



## Synthetic Biology

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***This article is based on “India needs a policy on synthetic biology” which was published in The Hindu Business Line on 17/12/2019. It highlights the need for a regulatory framework in India to leverage the benefits of an emerging field viz. synthetic biology.***

Synthetic biology is a **field of science** that involves **redesigning of organisms** for useful purposes by engineering them with new enhanced abilities. This technology, of developing new life forms, is being pursued by industry around the world. It aims to solve problems in varied fields ranging from medicine to manufacturing and agriculture despite there being no regulatory framework in place.

### What is Synthetic Biology?

- Synthetic biology is a new **interdisciplinary area** that involves the application of engineering principles to biology. It aims at **(re-)designing and fabrication** of biological components and systems that do not already exist in the natural world and also edit the genetic composition of available life. With this, **De novo synthesis** (starting from the beginning) of life is now possible.
  - Synthetic biology combines **chemical synthesis of DNA** with growing knowledge of genomics to enable researchers to quickly manufacture catalogued DNA sequences and assemble them into new genomes.
- The main objective of synthetic biology is to **create fully operational possible biological systems** from the smallest constituent parts, including DNA, proteins, and other organic molecules. It incorporates different scientific techniques and approaches.
  - The synthetic systems created may be used to generate products ranging from ethanol and drugs to complete synthetic organisms such as complex bacteria that can digest and neutralize toxic chemicals.
  - Ideally, these customized synthetic biological systems and organisms tend to be much **safer and less complicated** than approaches based on the manipulation of naturally occurring biological entities (like genome editing).

## Difference between Synthetic Biology and Genome Editing

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- Synthetic biology, to an extent, is similar to genome editing because both involve changing an organism's genetic code. However, there is a distinction between these two approaches **based on how that change is made**.
- In synthetic biology, scientists typically **stitch together long stretches of DNA and insert them** into an organism's genome. These synthesized pieces of DNA could be genes that are found in other organisms or they could be **entirely new**. But in genome editing, scientists typically use tools to make **smaller changes to the organism's own DNA**. Genome editing tools can be used to **delete or add small stretches** of DNA in the genome.

## Background

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- The first artificial life form- named as '**Synthia**' was created by **Craig Venter Institute, US**, in 2010.
- After that, in less than nine years, synthetic biology caught the imagination of scientists and the industry's market went up to **\$11 billion in 2016**, which is further expected to grow to **\$100 billion by 2025**.

## Application of Synthetic Biology

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- **Standardized Biological Parts- *identify and categorize*** standardized genomic parts that can be used (and synthesized quickly) to build new biological systems.
- **Applied Protein Design- *redesign*** existing biological parts and expand the set of natural protein functions for new processes.
  - For e.g, **Modified rice** to produce **beta-carotene** (a nutrient usually associated with carrots), that prevents **Vitamin A deficiency**.
- **Natural Product Synthesis- *engineer*** microbes to produce all of the necessary enzymes and biological functions to perform complex multistep production of natural products.
  - For e.g, **Microorganisms** harnessed for **bioremediation** (use of living microorganisms to degrade environmental contaminants into less toxic forms) to clean pollutants from water, soil and air.
- **Synthetic Genomics- *design and construct*** a 'simple' genome for a natural bacterium.
  - For e.g, **Yeast** engineered to produce **rose oil** as an eco-friendly and sustainable substitute for real roses that perfumers use to make luxury scents.

## Current Trend

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### Global Scenario:

- As many as 196 countries, under the aegis of the **UN Convention on Biological Diversity (CBD)**, have been working for more than four years in providing a global framework to deal with synthetic biology in the context of its **impacts on conservation and sustainable use of biological resources**.

The results of these discussions highlight the definition of what constitutes the synthetic biology and the decisions global policy-making favour for treating synthetic biology products and organisms on similar lines as living (or genetically) modified organisms.

- In the past few years, **Japan's** research and development into this technology has been phenomenal. Also in **Europe**, the foresight assessment of this technology has brought the elements of real opportunities at par with virtual problems.
- But, as of now there is **no consolidated information** on who does what, how, for how much, and when the technology will be commercialised with what policy prescriptions.

### Indian Scenario:

- India established the **Department of Biotechnology** in 1986 to harness the emerging science to the benefit of the country. However, there has been a **long-standing lack of clarity and consensus** on how India needs to deal with genetic modification technology in areas like agriculture.
- On the one hand, those who are developing this new technology are cautious of **India's changing stance on use and protection** of such technology while, on the other, the farmers are completely at a loss at comprehending how to increase productivity without having access to technology.

Even the Ministry of Environment, Forests and Climate Change is striving hard to gain approval for **commercialisation** of such new technology.

## Ethical and Social Implications of Synthetic Biology

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- Projects that propose to synthesize entire genomes raise important **ethical questions** about potential harms and benefits to society. Many of the ethical questions relevant to synthetic biology are similar to ethical discussions related to genome editing like:
  - Are humans crossing **moral boundaries** by redesigning organisms with synthetic biology techniques?
  - If synthetic biology yields new treatments and cures for diseases, who in our society will have **access** to them?
  - What are the **environmental impacts** of introducing modified organisms into the ecosystem?
- Such ethical questions have been the subject of research since the beginning of the **Human Genome Project** and will continue to be researched as technology will evolve and change.

## Way Forward

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- Leading voices in **bioethics** have expressed the need for enhanced public engagement and dialogue in the governance of emerging synthetic biology and genome editing technologies in order to efficiently harness its benefits.
- India is yet to formally come up with its **national strategy on synthetic biology** (both policy and regulatory). In this context, India's policy and regulatory framework needs to focus on issues like,
  - Defining what **constitutes** the science of synthetic biology,
  - What kind of **research and development** priorities will be made for **public sector**,
  - Guidance for **private sector** for future research and what all considerations will be undertaken related to relevant policy frameworks (as can be observed, the number of interventions the private sector is undertaking to focus on product development using synthetic biology are noticeable), including those in **intellectual property rights**; and
  - How India will regulate the development and use of this technology, considering issues related to **environment and socio-economics**.
- Like any other technology, synthetic biology is an emerging science with possible positive and negative impacts. The science is real and its applications are varied. However, the potential harms and benefits associated with synthetic biology are required to be addressed.

**Technological foresight** (generating reasoned statements about the future) comprises of **not only technologies and their applications** but also related **public policies and societal challenges**. Countries like India, are thereby in a dilemma where the industry is pushing ahead with investments in developing organisms and products with almost no regulatory or policy oversight on such technology.

Drishti Mains Questions

Highlight the benefits and challenges associated with the application of synthetic biology.