India's Biotech Revolution

This editorial is based on " Biotech enigma: On the BioE3 proposal and beyond" which was published in The Hindu on 30/08/2024. The article highlights the recent BioE3 policy as a significant initiative to boost India's biotechnology sector but emphasizes that its success hinges on sustained financial support and collaboration between central and state governments.

For Prelims: Biotechnology sector, Vaccine development, Climate-resilient Agriculture, Carbon capture, Biopharmaceuticals, Biotech-KISAN, Union Budget 2023-24, GenomeIndia Project, Diphtheria, Tetanus and Pertussis, Bt cotton, Golden rice, Active pharmaceutical ingredients, Biofuels.

For Mains: Current Status of India's Biotechnology Sector, Significance of Biotechnology for India, Key Challenges Hindering the Growth of Biotechnology in India.

India's Cabinet has approved the **BioE3 (Biotechnology for Economy, Environment and Employment)** proposal to **boost manufacturing in the** biotechnology sector. While India has made significant strides in areas like vaccine development, the country has yet to fully capitalize on the **broader potential of biotechnology.** The **BioE3** policy focuses on six **verticals, including bio-based chemicals, functional foods, precision biotherapeutics,** climate-resilient agriculture, carbon capture, **and marine/space research.** While well-intentioned, the policy's success depends on long-term financial and infrastructural support from both the central and state governments.

While the BioE3 policy is a promising step, it is essential to create a conducive environment for long-term capital investment and foster collaborations between the central and state governments. Without these enabling conditions, the policy's impact may be limited. India needs to progress more in the field of biotechnology to fully **realize its potential and contribute to global advancements in this sector.**

What is the Current Status of India's Biotechnology Sector?

- **Status**: India ranks among the **top 12 destinations for biotechnology worldwide.**
- It is the **3rd largest destination for biotechnology** in the Asia-Pacific region.
- India's Bioeconomy reached an estimated value of USD 130 billion in 2024.
- Biotechnology is **recognized as a sunrise sector,** playing a crucial role in India's ambition to become a USD 5 trillion economy by 2024.
- With about **3% of the global biotechnology market share,** India is becoming a hub for delivering innovative and affordable healthcare solutions.
- **Biotechnology Categories in India**
    - Biopharmaceuticals: India is a leading global supplier of low-cost drugs and vaccines.
- The country is also a pioneer in **biosimilars,** with the **highest number of biosimilars approved in the domestic market.**
    - **Bio-Agriculture:** With approximately 55% of Indian land dedicated to agriculture, India

holds the 5th largest area of organic agricultural land globally.
        - The Bio-Agriculture sector has the potential to nearly double its BioEconomy contribution from **USD 10.5 billion to USD 20 billion by 2025.**
    - **Bio-Industrial:** Biotechnology is transforming industrial processes, manufacturing, and waste disposal across the country.
    - **Bio IT & BioServices**: India has strong capabilities in contract manufacturing, research, and clinical trials.
        - The country hosts the **highest number of US FDA-approved plants outside the United States.**
- **Government Initiatives:**
    - **100% FDI is allowed under the automatic route** for greenfield pharma and for the manufacturing of medical devices.
        - FDI policies are favorable, with specific routes for brownfield pharma and medical devices.
    - **National Biotechnology Development Strategy 2021-25** aims to make India globally competitive in biotechnology research, innovation, translation, entrepreneurship and industrial growth and be a **USD 150 billion Bioeconomy by 2025.**
    - The **Department of Biotechnology** has funded **51** Biotech-KISAN hubs to connect farmers with scientists and institutions, focusing on sustainable agricultural practices, soil health, irrigation, and new agri-technologies.
    - Under the Union Budget 2023-24, the government announced the establishment of **500 new 'waste to wealth'** plants under the **GOBARdhan scheme**, with a total investment of INR 10,000 crore.
    - GenomeIndia Project aims to sequence and analyze the genomes of a representative Indian population to understand genetic diversity and its implications for public health.
    - The **Department of Biotechnology (DBT),** Government of India, announced the First National Biotechnology Development Strategy in **September 2007.**

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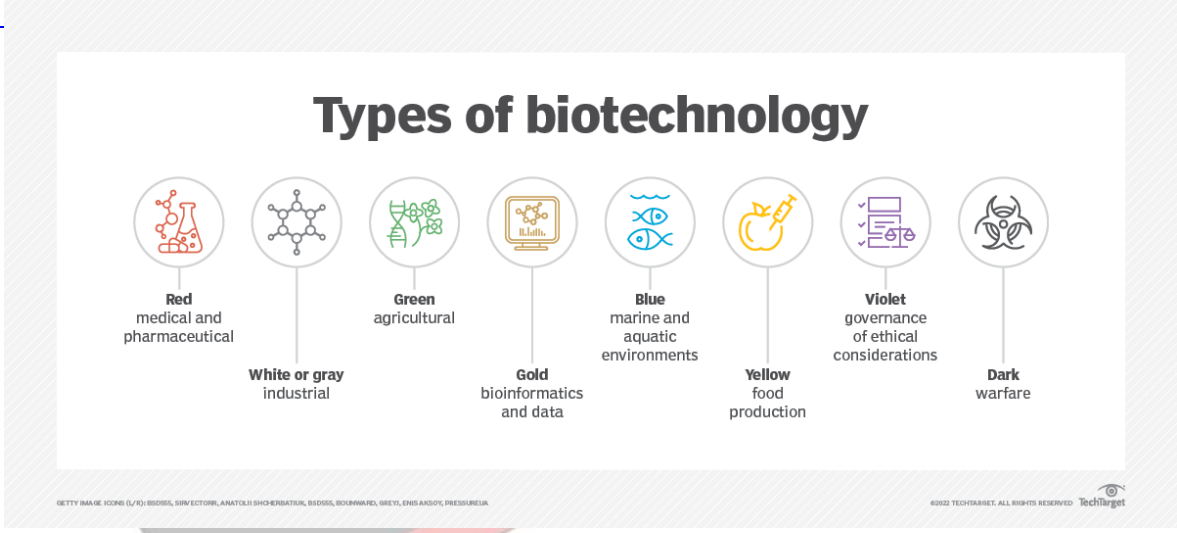

What is the Significance of Biotechnology for India?

- **Economic Powerhouse-Biotech's Billion-Dollar Promise:** India's biotech industry is poised for explosive growth, with projections suggesting it could reach **USD 150 billion by 2025.**
    - Success stories like **Biocon,** demonstrate the potential for Indian biotech firms to compete globally.
    - The government's push through initiatives like **BioE3 and the Biotechnology Industry Research Assistance Council (BIRAC)** aim to catalyze this growth, potentially creating millions of high-skilled jobs and significantly contributing to India's GDP.
- **Vaccine Prowess:** India's prowess in vaccine production has earned it the moniker **"pharmacy of the world."**
    - India accounts for **60% of global vaccine production**, contributing 40-70% of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT).

    - During the **Covid-19 pandemic,** India's Serum Institute became the world's largest vaccine manufacturer.
    - This capacity not only ensures India's health security but also positions it as a crucial player in global health initiatives, enhancing its **soft power and diplomatic influence.**
- **Agricultural Revolution 2.0:** Biotechnology offers solutions to India's pressing agricultural challenges, from climate-resilient crops to enhanced nutritional content.
    - Bt cotton. India's first genetically modified crop, now accounts for **95% of cotton cultivation**, significantly increasing yields and farmer incomes.
    - Ongoing research into **drought-resistant rice varieties and biofortified crops like** golden rice could revolutionize food security for India's growing population
- **Environmental Safeguard:** Biotechnology offers promising solutions to India's environmental challenges.
    - **Bioremediation techniques** are being developed to clean up polluted sites, with successful pilot projects like the **cleaning of Versova Beach in Mumbai.**
    - The development of biodegradable plastics and bio-based materials could help address India's waste management crisis.
    - Furthermore, **biotech approaches to carbon capture,** as outlined in the BioE3 policy, could play a crucial role in meeting India's ambitious climate targets under the Paris Agreement.
    - The government's push for **climate-resilient agriculture under BioE3** could be a game-changer in adapting to climate change impacts.
- **Innovation Ecosystem**: India's biotech sector is fostering a vibrant innovation ecosystem.
    - The country now boasts over 5,000 biotech startups, with hubs like **Bangalore Bioinnovation Centre and Hyderabad's Genome Valley** driving research and commercialization.
    - Government initiatives like the Atal Innovation Mission and the establishment of bio-foundries under BioE3 aim to further catalyze this ecosystem.
    - This could lead to breakthrough innovations and potentially position India as a global biotech innovation leader.
- **Self-Reliance in Critical Sectors:** Biotechnology is key to reducing India's import dependence in critical sectors.
    - Environmental biotechnology aids in **creating eco-friendly alternatives to imported plastics** and developing efficient waste management solutions.
    - In the energy sector, biotech advances support the **production of biofuels and bio-based materials,** reducing dependence on imported fossil fuels.
    - Additionally, industrial biotechnology facilitates the **domestic production of enzymes, biocatalysts, and other bio-based products,** minimizing imports for industries like textiles, leather, and food processing.
    - In the pharmaceutical sector, increasing domestic production of active pharmaceutical ingredients **(APIs)** through biotechnology could enhance India's health security and reduce vulnerability to supply chain disruptions.
- **Futuristic Frontiers- Marine and Space Biotechnology:** India's focus on futuristic marine and space research in biotechnology opens up exciting new frontiers.
    - Marine biotechnology could unlock the potential of India's vast coastline, leading to discoveries in biofuels ,**novel materials** and conservation of key marine species like coral reefs.
    - In space biotechnology, research on **extremophiles and closed-loop life support systems** could not only support India's space ambitions but also lead to innovations applicable on Earth, such as in **waste management and resource efficiency.**
- **Biotech-A Catalyst to Achieve Sustainable Development Goals:** Biotechnology serves as a powerful tool in India's pursuit of the UN Sustainable Development Goals (SDGs).
    - It addresses **SDG 2 (Zero Hunger)** through biofortified crops and GM varieties that enhance food security.
    - For **SDG 3 (Good Health),** affordable biopharmaceuticals and diagnostics improve healthcare access.
    - Biotech solutions contribute to **SDG 6 (Clean Water) and SDG 7 (Clean Energy) through advanced water treatment** and **biofuel production.**
    - Moreover, it aids in **climate action (SDG 13)** via carbon capture technologies and climate-resilient crops, while also supporting **marine and terrestrial biodiversity (SDGs 14 and**

15).
    - By aligning with these goals, biotechnology positions itself as an essential driver of India's sustainable future.

What are the Key Challenges Hindering the Growth of Biotechnology in India?

- **Regulatory Maze- Navigating the Bureaucratic Labyrinth:** India's complex and often slow regulatory environment poses a significant challenge to biotech innovation.
    - The approval process for **genetically modified organisms (GMOs)** is particularly cumbersome, with the **moratorium on Bt brinjal since 2010** serving as a prime example.
    - Multiple agencies involved in regulation, including the Genetic Engineering Appraisal Committee **(GEAC)** and the **Review Committee on Genetic Manipulation (RCGM),** often lead to overlapping jurisdictions and delays.
- **Funding Famine-The Capital Crunch in Biotech**: Despite government initiatives, access to adequate funding remains a major hurdle for Indian biotech firms.
    - Long gestation periods and high risks associated with biotech research deter many investors.
    - India's funding in 2022 for the biotechnology sector is critically low, as the entire Ministry of Science and Technology receives **only 0.05% of India's GDP as funding from the Central Government.**
- **Infrastructure Inadequacies-The Facilities Fallout**: Despite improvements, India's biotech infrastructure **lags behind global standards in many areas.**
    - High-end research equipment, state-of-the-art laboratories, and biocontainment facilities are often in short supply or concentrated in a few urban centers.
    - The **lack of reliable cold chain infrastructure** poses challenges for pharmaceutical distribution, as highlighted **during the Covid-19 vaccine rollout.**
    - While initiatives like the National Biopharma Mission aim to address these gaps, the scale of investment required is substantial, with estimates suggesting a need for over **USD 10 billion** in the next decade to bring facilities up to global standards.
- **IP Insecurity-Protecting Innovation in a Global Market:** Intellectual property protection remains a concern for biotech innovators in India.
    - Patent application filing increased by **24.64%**, from **66440 in 2021-22 to 80211 in 2022-23,** still enforcement challenges persist.
    - The ongoing debate over patent protection for Covid-19 vaccines highlights the delicate balance between innovation incentives and public health needs.
- **Global Gatecrashing-Competing in an Established Marke**t: Indian biotech firms face stiff competition from well-established global players, particularly in **lucrative markets like biopharmaceuticals**.
    - Breaking into these markets requires not just innovative products but also significant investments in clinical trials, regulatory compliance, and marketing.
    - While initiatives like the Production Linked Incentive (PLI) scheme aim to boost competitiveness, Indian firms still have **ground to cover in terms of global market presence and brand recognition.**
- **Talent Tug-of-War - Brain Drain and Skill Gaps:** India produces a large number of biotech graduates annually, yet faces a **paradoxical shortage of skilled professionals in cutting-edge areas.**
    - Brain drain remains a persistent issue, with many top talents seeking opportunities abroad.
    - Moreover, the industry cites a significant gap between academic training and industry needs, particularly in areas like **bioinformatics, computational biology, and bioprocess engineering.** This skills mismatch hampers the sector's growth and innovation potential.
- **Ethical Challenges- Navigating Moral and Social Dilemmas:** Biotechnology often intersects with complex ethical issues, creating roadblocks to research and commercialization.
    - The ongoing debate over genetically modified crops exemplifies this, with **public opposition stalling the introduction of GM mustard** despite regulatory approvals.
    - Recent advancements in gene editing technologies like **CRISPR have reignited discussions** on the ethical implications of human genome modification.
    - The lack of clear ethical guidelines and public engagement mechanisms often leads to

regulatory paralysis, hindering progress in potentially beneficial areas of research.

What Measures can India Adopt to Enhance the Biotechnology Sector?

- **Regulatory Reimagining-Streamlining for Innovation:** India should establish a **single-window clearance system for biotech projects,** similar to the successful model used in the **IT sector.**
    - This could be achieved by creating **a unified Biotechnology Regulatory Authority of India (BRAI),** consolidating the functions of multiple existing agencies.
    - Implementing a **risk-based assessment approach,** as opposed to the **current one-size-fits-all model,** would accelerate approvals for low-risk innovations while maintaining stringent oversight where necessary.
    - Recent initiatives like the **DNA Technology Regulation Bill (withdrawn)** can provide a framework that could be expanded to cover broader biotech regulations.
- **Capital Catalyst-Innovative Funding Mechanisms:** To address the funding gap, India should create a dedicated **Biotechnology Investment Fund,** leveraging a public-private partnership model.
    - This fund could offer a **mix of grants, soft loans, and equity investments** tailored to different stages of biotech development.
    - Recent success stories like the government's **Covid Suraksha mission,** which accelerated vaccine development through targeted funding, provide a template for future crisis-responsive funding mechanisms.
- **Talent Transformation-Bridging Academia and Industry**: Launch a National Biotechnology Skill Development Program, focusing on emerging areas like **synthetic biology, bioinformatics, and precision medicine.**
    - Mandate **industry internships as part of biotech curricula** and incentivize companies to offer these opportunities.
    - Encourage interdisciplinary education by integrating biotech modules into engineering, computer science, and business programs to create a versatile workforce.
- **Infrastructure Imperative-Building World-Class Facilities:** Develop a network of shared high-end research facilities across the country, accessible to both academia and industry on a **pay-per-use basis.**
    - Establish **specialized biotech manufacturing zones** with plug-and-play facilities, streamlined approvals, and shared utilities to reduce setup costs for companies.
    - Invest in upgrading and expanding the cold chain infrastructure critical for biopharmaceuticals.
- **IP Empowerment-Nurturing a Culture of Innovation:** Strengthen the intellectual property rights (IPR) regime by **increasing the number of patent examiners** specializing in biotechnology and reducing patent processing times.
    - Establish a **Biotech Patent Pool** to facilitate **collaborative research and technology transfer, e**specially for neglected diseases and agricultural innovations.
- **Leveraging Make in India for Biotech Manufacturing:** Expand the Production Linked Incentive (PLI) scheme to cover a wider range of biotechnology products, including **enzymes, bioplastics, and biofortified crops.**
    - This aligns with the Make in India initiative and addresses the BioE3 policy's focus on boosting domestic manufacturing.
    - Establish **Biotech Manufacturing Corridors** in states with strong biotech presence (e.g., **Karnataka, Telangana, Maharashtra)** with specialized infrastructure and single-window clearances.

Conclusion

The **BioE3 initiative** represents a significant step towards harnessing India's biotechnology potential. For its success, **robust financial and infrastructural support is crucial.** This initiative could drive economic growth, enhance environmental sustainability, and create employment, but it requires effective collaboration between central and state governments to overcome existing challenges. India's continued progress in biotechnology will be pivotal for its global standing and sustainable development goals.

Drishti Mains Question:

India's biotechnology sector holds immense potential for driving economic growth, environmental sustainability, and employment generation. Analyze the role of BioE3 initiative in realizing this potential.

UPSC Civil Services Examination, Previous Year Question (PYQ)

Q. Other than resistance to pests, what are the prospects for which genetically engineered plants have been created? (2012)

1. To enable them to withstand drought
2. To increase the nutritive value of the produce
3. To enable them to grow and do photosynthesis in spaceships and space stations
4. To increase their shelf life

Select the correct answer using the codes given below:

(a) 1 and 2 only

(b) 3 and 4 only

(c) 1, 2 and 4 only

(d) 1, 2, 3 and 4

Ans: (c)

Q. Mycorrhizal biotechnology has been used in rehabilitating degraded sites because mycorrhiza enables the plants to (2013)

1. resist drought and increase absorptive area
2. tolerate extremes of pH
3. resist disease infestation

Select the correct answer using the codes given below:

(a) 1 only

(b) 2 and 3 only

(c) 1 and 3 only

(d) 1, 2 and 3

Ans: (d)