safety; clean energy, biofuel, and bio-manufacturing.

Further, there is strong emphasis on skill development programmes in close coordination with State Governments. The policies announced by the Government have strengthened the institutional mechanisms for empowering innovation and ensuring scale up and sustainability. The emphasis has been on technology-driven research aimed at improving lives and living

of millions by providing affordable solutions to public health problems impacting the society at a large.

There has been a paradigm shift in the relationship between Government, Academia, Industry, Startups and Civil Society. The Department has made special efforts to contribute through its various programmes to the National Missions launched by Indian Prime Minister Mr Narendra Modi. Some of the prominent missions are Swasth Bharat, Swatch Bharat, Startup India, Make in India and Digital India.

The Department through its Public Sector Undertaking-BIRAC has created a vibrant ecosystem for innovation to thrive in our country as well. Innovate in India (I3) is an industry- academia collaborative mission of DBT in collaboration with World Bank for accelerating discovery research to early development of Biopharmaceuticals and to be implemented by Biotechnology Industry Research Assistance Council (BIRAC). The aim of the mission is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceutical to a level that will be globally competitive over the next decade, and transform the health standards of India's population through affordable product development. The program will specifically focus on the development of new vaccines, biotherapeutics, diagnostics and medical devices to address the rising burden of diseases in the country.

Our continuous effort is to engage with all stakeholders as we move forward in our journey to make India a \$100 billion BioEconomy by 2025. We understand that a holistic approach with continuous innovation is important in developing a BioEconomy that is based on the principles of affordability, accessibility, and sustainability.

#### DR RENU SWARUP

Secretary, Department of Biotechnology, Government of India

# EXECUTIVE SUMMARY: MAPPING OF INDIA'S BIOECONOMY

- The India BioEconomy Report (IBER) is an effort to map India's BioEconomy and monitor the extent to which policies adapt to growth, resilience and sustainability needs.
- Efficient policies are essential to meet increasing demand for better health, fuel, and feed in a sustainable way.
- While growth in demand presents significant opportunities for application of biotechnology, government policies have a proactive role in addressing challenges such as increasing productivity growth, enhancing environmental performance and adaptation to climate change, and improving resilience of unforeseen circumstances.
- Further, Policy evaluation provides needed evidence for governments to ensure that these policies address these challenges properly.
- Policy packages are also needed to be coherent and efficient to enable the sector to develop to its full potential and achieve key public policy objectives.

# INTRODUCTION

#### **BIOTECHNOLOGY SECTOR**

The Government of India (GOI), through the Department of Biotechnology (DBT), since 1986, has been promoting and nurturing the cause of biotechnology in India. The result of this is India is bestowed with a large pool of outstanding people and infrastructure, innovative schemes to fund and nurture the entire ecosystem, and a system that is put in place that can nurture the future growth of this sector. A cornerstone of India's thinking has been to align with world trends, yet take measures that are helpful to local conditions. India embarked on the vision to become a BioEconomy and to extend benefits of biotechnology to its citizens during early part of last decade. One of the visions was to see if India can reach \$100 billion BioEconomy by 2025. The key components of this BioEconomy was to take all aspects of the biotechnology sector like new forms of vaccines, novel protein therapeutics, biosimilar manufacturing, stemcells, systems biology, synthetic biology, improved hybrids in agriculture, renewable energy from biological sources, clean technologies, and sustainable development.

BIRAC, a public sector undertaking of DBT has established several industry focused schemes such as SBIRI, BIPP Biotechnology Ignition Grant, BioNEST, SITARE, PACE, SIIP, SEED, LEAP, Fund of Funds – AcE, etc. These programmes are some of the first of its kind to help the industry. This was to help support innovation in R&D, help build capacities for future growth, and are enabling mechanisms for better collaborations between industry and academia and focus

on translational research.

Regular interaction with all stakeholders of the sector from academia to industry to consumers has led to bringing in timely policy interventions and give fillip to the sector.

#### **BIOECONOMY**

BioEconomy concept acquired prominence when European Union announced BioEconomy strategy as early as 2012. This strategy was reviewed for the relevancy in 2018. As per the revised strategy the BioEconomy covers all sectors and systems that rely on biological resources (animals, plants, micro-organisms and derived biomass, including organic waste), their functions and principles. It includes and interlinks: land and marine ecosystems and the services they provide; all primary production sectors that use and produce biological resources (agriculture, forestry, fisheries and aquaculture); and all economic and industrial sectors that use biological resources and processes to produce food, feed, bio-based products, energy and services. The European BioEconomy is aimed to have sustainability and circularity at its heart to drive the renewal of its industries, the modernisation of primary production of systems, the protection of the environment and biodiversity.

The Biotechnology Innovation Organization (BIO) in October 2019 submitted its comments to the Office of Science Technology and Policy (OSTP) on the BioEconomy, explaining the critical role

America's biotechnology industry plays in feeding, fueling, and healing the world. The comments were highlighted by Tom DiLenge, president of BIO's Advocacy, Law & Public Policy Division, during The White House Summit on America's BioEconomy as follows.

"It's a remarkable time for the biotechnology industry in America. Our world-class scientists, brilliant researchers, and savvy entrepreneurs are making an enormous difference in improving the health of our loved ones and our planet," DiLenge noted.

"Yet while our progress has been amazing, the continued success and leadership of the American biotech industry is not guaranteed. We cannot abandon the policies that have made our BioEconomy the strongest and most dynamic in the world, and we must work to update our policies to meet the challenges posed by the next wave of biotechnological innovations."

Increasingly all regions of the world are looking at strategies to boost their respective BioEconomies. India is one of the early adopters of this core philosophy.

# BACKGROUND AND METHODOLOGY OF BIOECONOMY CALCULATIONS

#### **THEORETICAL OVERVIEW**

The term BioEconomy generally refers to an economy using renewable natural resources to produce food, energy, products and services. The important renewable natural resources include the biomass in forests, soil, fields, bodies of water and the sea and fresh water.

Europe has been at the forefront of pushing the BioEconomy and let us take the Finnish BioEconomy Strategy (2014) as a case to understand how the BioEconomy is calculated. The growth of the BioEconomy and its significance in the national economy are monitored using the indicators provided by Statistics Finland. The National Forest Strategy 2025 (2015) emphasises the need to extend forest statistics to cover the entire BioEconomy. The objective of the project entitled "Statistics of the modernized forest sector" (2015–2018), co-ordinated by Luke, was to "develop the statistics of forest, energy and chemical industry interfaces, nature tourism, forestry-related services and other forest-based businesses and ecosystem services."

Basically, the scope of BioEconomy calculations is based on several publicly available statistics. And some nations are also focusing on obtaining statistics for import constituents so that they can help in better estimates. So the transactions that are recorded try to capture calculations related to output, value additions, investments, employment, exports and imports of BioEconomy goods, etc.

Also sectors that are defined as being part of the BioEconomy have been selected in their entirety for the calculations by many nations in their estimates. Further the relative share of the BioEconomy has been estimated for some sectors using expert opinions and other statistical sources including media reportage.

In Finland the output and value added are measured at basic prices and calculated using both current prices and fixed prices at the previous year's prices. Exports are measured at purchasers' prices and calculated using both current prices and fixed prices. Export volumes of bioproducts are based on the product classification applied in Export Import statistics.

The calculations only take into account the direct effects generated by BioEconomy sectors. The indirect effects on sectors supplying e.g. machinery and equipment, raw materials or services as inputs to the BioEconomy are deliberately excluded.

The Indian BioEconomy calculations are also based on some of the best practices followed as mentioned above and below are the definitions that have been assumed.

#### **ACCOUNTING DATA**

Output at basic prices consists of products manufactured during a calendar year. Three categories of output are distinguished: market output, output for own final use, and other non-market output. Non-market output is excluded from the BioEconomy calculations.

Value added (gross) refers to the total value generated by units engaged in production activities. In market production, it is calculated by deducting from the unit's output the intermediates (goods and services).

Number of people employed includes people drawing a salary and independent entrepreneurs who participate in production activities in the national economy. The statistics covers all employees and no age limits are defined for employed people.

Investments consist of acquisitions, less disposals, of fixed assets. Fixed assets are tangible or intangible assets produced as outputs from production processes that are used repeatedly, or continuously, in processes of production for more than one year.

## STANDARD SECTORS USED FOR BIOECONOMY CALCULATIONS

The datasets take into consideration various sectors either completely or partially in the BioEconomy.

Reliability of calculations: In interpreting sector-specific figures many variables that can affect the coverage and quality of calculations are applied. Further, in many important sectors, where there are no

statistics or data, the relative share of that sectors' contribution to BioEconomy is arrived at seeking estimates from experts. The data is also collated from various publications and analysts report as well.

The most important sector-specific characteristics are also taken into account. For example, the share of renewable energy sources are used to calculate the totals of BioEconomy. Similarly, the textiles industry may be input statistic for the BioEconomy estimate for the BioAgri market. The size of

chemical or food industry is uses for arriving the figures of Bioindustrial segment.

The statistics on BioEconomy exports are estimated using the Export data from Government.

This is a first time effort to initiate the process of tracking BioEconomy every quarter in a methodical way so that it helps the Government to assess the Roadmap and steer the BioEconomy.

# STATE OF PLAY: IMPORTANCE OF BIOTECHNOLOGY

## OVERALL SIZE AND STRUCTURE OF THE BIOTECHNOLOGY SECTOR

The Biotechnology industry's economy is valued at \$62.5 billion for calendar year 2019 as against \$51 billion in 2018 and \$44.47 billion in 2017. The BioEconomy registered 23 percent growth compared to the 14.68 percent growth in 2018 and 6.8 percent growth in 2017.

#### **STRUCTURE**

It was a good year for India's BioEconomy in 2019. The economy was boosted by the performance of the BioPharma and BioServices sector, specifically the contract research and manufacturing services. The BioEconomy continues to be spearheaded by the BioPharma segment. It has alone

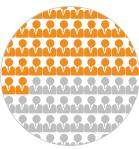
contributed to 58 percent share of the total BioEconomy by value. Half of the BioPharma economy is through diagnostics and medical devices. Vaccines account for 30 percent of the BioEconomy by value, while biotherapeutics contributed for the rest.

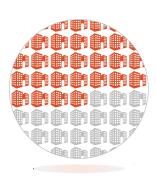
BioAgri is the second largest contributor to the country with 19 percent share. Bt cotton generates nearly 99 percent of the value and pesticides and fertilizers account for less than one percent share within the sector.

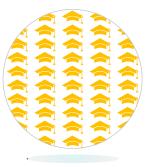
Research services' contribution to BioEconomy along with the BioIT and IT healthcare portfolio is estimated at \$9.5 billion. Most of the companies have a biotech R&D arm and offer contract services, while

#### **INDIAN BIOTECH INDUSTRY (PROJECTIONS)**









\$51 Billion

\$62.5 Billion

\$85 Billion

\$102 Billion

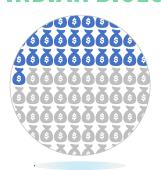
2018

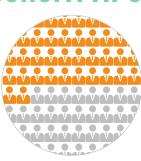
2019

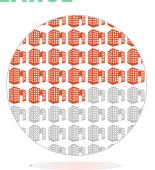
2023

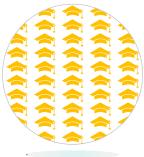
2025

#### INDIAN BIOECONOMY AT GLANCE









\$12 Billion

1 Million

2500 +

15,500+

India's Biotech Industry Revenue India's Biotech Workforce Biotech Companies in India

Biotech Graduates Every Year

Source: ABLE ( Association of Biotechnology Led Enterprises)

there are some dedicated CROs offering the entire spectrum of CRO services including contract discovery, development, and even manufacturing. The sector recorded 19 percent growth.

BioIndustrial segment has also performed

well. The sector accounted for nearly 8 percent share. The contributions of the enzymes and biofuels sectors are estimated at 46 and 54 percent share of the total BioIndustrial segment respectively. The BioIndustrial segment has recorded nearly 25 percent growth. While the enzymes

business generated \$2.3 billion BioEconomy, the Biofuels accounted for \$2.7 billion BioEconomy. The total BioIndustrial sector was valued at \$5 billion. India continues to import large volumes of products. This gap in import and export presents an immense potential that can be harnessed in order to make India a leading producer of Biotechnology and allied products and services.

Here are some of the other interesting developments in 2018 that can propel the BioEconomy further: India approved "The DNA Technology (Use and Application) Regulation Bill, 2018". The Bill has been formulated for the regulation of the use and application of Deoxyribonucleic Acid (DNA) technology with the aim to establish the

identity of certain category of persons and provides provision for establishment of a DNA Regulatory Board (DRB). A major Mission program on Antimicrobial Resistance (AMR) was launched in October, 2018 with the vision to develop indigenous and cost-effective therapies against AMR. India has embarked on large multi institutional microbiome project to find out country- specific health solutions. The project is funded by the Department of Biotechnology (DBT) for a period of five years and ends in 2022. This microbiome project has identified 19 major endogamous groups and 13 tribes.

#### **INDIAN BIOECONOMY IN 2019**

The Indian BioEconomy in 2019 recorded a good growth looks like it is on the path to achieve \$100 Billion by 2025.

# INDIA'S BIOECONOMY VALUED AT \$62.5 BILLION IN 2019

INDIAN BIOECONOMY	
SEGMENT	VALUE IN \$BILLION (2019)
BIOAGRI	12.0
BIOINDUSTRIAL	5.0
BIOPHARMA	36
CRO/BIOIT/Research	9.8
TOTAL BIOECONOMY	\$62.5 B

DIOECONOMY D	VVALUE			
BIOECONOMY - B	Y VALUE			
INDIAN BIOECONOMY	SUB-SEGMENT	VALUE IN \$BILLION (2019)		
BIOAGRI		12.00		
	BT COTTON	11.1		
	BIOFERTILIZERS / BIOPESTICIDES	0.9		
BIOINDUSTRIAL		5.00		
	ENZYME	2.30		
	BIOFUELS	2.70		
BIOPHARMA		36.00		
	BIOLOGICS / THERAPEUTICS	7.00		
	VACCINE	12.00		
	DIAGNOSTICS / MEDICAL DEVICES	17.00		
BIOIT/CRO/HEALTHCARE RESEARCH		9.50		
TOTAL BIOECONOMY		\$62.50 B		

<b>BIOECONOMY</b>	- BY KEY PRODUCTS	
SEGMENT	SUB-SEGMENT	PRODUCT SHARE (2019)
	Diagnostics / Medical Devices	50.60%
	Vaccine	35.71%
	BT Cotton	33.04%
	Biologics / Therapeutics	20.83%
	BIOIT/CRO/Healthcare Research	15.20%
	Biofuels	8.04%
	Enzyme	6.85%
	Biofertilizers / Biopesticides	2.68%
TOTAL BIOECONOMY		\$62.5 B

BIOECONOMY - BY SEGMI	ENT
SEGMENT	VALUE IN \$BILLION (2018)
BIOAGRI	11
BIOINDUSTRIAL	4
BIOPHARMA	28
CRO/BIOIT/Research	8
TOTAL BIOECONOMY	51.00

# RECOMMENDATIONS

BioEconomy action plan suggested by Industry

The Association of Biotechnology Led Enterprises (ABLE) has been engaging the members and key stakeholders to raise India's efforts in the direction of Bio-based BioEconomy. It is important that we have two important traits in the BioEconomy Strategy.

- 1. A system to incorporate and action the suggestions and recommendations after due deliberations and:
- 2. A system to measure, monitor, analyze and record the benefits of the BioEconomy system.

#### WHERE WILL WE BE IN 2025?

- In Business-as-Usual scenario, India's BioEconomy to be around \$80 billion by 2025.
- But India's BioEconomy will approach \$100 billion in 2025 if various bottlenecks in regulation and policies are removed and industry given stimulation
- Further, India's BioEconomy can support
  10 million jobs in 2025 @ \$100 bn revenue
- Over 100 "Made in India" Biotech products will be in global markets
- Emerging cell and gene therapies will tap into the Indian Market to access high skilled talent and low delivery cost. This can create a large Medical Tourism opportunity.

 Environmentally sustainable solutions for improving food, energy and water security in India using Biotechnology will become more commercially prominent.

#### **OUR NATIONAL VISION & GOAL: 2025**

- A \$100 billion thriving BioEconomy by 2025.
- 10 million jobs driving the BioEconomy led by products and services
- Delivering affordable access to global healthcare through high quality, cost competitive Biological medicines, vaccines and diagnostics.
- Providing access to high value medical treatments in emerging areas like gene therapy, vein to vein cell therapy and stem cells therapy
- Producing high tech agricultural products that are high yielding & environmentally sustainable
- Adopting bioremediation, enzyme technologies and bio-fuels to reduce the carbon footprint and build a green future for India.
- An innovation engine to improve the lives of people in India and around the world.

#### **ABLE'S OTHER RECOMMENDATIONS**

ABLE sought feedback from the stakeholders to suggest action points to strengthen India's

BioEconomy Efforts.

Here are the key suggestions for the short and long-term.

- The 150% weighted Tax Deduction for Research Investment should be extended to outsourced research services and not just in-house R&D work.
- More investment mechanisms for innovative biotech companies to access growth capital
- 5-year Tax Holiday for registered biotech start-ups from TDS, GST
- Tax exemption for investments up to Rs 10 crore in biotech startups.

## OTHER FINANCIAL ISSUES INCENTIVES FOR STARTUPS

- Key amendments to the Biodiversity Act to make it more industry-friendly.
- Interest free loans for foreign technology transfer
- Duty-free manufacturing zones for Biomed industry
- Fast track regulatory approval for authorized cell & gene therapies transferred from USA, Europe and Japan
- Loans without collateral up to Rs 10 crore for SMEs to set up manufacturing facilities.
- Loans without collateral up to Rs 5 crores for marketing support for SMEs with approved products.
- Allow CSR funds to be invested in

registered biotech startups.

- 200% Weighted Tax deduction on all R&D expenses.
- Reimbursement of foreign patent filing expenses.
- Reclassify and adopt 5% GST for biotech research services
- Duty free import of biological materials. (Many highly useful enzymes used in key food sector and bioremediation etc attract 25% taxation as import duty & GST. These enzymes cost is about 60% of such projects and hence unaffordable. India not benefiting from enzyme tech advances)
- Special incentives 200% weighted tax deduction) for technology transfer to foreign countries. (To encourage India's innovators to access global markets for their technologies and bring in forex too)
- No capital gains for investments in startups at exit or IPO up to 5X.
- Reduce import duties on biotech products & consumables. (About 45% of India's BioEconomy is accounted for by imports and hence impacts affordability for our citizens)
- Import duties on materials and machines to be waived off for startups. (2) All materials and machines used in agriculture should be brought under NiI (0%) GST
- A robust public market interface to be favorable to innovation-led growth. India should have similar avenues like London or New York.

- Idea to Proof-of-concept (Seed Capital, SBIRI)
- POC to Product/Service Platform (VC-Series A+B)\*
- Scale for Market Share / Diversification / M&A consolidation (Private Equity)

#### Policy & Regulatory Issues

- DCGI be the sole authority to approve biosimilars/biotherapeutics for product approval and market authorization. Presently, there are multiple agencies involved in the approval process: RCGM, GEAC, DSIR, DCGI, CSDCO, NPPA etc
- Exemption to all cultivated biodiversity from the provisions of the National Biodiversity act. When biological species ( including microorganisms, plants and animals ) are cultivated by people for economic use, such activities automatically ensures their preservation maintenance and protection ( as opposed to wild harvested species). Hence such species should be exempted from the provisions of the BDA or classified as "Normally Traded Commodities" under Sec 40 of Biodiversity Act. For example cultivated seaweed should be exempted whereas wild harvested seaweed should not be exempted. Also remove restrictions on export of cultivated biodiversity and removed from the Restricted Category in Schedule 2 of export rules under DGFT.
- Exemption to startups from Biodiversity laws, similar to Hakims, till IP is filed

# ADMINISTRATIVE & POLICY CHANGES (LONG-TERM) POLICY & REGULATORY ISSUES

- Harmonization of DCGI with ICH to enable Indian Dossiers to be accepted overseas.
- Regulatory guidelines CRISPR/Geneedited products in human health and agriculture.
- Accelerate new framework/regulations for approval of Agricultural Biostimulants, Bio fertilizers & Novel Biocontrol Agents. (Currently mainly covered by the Pesticides Act)
- Set up a nodal agency for trials, validation and certification of MedTech and BioTech innovation under DCGL
- Rework Agriculture policy to give clarity on GMOs
- Develop a National Agriculture Policy that promotes use of emerging technologies like gene-editing/CRISPR, use of biomarkers, development of food alternatives or plant varieties with improved yield and quality, Molecular Farming
- Amend Section 3(2) of the Biodiversity Act to align the definition of foreign companies as per Corporate Law.
- Make other amendments in the Biodiversity Act to remove draconian provisions, restriction on scientific exchange of information, patent filings etc. All of these provisions are detrimental to bio-innovation in India. Distinction between cultivated/cultured and Natural can eliminate the ambiguity and anomaly that currently exists.
- Government tenders should have preferential norms for indigenously manufactured medicines, vaccines,

diagnostics, devices and medical equipment.

- Stronger push to ensure Indian companies file global IP (subsidize or reimburse patent fees.)
- Access to lab infrastructure in public laboratories at nominal rates for biotech companies
- 'Make in India' pavilion @ all major biotech conferences & trade shows globally to showcase Indian Biotech products.
- BIRAC should facilitate manufacture of key equipment used in biotech research and industry under Make in India program. This will reduce costs and increase availability within the country.
- Incentivize foreign technology vendors to manufacture their products in India under Make in India program.
- Induction of more experts in agencies like FSSAI, DCGI, Ayush Ministry, Patent office
- Lateral entry of biotech industry leaders in scientific ministries at joint secretary level and above
- A Vision Group for Biotechnology under DBT/Niti Aayog . ( Karnataka has such groups for biotech, IT, S&T since 2003)
- Policy emphasis on emerging technologies like synthetic biology, gene therapies to allow these areas to gain traction
- Encourage funding mega Genomics project in the private sector because public

sector facilities are under utilized-

• Fund large population genomics studies (National Bioscience Mission proposal with PSA should trigger some of this). The new data sharing and storage policies drafted by DBT are skewing genomics towards academia. Industry too should benefit.

#### **INFRASTRUCTURE & FUNDING**

- Create Biotechnology Industrial Estates with the following minimum infrastructure starting with existing DBT/Government funded incubators to promote the natural growth of startups.
- The estate should have a reliable and continuous source of power @ 500 KVA / acre of land
- The estate should be laid with proper roads, storm water drains, street lights and developed green spaces.
- The estate should have a reliable source of water @ 1 MLD per acre and potable water treatment plant with distribution
- The estate should have a Common Effluent Treatment Plant to handle the effluent from each of the plots with a capacity of 0.7 MLD per acre
- The estate should have good connectivity to highways, airports and railway station
- The estate should be close to training centers, Biotechnology Clusters, Universities, including finishing schools dedicated to the biotechnology industry.

# HOW THE WORLD SEES BIOECONOMY?

#### **GLOBAL TRENDS IN BIOECONOMY**

According to Science Direct, about 50 countries have newly adopted BioEconomy-related policy strategies in the past decade.

The second Global Bioeconomy Summit held in Berlin from April 12–14, 2018, highlighted that this global trend toward BioEconomy is driven by the need to address resource constraints, by advances in microbiology, and by shifts in consumer preferences toward sustainability.

New opportunities are arising for BioEconomy in manufacturing, biochemistry and agriculture, but strategies also need to include accelerated innovations for food security, and resource protection.

#### **BIOECONOMY VALUE**

The U.S. Department of Agriculture (USDA) released a new report on the BioEconomy, "Indicators of the U.S. Biobased Economy",

which measures substantial economic growth, job creation, and household income for the agricultural sector from biofuel and bioenergy production. Using the same U.S. data along with worldwide data from Research and Markets, BIO, the U.S. Biotechnology Innovation Organization, calculates that the global economic value of the biobased economy – including industrial biotechnology, renewable chemicals and polymers, biofuels, enzymes and biobased materials is \$355.28 billion. The United States generates 58 percent of the value, or more than \$205 billion.

Using data from USDA, the US DOE, ABF Economics, and MarketLine, BIO estimates the direct value of the U.S. biobased economy at \$205 billion, generating 1.665 million jobs. Every direct job creates additional employment and economic opportunities, so the overall impact is \$505 billion and 4.63 million jobs.

# SECTORS INCLUDED INTO BIOECONOMY STRATEGY AND MONITORING IN THE SELECTED COUNTRIES, PLUS THE EU

	ARGENTINA	AUSTRALIA	GERMANY	MALAYSIA	NETHERLANDS*	SOUTH AFRICA	USA*	EU
AGRICULTURE	XX	Х	XX	XX		Х	XX	XX
AUTOMOTIVE AND MECHANICAL ENGINEERING								
CHEMISTRY (INCL. BIOPLASTICS)	XX	X	XX	XX	XX	X	XX	XX
BIOFUELS/ BIOENERGY	XX	X	XX	XX	XX	Х		XX
BIOREFINING		Х	XX	XX		Х	XX	
CONSTRUCTION/ BUILDING INDUSTRY			XX					
CONSUMER GOODS SUCH AS COSMET- ICS AND CLEANING PRODUCTS	XX		XX			X		
FEED	XX	Х	XX	XX		Х		XX
FISHERIES	XX	Х	XX	XX		Х		XX
FOOD AND BEVERAGE INDUSTRY	XX	Х	XX	XX		Х		XX
FORESTRY	XX	Х	XX	XX	XX <sup>1</sup>	Х	XX	XX
HEALTH				XX		Х		
KNOWLEDGE/ INNOVATION		X	XX	XX	XX	Х		Χ
MINING						X		
PHARMACEUTI- CALS INDUSTRY	XX	X	XX	XX	XX	Х		XX
PULP AND PAPER	XX		XX		XX	X		XX
TEXTILES	XX		XX		XX	Х	XX	XX

**Notes: X:** sector included in BioEconomy strategy, XX: included in the BioEconomy strategy and monitored or measured.

Source: Elaborated on the basis of several studies; Wierny, Coremberg, Costa, Trigo, & Regunaga (2015) for Argentina; Alex Cooke, personal communication (2018) for Australia; BMBF & BMEL (2015) for Germany; Zurina Che Dir, personal communication (2018) for Malaysia; RVO (2016) for the Netherlands; Ben Durham, personal communication (2018), and DST (2013) for South Africa; USDA (2016) for the USA and EC JRC (2018) for the EU.

<sup>\*</sup>The results for the Netherlands monitor bio-based economy (BBE) and the results for the USA refer to bio-based products industries.

# BIOECONOMY DEFINITIONS AND STRATEGIES OF DIFFERENT NATIONS

SOURCE: FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

**Argentina:** According to the Argentine Ministry of Agroindustry (MINAGRO, 2016), BioEconomy consists in the "sustainable production of goods and services through the use or transformation of biological resources". For a country like Argentina, with opportunities for biomass production, experiences in the management of biological productions, sound industrial capacities, services, technologies, information and knowledge, BioEconomy represents an important opportunity to generate economic progress and access world markets, as well as to respond to its climate change commitments within the framework of international agreements (MINAGRO, 2016).

Australia: The Australian Government generally refers to the BioEconomy as "the sustainable production and conversion of biomass for a range of food, health, fibre and other industrial products as well as energy" (Department of Industry, 2018). For the Australian Department of Industry, Innovation and Science, the BioEconomy encompasses "all industries and sectors producing, managing or otherwise making use of biological resources (including organic waste), such as agriculture, forestry, and

fisheries. The modern BioEconomy is based on knowledge and innovation in biosciences, together with other technologies such as engineering, chemistry, computer science and nanotechnologies" (Department of Industry, 2018).

Germany: The German national BioEconomy strategy defines BioEconomy as "the knowledge-based production and utilization of renewable resources in order to provide products, processes and services in all economic sectors, within the context of a future-capable economic system" (BMBF & BMEL, 2015). The concept of BioEconomy encompasses all economic sectors and their associated commercial services involved in producing, working or processing, using or trading with renewable resources.

Malaysia: It defines BioEconomy as "the sustainable production of renewable biological resources and their conversion into food, feed, chemicals, energy, and healthcare and wellness products via innovative and efficient technologies". In addition to biotechnology, the BioEconomy encompasses all industries and economic sectors that produce, manage and utilise

biological resources. This includes agriculture, forestry, fisheries, food production, healthcare, chemicals and renewable energy.

The Netherlands: The Dutch definition of BioEconomy includes every "economic activity based on vegetable or animal raw materials" (RVO, 2013). It refers to the production of biomass for food, fodder, materials, transport fuels and energy, from forestry, agriculture and aquaculture (van Esch, personal communication, 2018).

**South Africa:** According to South Africa, the term BioEconomy refers to "activities that make use of bioinnovations, based on biological sources, materials and processes to generate sustainable economic, social and environmental development" (PUB, 2014). It encompasses biotechnological activities and processes that translate into economic outputs, particularly those with industrial application.

#### **BIOENERGY**

The International Energy Agency (IEA) released a report titled, 'Renewables 2018 Market Analysis and Forecast Report,' in 2018. As per the IEA report Modern bioenergy will have the biggest growth in

renewable resources between 2018 and 2023, underscoring its critical role in building a robust renewable portfolio and ensuring a more secure and sustainable energy system, according to the International Energy Agency's latest market forecast.

Renewables will continue their expansion in the next five years, covering 40% of global energy consumption growth, according to the IEA's Renewables 2018 market analysis and forecast report. "Modern bioenergy is the overlooked giant of the renewable energy field," said Dr Fatih Birol, the IEA's Executive Director. "Its share in the world's total renewables consumption is about 50% today, in other words as much as hydro, wind, solar and all other renewables combined."

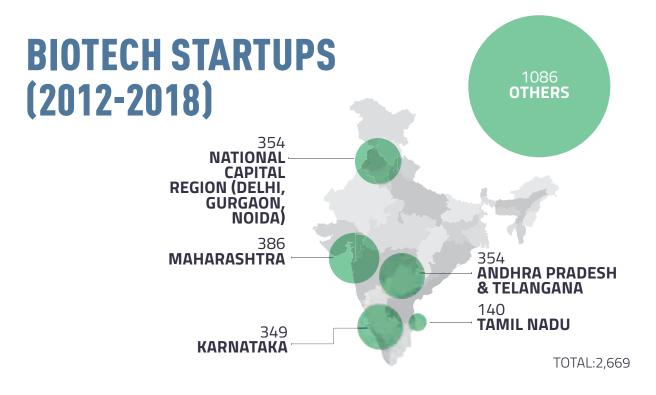
The focus on bioenergy is part of the IEA's analysis of "blind spots" of the energy system – issues that are critical to the evolution of the energy sector but that receive less attention than they deserve – such as the impact of air conditioners on electricity demand, or the growing impact of petrochemicals on global oil demand. Assuming strong sustainability measures are in force, the report identifies additional untapped potential for bioenergy to "green" and diversify energy usage in the industry and transport sectors.

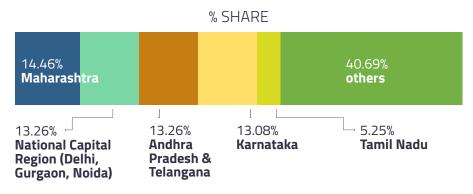
# **ECOSYSTEM IN INDIA**

#### Start-ups

With the incorporation of a record 937 startups in 2018, the number of biotech startups in the country has zoomed to 2,669 at the end of 2018. India witnessed a frenzied 32% increase in biotech startup formation in 2018. The average growth rates in the previous years in startup formation has been in the 20-30% range. The Make In India Facilitation Cell at Biotechnology Industry Research Assistance Council (BIRAC) and the Department of Biotechnology (DBT) of

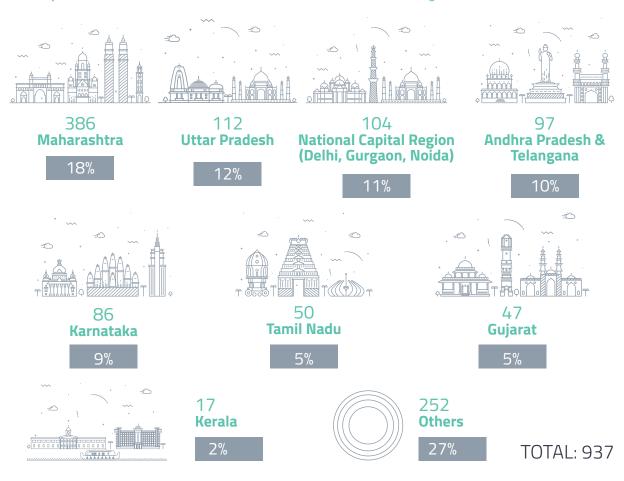
Government of India have been targeting 2000 biotech startups in the country by the year 2020 and the target has been surpassed in 2019 itself. The startup count was done by ABLE's Research Group, analyzing data from the Registrar of Companies under the ministry of Corporate Affairs. On an average, 10,000 companies are incorporated in the country every month. A biotech company incorporated within the last 10 years is considered as a startup by government norms to avail various fiscal incentives.





# LOCATION OF BIOTECH STARTUPS IN 2018

Mumbai, Delhi, Hyderabad, and Bangalore are the cities of choice of registration of startups. These four cities account for 43% share of the total registrations.



# POLICIES THAT COULD FURTHER TRIGGER INDIA'S BIOECONOMY

#### National Policy on Biofuels - 2018

The Union Cabinet, chaired by the Prime Minister Shri Narendra Modi, approved National Policy on Biofuels – 2018 in May last year.

The document states that the crude oil price has been fluctuating in the world market. Such fluctuations are straining various economies the world over, particularly those of the developing countries. Road

transport sector accounts for 6.7% of India's Gross Domestic Product (GDP). Currently, diesel alone meets an estimated 72% of transportation fuel demand followed by petrol at 23% and balance by other fuels such as CNG, LPG etc. for which the demand has been steadily rising. Provisional estimates have indicated that crude oil required for indigenous consumption of petroleum products in FY 2017-18 is about 210 MMT. The domestic crude oil production is able to meet only about 17.9% of the demand, while the rest is met from imported crude. India's energy security will remain vulnerable until alternative fuels to substitute/supplement petro-based fuels are developed based on indigenously produced renewable feedstock. To address these concerns, Government has set a target to reduce the import dependency by 10 per cent by 2022."

The Salient Features being:

- i. The Policy categorises biofuels as "Basic Biofuels" viz. First Generation (1G) bioethanol & biodiesel and "Advanced Biofuels" Second Generation (2G) ethanol, Municipal Solid Waste (MSW) to drop-in fuels, Third Generation (3G) biofuels, bio-CNG etc. to enable extension of appropriate financial and fiscal incentives under each category.
- ii. The Policy expands the scope of raw material for ethanol production by allowing use of Sugarcane Juice, Sugar containing materials like Sugar Beet, Sweet Sorghum, Starch containing materials like Corn, Cassava, Damaged food grains like wheat, broken rice, Rotten Potatoes, unfit for human consumption for ethanol production.
- iii. Farmers are at a risk of not getting

appropriate price for their produce during the surplus production phase. Taking this into account, the Policy allows use of surplus food grains for production of ethanol for blending with petrol with the approval of National Biofuel Coordination Committee.

- iv. With a thrust on Advanced Biofuels, the Policy indicates a viability gap funding scheme for 2G ethanol Bio refineries of Rs.5000 crore in 6 years in addition to additional tax incentives, higher purchase price as compared to 1G biofuels.
- v. The Policy encourages setting up of supply chain mechanisms for biodiesel production from non-edible oilseeds, Used Cooking Oil, short gestation crops.
- vi. Roles and responsibilities of all the concerned Ministries/Departments with respect to biofuels has been captured in the Policy document to synergise efforts.

Expected Benefits:

**Reduce Import Dependency:** One crore lit of E10 saves Rs.28 crore of forex at current rates. The ethanol supply year 2017-18 is likely to see a supply of around 150 crore litres of ethanol which will result in savings of over Rs.4000 crore of forex.

Cleaner Environment: One crore lit of E-10 saves around 20,000 ton of CO2 emissions. For the ethanol supply year 2017-18, there will be lesser emissions of CO2 to the tune of 30 lakh ton. By reducing crop burning & conversion of agricultural residues/wastes to biofuels there will be further reduction in Green House Gas emissions.

Health benefits: Prolonged reuse of

Cooking Oil for preparing food, particularly in deep-frying is a potential health hazard and can lead to many diseases. Used Cooking Oil is a potential feedstock for biodiesel and its use for making biodiesel will prevent diversion of used cooking oil in the food industry.

MSW Management: It is estimated that, annually 62 MMT of Municipal Solid Waste gets generated in India. There are technologies available which can convert waste/plastic, MSW to drop in fuels. One ton of such waste has the potential to provide around 20% of drop in fuels.

Infrastructural Investment in Rural Areas: It is estimated that, one 100klpd bio refinery will require around Rs.800 crore capital investment. At present Oil Marketing Companies are in the process of setting up twelve 2G bio refineries with an investment of around Rs.10,000 crore. Further addition of 2G bio refineries across the Country will spur infrastructural investment in the rural areas.

**Employment Generation:** One 100klpd 2G bio refinery can contribute 1200 jobs in Plant Operations, Village Level Entrepreneurs and Supply Chain Management.

Additional Income to Farmers: By adopting 2G technologies, agricultural residues/waste which otherwise are burnt by the farmers can be converted to ethanol and can fetch a price for these waste if a market is developed for the same. Also, farmers are at a risk of not getting appropriate price for their produce during the surplus production phase. Thus conversion of surplus grains and agricultural biomass can help in price stabilization.

# "THE DNA TECHNOLOGY (USE AND APPLICATION) REGULATION BILL - 2019"

In a landmark decision, the Lok Sabha passed "The DNA Technology (Use and Application) Regulation Bill - 2019". The Bill has been formulated recognizing the need for regulation of the use and application of Deoxyribonucleic Acid (DNA) technology, for establishing identity of missing persons, victims, offenders, under trials and unknown deceased persons.

The purpose of this Bill is to expand the application of DNA-based forensic technologies to support and strengthen the justice delivery system of the country. The utility of DNA based technologies for solving crimes, and to identify missing persons, is well recognized across the world. By providing for the mandatory accreditation and regulation of DNA laboratories, the Bill seeks to ensure that with the proposed expanded use of this technology in this country, there is also the assurance that the DNA test results are reliable, and furthermore that the data remain protected from misuse or abuse in terms of the privacy rights of our citizens.

The key components of this Bill include: establishment of a DNA Regulatory Board; accreditation of DNA laboratories, undertaking DNA testing, analysing, etc.; establishment of the National and Regional DNA Data Banks, as envisaged in the Bill, will assist in forensic investigations. This will aid in scientific up-gradation and streamlining of the DNA testing activities in the country with appropriate inputs from the DNA Regulatory Board which would be set up for the purpose.

### GENETIC ENHANCEMENT OF PULSES: A MISSION PROGRAMME

Improvement of legumes is one of the priority areas of Department of Biotechnology (DBT). Department has initiated a mission program on "Genetic Enhancement on Pulses". NITI Aayog has directed to take necessary scientific interventions in a targeted and mission mode approach in this direction. Department through this "Mission programme on Genetic Enhancement of Pulses" is targeting complex biological system of pulses which has been neglected. Programme envisages providing farmers with improved and productive varieties, disease and climate resilience. Under the programme Department has funded a first network project entitled "Genetic Enhancement of Minor Pulses: Characterization. Evaluation. Genetic Enhancement and Generation of Genomic Resources for Accelerated Utilization and Improvement of Minor Pulses" with ILS, Bhubaneswar as coordinating centre. Project has thirteen participating Institutions across the country. Pulses targeted under the project are Green gram (Vigna radiata, mung bean), Moth bean (Vigna aconitifolia), Black Gram/ Urad Bean (Vigna mungo), Cow pea (Vigna unguiculata), Horse gram (Macrotyloma uniflorum, Kulthi) and Rice Bean (Vigna umbellata).

#### **MAKE-IN-INDIA, STARTUP INDIA**

Biotechnology has emerged as an integral part of the Indian BioEconomy. Currently, Indian biotech industry holds 3% of the global market share and is third largest in Asia-Pacific region.

The DBT along with BIRAC is playing a crucial role in the implementation and delivery of the flagship programs of the Government of

India, such as 'Make-in-India' and 'Startup India'. DBT recognizes the necessity for entrepreneurship development among the youth in the country and hence has several pioneering initiatives.

After successful completion of Make-in-India 1.0, the facilitation cell at BIRAC under the guidance of DBT has formulated the Make-in-India Action Plan 2.0. The Make-in-India Facilitation Cell at BIRAC is also involved in promotion and facilitation of State's Biotech Startup policy, Startups exposure for international and national outreach, strategy discussions of stakeholders for inputs on policy matters, various communication and outreach activities for disseminating information on the initiatives of DBT and BIRAC.

The Prime Minister of India formally launched the Startup India initiative on January 16, 2016. BIRAC's endeavors to scale up the number of Startups in the country by 4-5 folds in next 5 years.

## BIOTECHNOLOGY PARKS/INCUBATORS

The Department of Biotechnology and BIRAC have established Biotechnology Parks and Incubators respectively across the country to translate research into products and services by providing necessary infrastructure support. These Biotechnology Parks offer facilities to Scientists, and Small and Medium sized Enterprises (SMEs) technology incubation, technology demonstration and pilot plant studies for accelerated commercial development. The Department so far, has supported 9 Biotechnology Parks in various States. These are: i) Biotech Park, Lucknow, Uttar Pradesh; ii) Biotechnology Incubation

Centre, Hyderabad, Telangana; iii) Tidco Centre For Life Sciences (TICEL) Biotech Park, Chennai, Tamil Nadu; iv) The Golden Jubilee Biotech Park For Women, Chennai, Tamil Nadu; v) Biotech Park Technology Incubation Centre, Guwahati, Assam; vi) Biotechnology Incubation Centre, Cochin, Kerala; vii) Biotechnology Park, Bangalore, Karnataka; viii) Industrial Biotechnology Parks (IBTPs), Jammu & Kashmir; and ix) Chhattisgarh Biotech Park, Naya Raipur, Chhattisgarh. The Department has come up with 'National Biotechnology Parks Scheme' in which it is proposed to create an ecosystem to absorb the start-ups which have graduated from the incubators and give them a platform for further scaling up their R&D activities in collaboration with the state government and industry.

BIRAC has supported 41 bio-incubators to provide incubation space to Startups and entrepreneurs along with access to high end instrumentation; technical, business, regulatory compliances & IP mentorship and networking opportunities with investors and stakeholders. This BioNEST incubator network is spread out across India including tier 2 cities and expected to grow to 50 in FY 2019-20.

## PROMOTING BIOTECHNOLOGY IN NORTH EAST REGION

The North East Region (NER) of India has been identified as one of the biodiversity hotspots of the world. Rich bioresources spread across NER's diverse ecosystems and nurtured by indigenous communities, provide ample opportunities for furthering economic development of the region. In order to give focused attention for the North Eastern Region, the Department of Biotechnology (DBT), Ministry of Science

& Technology, Government of India, has earmarked 10% of its annual budget every year for promoting and strengthening biotechnology activities in the region. Towards this the DBT has also established a North Eastern Biotechnology Programme Management Cell (NER-BPMC).

DBT has proactively launched several region-specific programmes through the intervention of modern biology and biotechnology in NER. These programs are towards flagship R&D programmes, skilling of human resource, establishment of research and training infrastructure with specific network programmes targeting local problems including entrepreneurship development.

DBT has established a network of 126 Biotech Hubs across NER, providing necessary infrastructure in universities/colleges/ institutions and the required training in sophisticated technologies so as to support and promote biotechnology education and research.

DBT has announced a ₹ 50 crore mission aiming at conservation and cultivation of endangered and threatened endemic medicinal plants of North East India and discovery of new botanical drugs for unmet medical needs using the rich traditional ethno-botanical knowledge and biodiversity of these states. This mission would also help to improve the availability of authentic and quality botanical raw material on sustainable basis for a boom in the phytopharmaceutical industry.

It is expected that this mission would enable farmers and phytopharmaceutical industries from NE states to become global leaders in production and export of some quality botanical drugs DBT would be the nodal coordinating and implementing department for this mission and work closely with Ministry of DONER and other identified institutions.

BIRAC has supported 3 incubation centers in NER under its BioNEST program at Guwahati, Mizoram and Shilong. These incubation centres are to support Biotech Startups and entrepreneurs with access to instrumentation, technical and business mentorship and expertise. Additionally, BIRAC has also announced special awards – BIRAC-TIE WINER award for Women Entrepreneurs and BIG award for Startups to encourage implementation of innovative products and technologies in NER.

## BIRAC BIO-INNOVATIONS: PROPELLING THE BIO-ECONOMY

The Biotechnology Industry Research Assistance Council (BIRAC), a public sector undertaking of the Department of Biotechnology (DBT), has made a big impact on entrepreneurship and innovation in the country.

BIRAC has been able to create a pan-India presence supporting 1000+ biotech Startups and entrepreneurs, 150+ research institutes, small and medium scale enterprises (SMEs) and large industries. These beneficiaries have filed 200+ patents creating Intellectual Property (IP) wealth with the support of BIRAC. Noticeably, there are 110+ products and technologies from BIRAC supported startups that have reached to the markert thus far. BIRAC supported Product Showcase can also be seen online http://www.biotechsolutions.com

BIRAC's BIG programme has become one of the largest early stage programs and has supported more than 500 start-ups and entrepreneurs. Many of these BIG grantees have been able to generate and receive follow on funding of Rs 250 crore from both public and private agencies.

#### **NATIONAL BIOPHARMA MISSION**

The National Biopharma Mission was formally launched on June 30, 2017 and the legal agreement with World Bank for flexible financing arrangements for this Mission of DBT was executed on April 24, 2018. The Mission aims to make India a hub for design and development of novel, affordable and effective biopharmaceutical products for combating public health concerns. It would strengthen translational capability of academic researchers; empower bioentrepreneurs and SMEs by decreasing the cost and risk during early stages of product development and also elevate the innovation quotient of the industry. The global experience of World Bank would be instrumental in building sustained global linkages, technical assistance and knowledge flow between public private partners for business promotion in biotech sector.

Following capacity building activities have been initiated under the mission

2 GLP bio-analytical labs (Bangalore, EDC-Pune); 1 CMC Facility for GMP mammalian work (Dharvad); 2 GCLP labs for supporting vaccine clinical trials (Pune; Bangalore); 2 Facilities for Rapid prototyping; EMI-EMC safety testing (Kanpur); Preclinical Large (swine) animal facility for Med Tech Devices (Hyderabad); 4 Vaccines candidates; 6 Biosimilar candidates for advancing

development; 2 Translational Research Consortia for dengue & chikungunya diseases and setting up of 5 Technology Transfer Offices are being supported.

It is envisaged that this programme will help deliver 6-10 new products in the next five years, create several dedicated facilities for next-generation skills, and hundreds of jobs in the process.

#### **MISSION PROGRAM "IND-CEPI"**

DBT is implementing a Mission Programme "Ind-CEPI" to strengthen development of vaccines for the diseases of epidemic potential in India. This Mission Programme aims to implement targeted support for rapid vaccine development and also build public health preparedness system for emerging infectious diseases in India. This will help in strategic engagement with the global Coalition for Epidemic Preparedness Innovations (CEPI) —an innovative global

partnership between the public, private, philanthropic and civil society sectors undertaken with the aim to explore new ways of working to drive vaccine innovation to address public health in alignment with the WHO blueprint for R&D .The SFC approval for the IndCEPI Mission has been obtained in March 2019, for implementation by BIRAC.

### MISSION PROGRAM ON SICKLE CELL ANEMIA

Under the Control Program for hematological disorders such as sickle cell anemia and thalassemia, an MoU has been signed with the Department of Health and Family Welfare, Govt. of Odisha. The program has been initiated in phased manner starting with Khorda, Sambalpur, Koraput (Aspirational district) and Balasore districts for starting the screening and testing of the risk population.

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Department of Commerce, Ministry of Commerce & Industry, Government of India

Biotechnology Industry Research Assistance Council (BIRAC), a public sector entreprise of DBT, Government of India

The Food and Agriculture Organization (FAO) is a specialized agency of the United Nations

Bioeconomy - Research & Innovation, European Commission

Press release of various organizations and Market Research agencies and Media Publications

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Association of Biotechnology Led Enterprises (ABLE) is a not-for-profit pan-India forum that represents the Indian Biotechnology Sector.

ABLE (www.ableindia.org.in, Twitter @able\_indiabio) has over 400 members from all across India representing all verticals of the sector like Agribiotech, Bio-pharma, Industrial biotech, Bioinformatics, Investment banks and Venture Capital firms, leading Research and Academic Institutes and Law Firms and Equipment Suppliers.

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