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ARTICLE

Synthetic Biology and the Next Wave of Science Diplomacy

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Introduction

Science diplomacy involves leveraging scientific collaborations between countries to tackle shared challenges confronting humanity in the 21st century and to foster positive international alliances (Fedoroff, 2009). The role of Science Diplomacy in emerging technologies is recognized although there are not many initiatives in Science Diplomacy that focus on emerging technologies and the literature on this is quite limited. One reason could be that traditionally Science Diplomacy is associated with science per se, mega-science projects, and international collaboration in science. On the other hand, in this era of technoscience-driven Science, Technology, and Innovation, the potential of Science Diplomacy in contributing to the development of emerging technologies, their governance and adoption needs to be explored and realised.

But in the context of the war in Ukraine scenario the role of and scope for Science Diplomacy became contentious.[1] Another issue is that those who do research and write on the global governance of Synthetic Biology, hardly assess the potential of Science Diplomacy, perhaps because there are not many successful examples of Science Diplomacy's engagement with emerging technologies. Still, as "Emerging technologies pose several challenges to diplomacy: 1) they deal with many scientific fields and have diverse applications, some unknown, 2) they have the potential for serious national security risks, risks that are constantly evolving, and 3) they are the subject of tensions across nations. These challenges call

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for a role for science diplomacy in all three dimensions of the AAAS and Royal Society New Frontiers in Science Diplomacy framework. If science diplomacy is to be an effective tool for using scientific knowledge, scientific expertise, and/or scientific engagement to accomplish concrete objectives related to emerging technologies, then the immediate task is to specify the objectives sought and the means for achieving them."[2]

In this paper, Synthetic Biology is taken as an example to argue that Science Diplomacy can play a key role in addressing many issues related to Synthetic Biology, if not resulting in the development of globally acceptable solutions. While Synthetic Biology is developing fast, the regulations are not keeping pace with that, and the global governance of Synthetic Biology will likely be a patchwork of governance regimes without any binding treaty or convention to regulate it. For example, there may be a Protocol under the Convention on Biological Diversity (CBD) regulating Synthetic Biology, similar to the Cartagena Protocol (CP) under CBD. But as CP is limited to Living Modified Organisms its mandate cannot cover Synthetic Biology. Science Diplomacy's role can encompass multiple aspects of global Synthetic Biology, particularly in capacity building, reinforcing trust and confidence, and harnessing Synthetic Biology. We argue that there is good potential for India to use Science Diplomacy imaginatively in this.

The origin and evolution of Synthetic Biology

A. **The Need for a New Kind of Science:** In a general sense, two primary methodologies in scientific inquiry exist i.e., reductionism and integration.

Reductionism involves characterizing a system based on its constituent parts. For instance, when attempting to elucidate the behaviour of a complex organism, researchers dissect organisms to examine their internal makeup, aiming to gain insight into their higher-level functions. In eukaryotes, this could entail dissecting the body to analyze the interconnections between organs (gross anatomy). With the development of technologies, deeper layers of biological constructions were uncovered. Terms like histology, cell biology, molecular biology, and biochemistry were coined to indicate a progressively increasing resolution of biological construction.

Owing to the remarkable achievements in delving into the depths of biology and extracting insights from low to high throughput, huge data sets were generated that required massive *integration* using computer-assisted approaches that involved storage, annotation, querying, analysis, reporting, security, and more of biological data produced from reductionistic approaches.

More than twenty years ago, people wondered if a third approach could find a way in the biological sciences i.e., the *construction of biological systems from scratch*. This inquiry aimed to develop an engineering approach to constructing complex biological systems from a set of standard DNA parts library.

B. **Building Scientific Foundation Synthetic Biology:** The initial proof-of-the-concept came in early 2000 when a genetic toggle switch and a three-gene circuit called a repressilator were reported. The idea was to chemically synthesize genomes, cellular organelles, and whole cells as a ground-up construction process. This led to the first conference at MIT (June, 2004) signalling the emergence of a novel field called *synthetic biology*. As the new approach involved creating a standard parts library, people also used the term '*Biological Engineering*', as a proxy for Synthetic Biology, as it looked closer to real practice than theoretical understanding.

Essentially Synthetic Biology indicates a rational design and construction of biological components leading to a novel product – the product may be a design or a molecule.

The origins of the engineering-inspired approach can be traced to the similarities between biology and engineering. However, there are also key differences between them that make the pursuit of engineering biological systems, unique and more challenging (Table 1).

Table 1: A Quick Comparison between Biology and Engineering

	Biology	**Engineering**
Similarities	robust, non-linear, multi-tasking, fault-tolerant, complex, serial and parallel, adaptable	
Differences	mobile components, predominately analog, standards lacking, noise used	anchored components, predominately digital, standards well established, noise-filtered

Due to the unpredictability of biological engineering, the ability to construct novel devices, circuits, and organisms comes with more challenges and responsibilities.

It is crucial to emphasize that Synthetic Biology diverges significantly from recombinant DNA technology, which primarily relies on combinations and statistical likelihoods of designs stably working in a given host. While Synthetic Biology draws inspiration from genome engineering, pathway engineering, tissue engineering, and directed evolution, it fundamentally operates on the foundation of established standards and construction principles. These principles enable the precise engineering of cellular components and even entire multicellular systems.

Essentially, key tools used in Synthetic Biology comprise long DNA synthesis, DNA editing, high throughput screening platforms, and so on (Table 2). These are in addition to the standard tools used by researchers such as electrophoresis, cloning, transformation, blotting, sequencing, metabolomics, transcriptomics and

Table 2: List of Key Tools Used in Synthetic Biology

	Tools	Key references
1	**DNA writing** *(long DNA synthesis)*	Kosuri & Church (2014), Eisenstein (2020)
2	**DNA editing** *(CRISPR Cas9 and beyond)*	Doudna & Charpentier (2014), Doudna (2020)
3	**High throughput screening** *(automated strain engineering platforms)*	Wang *et al* (2009) Iwai *et al* (2022)
4	**Chemical biology** *(synthetic chemistry, cell-free systems)*	Endo *et al* (1977), Yue *et al* (2019)
5	**3D culture** *(bioprinting, organoid, organ-on-the-chip)*	Dey *et al.* (2020), Mladenovska *et al* (2023)

proteomics technologies, bioreactor, computational biology, bioinformatics, systems biology, and so on.

In this context, it may be relevant to underline our work on making novel biomolecules from the dark matter of the genome (Dhar *et al.*, 2009). The term 'dark genome' refers to non-expressing, non-translating, and extinct DNA sequences that can be artificially encoded into functional molecules. The non-expressing component consists of antisense, reverse coding, repetitive sequences, and intergenic sequences of DNA while the non-translating component comprises transfer RNA, noncoding RNA, ribosomal RNA, and introns. The extinct DNA sequences refer to pseudogenes that were active at one time in evolution but were retired over time.

C. **The Market impact:** The influence of synthetic biology on the market is substantial and continues to expand as the field progresses and novel applications emerge.

Researchers are crafting engineered microorganisms proficient in producing valuable substances like pharmaceuticals, enzymes, biofuels, and specially chemicals with heightened efficiency. The capacity to engineer biological systems for drug discovery is an incredible upgrade over traditional genetic engineering practices.

Synthetic biology stands poised to facilitate the cultivation of genetically modified organisms possessing enhanced attributes, such as elevated crop yields, resistance to pests, and augmented nutritional value. Engineered microorganisms can be harnessed to generate alternative sources of protein and other constituents for food production. Likewise, the large-scale manufacturing of bio-derived materials, encompassing bioplastics, textiles, and bio-based chemicals, can be enriched through the application of synthetic biology methodologies. Scientists are also working towards the possibility of fabricating organisms capable of remedying pollution, ameliorating contaminated sites, and bolstering endeavours towards environmental sustainability.

The horizons of synthetic biology are poised to continuously broaden, propelled by the global advancement in biological knowledge, decreasing costs associated with DNA writing and editing, and the increasing accessibility of synthesizing tools.

Much like how synthesis brought about transformations in chemistry and chip design that revolutionized computing during the previous century, biologists have capitalized on progress in molecular, cellular, and systems biology to fundamentally reshape the discipline from one of analysis to one of engineering.

As we approach the close of this decade, there's a strong likelihood that synthetic biology (SynBio) will find widespread application across manufacturing sectors that collectively contribute to over a third of the world's total output, equivalent to nearly $30 trillion in terms of value (Candelon F *et al.*, 2022). Analogous to the way synthesis reshaped the field of chemistry and chip design revolutionized computing during the past century, biologists have leveraged progress in molecular, cellular, and systems biology to fundamentally reshape the discipline, transitioning it from an analytical focus to a bona fide engineering discipline.

D. The Ethical, Legal, and Social Implications (ELSI) Paradigm: The elegance of synthetic biology (biological engineering) lies in its capacity to accommodate innovation across a broad spectrum. Therein lies in the opportunity and challenges from ELSI of a new kind of science that goes beyond studying natural systems and focuses on generating new designs in the lab.

To bring synthetic biology on a level playing field, it is important to have a crisp definition that finds acceptance across sectors and geographies. For example, a *chemical engineer* may consider synthetic biology as an approach to installing innovative controls in biomolecular pathways. A *metabolic engineer* may perceive synthetic biology as a science of introducing new metabolic pathways or tuning existing ones. A *molecular biologist* may see Synthetic Biology as an approach toward the construction of biological standards, synthesising genome, installing logic gates in the cells, and building tools for DNA editing. An *organic chemist* might look at synthetic biology as an opportunity to synthesize chemicals and biochemicals using microbial factories, or the creation of non-ATGC functional DNA. For a s*ystems biologist*, synthetic biology might entail process analysis of studying how cells organise complex massively parallel, and interactive processes, utilizing nature's designs to construct novel and stable networks.

Individual interpretations can differ, but it's vital to establish a clear differentiation between 'genetic manipulation' and 'genetic construction'. This differentiation aids in recognizing gaps in understanding and enhancing regulatory frameworks. It's advisable to address terms like 'Unintended consequences' and 'Unpredicted events', as they could foster unrealistic scenarios and impede sound scientific progress. The Centre for Biodiversity lists several key definitions of synthetic biology in its 2015 report.

- *Synthetic biology aims to design and engineer biologically based parts, novel devices, and systems – as well as redesigning existing, natural biological systems.'' (Kitney and Freemont, 2012)*
- *Synthetic biology … combines elements of biology, engineering, genetics, chemistry, and computer science. The diverse but related endeavors … rely on chemically synthesized DNA, along with standardized and automatable processes, to create new biochemical systems or organisms with novel or enhanced characteristics. (Wagner, 2010).*
- *Synthetic biology attempts to bring a predictive engineering approach to genetic engineering using genetic 'parts' that are thought to be well characterized and whose behaviour can be rationally predicted. (International Civil Society Working Group on Synthetic Biology, 2011).*
- *Synthetic biology aims to design and engineer biologically based parts, novel devices, and Engineering systems as well as redesign existing, natural biological systems. (The Royal Academy of Engineering UK, 2009).*

From an ethical standpoint, there are safety, dual-use dilemmas that touch the boundaries between living and non-living systems. Engineering life forms could pose dangers to health and the environment and raise concerns about possible outcomes. Changing life at the genetic level raises ethical questions about how we treat living things and where we draw the line between human action and natural processes.

Due to the creation of new biological entities in the lab, governments and international organizations need to make uniform standards for ensuring that engineered life forms are safely contained and released into the environment subject to restrictions and monitoring. The possibility of intentional harm may require regulations and protections to prevent potential bioterrorism.

The cost and availability of synthetic biology technologies could affect who benefits from them, raising questions about fair distribution. People's views and knowledge of synthetic biology may influence how people support or oppose it, requiring education and communication efforts. Synthetic biology may clash with some cultural beliefs and religious values, prompting discussions about how far one should go in designing or redesigning organisms.

It has been repeatedly emphasized that engineered life forms released into the environment could affect ecosystems in unexpected ways, posing difficulties for risk evaluation and ecological harmony. Addressing the ELSI aspects of synthetic biology is vital for fostering responsible research and innovation, promoting ethical practices, ensuring the safe deployment of technologies, and minimizing potential negative impacts on society and the environment.

The Global Diplomacy

As countries face complex challenges that transcend borders, scientific collaboration becomes a vital tool for addressing issues such as climate change, health crises, and technological advancements. The relationship between science and global diplomacy is symbiotic with both elements dynamically influencing each other.

A. **Foundational Concepts:** Global diplomacy refers to the art and practice of managing international relations, negotiations, and interactions between countries and international entities. It involves addressing various issues, including political, economic, social, and environmental concerns, through dialogue, negotiation, and cooperation. The aim is to promote peace, resolve conflicts, facilitate cooperation, and advance common interests. Science and global diplomacy are intertwined in a dynamic relationship that influences international relations, fosters cooperation, and drives societal progress.

B. **Science and Diplomacy:** The relationship between science and global diplomacy is symbiotic with both elements influencing each other dynamically. In the past when resources were less and only a few dominant players existed, global diplomacy impacted scientific pursuits in countries, using their national resources to develop socially useful innovations. However, with the rapid diffusion of technologies across the world, improvement of education, and economic situation, science and engineering sectors have seen significant national funding towards further strengthening economies. Due to the immense success of this strategy, recently we have seen examples of science such as climate change and a global outbreak of microbial diseases driving diplomacy.

Solutions rooted in scientific research can provide a common ground for countries to join hands and look for viable solutions. Scientific developments can guide policy decisions and help in bridging gaps within society.

Likewise, Diplomatic negotiations and international agreements can influence the direction of scientific research. Treaties related to environmental protection, arms control, Intellectual Property and trade have shaped research priorities and funding allocation. Diplomacy can foster an environment conducive to scientific cooperation, leading to the exchange of knowledge, resources, and expertise across borders. In this context, it is important to mention that international collaboration has provided funding for research projects that align with diplomatic objectives, such as promoting peace, addressing global health issues, or achieving sustainable development goals.

Essentially, the interplay between science and global diplomacy is a feedback loop. Scientific advancements provide the knowledge and tools needed to address global challenges, while diplomatic efforts create frameworks for collaboration, funding, and policy implementation.

In this context, it may be relevant to highlight several anatomical features of global diplomacy. Bilateral diplomacy involves direct communication and negotiations between two countries, with a focus on issues specific to their relationship. These matters encompass trade agreements, security arrangements, cultural exchanges, and more. Multilateral diplomacy, on the other hand, revolves around interactions among multiple countries within international organizations or forums. Examples include the United Nations, World Trade Organization, International Monetary Fund, and regional entities like the European Union and African Union. This approach strives to consider individual sensitivities and priorities while effectively addressing global concerns demanding collective action, such as climate change, disarmament, and public health. High-level meetings and discussions bring together leaders and diplomats from diverse countries to tackle specific issues or challenges. Notable diplomatic events, like the G7, G20, or ASEAN gatherings, exemplify forums that encourage dialogue and cooperation.

C. **Synthetic Biology and Diplomacy:** The regulatory framework of Synthetic biology must be an outcome of dialogues occurring within international, regional, and privately driven arenas, reflecting diverse perspectives and interests. Numerous international agreements and organizations are presently assessing the ramifications of synthetic biology and engineered gene drive systems within the scope of their respective accords.

   I. *Convention on Biological Diversity (CBD):* The Convention on Biological Diversity (CBD) has been ratified by 196 states. The United States of America (USA) is a non-party to the convention. USA refused to join the Convention as it had reservations about Access and Benefit Sharing under CBD. Synthetic biology is a new and emerging issue in the context of realizing the objectives of the convention. The twelfth Conference of the Parties (COP12) and COP13 produced decisions seeking a more robust assessment of synthetic biology against the Convention's new and emerging criteria[11]. The Parties decided to establish an Ad Hoc Technical Expert Group (AHTEG) and convened a moderated online forum.1 The AHTEG has produced multiple reports and recommendations but is yet to come up with a robust assessment against the new and emerging criteria as mandated by the COP12. At COP 14, Parties agreed on a need for regular horizon-scanning of the most recent technological developments for reviewing new information regarding the potential impacts of synthetic biology. (CBD, 2023).

   II. *The Cartagena Protocol on Biosafety:* The CBD COP extended the AHTEG on synthetic biology, taking into account the work under risk assessment under the Cartagena Protocol on Biosafety. Current deliberations are also considering whether any living organism developed thus far through new developments in synthetic biology fell or could potentially fall outside the definition of a living modified organism (LMO) and thus be subject to the risk assessment requirements of the Cartagena Protocol on Biosafety (CBD, 2003).

III. *The Nagoya Protocol on Access and Benefit Sharing:* In 2017, the Secretariat of the CBD commissioned a report examining the impacts of digital sequence information (DSI) as it relates to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity. *Food and Agricultural (FAO): The FAO International* Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) report commissioned in 2017 examined the impacts of synthetic biology and digital sequence information (DSI) on the Plant Treaty. The report addresses the phenomenon of "dematerialization", defined as that "the information and knowledge content of genetic material extracted, processed and exchanged in its own right, detached from the physical exchange of the plant genetic material". It included the scientific and technological changes affecting the Treaty and the broader legal considerations and opportunities for benefit sharing within the ITPGRFA framework. (Welch, *et al.*, 2017)

IV. *Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES):* CITES has been engaged in discussion on the question of synthetic products that are indistinguishable from products from listed specimens and the status of modified organisms and products under the Convention. Seventieth meeting of the CITES Standing Committee in October 2018 adopted a report on the "Specimens Produced from Synthetic and Cultured DNA". The study notes that regulation under the treaty becomes challenging since synthetic biology specimens may be extremely difficult to differentiate from wild specimens by visual or analytical means.

V. *International Union for the Conservation of Nature (IUCN):* IUCN Members adopted a Resolution titled "Development of IUCN policy on biodiversity conservation and synthetic biology" to map the impacts on conservation and sustainable use of biodiversity. In early 2018, an IUCN Synthetic Biology and Biodiversity Conservation Task Force, was created to oversee the implementation of the Resolution and to develop policy recommendations before the 2020 World Conservation Congress.

VI. *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS):* The focus under TRIPS, on issues related to synthetic biology, pertains to intellectual property rights issues. The results of current synthetic biology research that is focused on modifying existing "natural" genomes could qualify for the "breeder's right" under the International Union for the Protection of New Varieties of Plants (UPOV Convention) If, in the future, there are new plant varieties developed as a result of the production of entirely novel genomes, protection under breeder's rights needs to be discussed. It is also possible that they can be patented. For reasons of space, we are not elaborating on this further. It is worth pointing out that "Intellectual property is likely to be complicated as applications of synthetic biology involve several disciplines and likely will embody multiple patented inventions. Clear structures for managing intellectual property rights are important to promote continued innovation."[2]

VII. *UN Convention on the Law of the Sea (UNCLOS):* UNCLOS includes activities and resources beyond national jurisdiction. BBNJ treaty covering Marine Genetic Resources (MGR) and Access and Benefit Sharing (ABS) related to that has been ratified with eighty three signatories.3

VIII. *Liability for International Harm:* The international legal principle of state responsibility for international harm provides for liability for possible damages attributable to synthetic biology. The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol provides for states to establish national frameworks for liability in cases of environmental harm.

Given the easy availability of communication pathways, science crosses national borders, making it important to harmonize regulations and standards. *Multilateral diplomacy must play a role in facilitating international agreements on regulatory frameworks in the development and deployment of emerging technologies*. There can be voluntary guidelines and other soft law instruments in regulation. While it takes a long time to negotiate and get treaties/conventions ratified they are essential for regulating Synthetic Biology globally. Legally binding Treaties are impossible without multilateral diplomacy and Science Diplomacy can contribute to Treaty-making process in the context of global regulation of Synthetic Biology.

The last two decades have seen the creation of new bio-based products and industries. It's time for diplomatic efforts to promote trade relationships, collaboration, and investment in the development of synthetic biology-related technologies.

Synthetic biology research needs to be collaborative, and international partnerships are essential to advancing the field. Diplomacy can facilitate the exchange of knowledge, expertise, and resources among researchers and institutions around the world. Diplomacy can contribute to the establishment of international norms and codes of conduct for synthetic biology research and its applications, ensuring that responsible practices are followed globally. It's about time to think of establishing frameworks to coordinate research, development, and deployment of lab-made designs and organisms.

Case studies

A. Jurassic Park

Biodiversity has been defined as "the variability among living organisms from all sources including, inter alia, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species, and of ecosystems"

The Earth's extensive global variety of life forms constitutes a vast reservoir containing nucleic acids, proteins, cells, tissues, and organisms that form intricate food chains and serve ecological functions. This encompasses tangible resources such as food, timber, and medicines, as well as critical ecological roles like flood control, temperature regulation, and nutrient cycling. Additionally, non-material benefits such as recreational opportunities arise from biodiversity. The significance of biodiversity is further evident in its contributions to agriculture, the facilitation of the carbon cycle, and the maintenance of human well-being. Moreover, it imparts robustness to environmental fluctuations and yields social and economic advantages.

Human activities have induced transformations in ecosystems, altering natural landscapes into urban landscapes dominated by concrete structures. The introduction of non-native species and the destruction of wildlife are among the consequences. Although ongoing endeavours seek to restore equilibrium, the decline of biodiversity continues at varied rates across the globe

Of late people are asking - Is Jurassic Park going to be a reality? In the future, we might witness the presence of woolly 'mammoths' freely traversing the Siberian tundra. Could the revival of creatures like dodos and dinosaurs be the next step in the process of de-extinction? Taking lessons from the Human Genome Project, computational biology and bioinformatics have evolved to the extent of writing a genetic code that fills in the missing DNA sequence links. Genome Editing and long DNA synthesis tools may help rewrite the genome of an Asian elephant to create a Mammoth!

From what we understand the de-extinction programs have already been started. Even if the rewritten genome does not entirely match the extinct animals, it would give enough starting material to reintroduce lost species to local habitats.

Some of the reports indicate dodo stands as a prominent contender for de-extinction, having been originally confined to Mauritius and succumbed to extinction during the 17th century following human settlement on the island. The loss of its habitat, coupled with the introduction of pigs, cats, and monkeys by sailors, compounded the threats the dodo faced. Theoretically, it may be plausible to incorporate dodo DNA into an evolutionarily related species. However, de-extinction projects must consider the non-availability of the habitat that the organism once enjoyed.

The Colossal project[6] is about the de-extinction of the woolly mammoth. The first step is to find a well-preserved sample of woolly mammoth from areas close to the North Pole. Following this building a full genome sequence, identifying cold weather genes, using gene edits to create suitable cell lines and animal models to test for various traits, transferring an engineered nucleus to an Asian elephant egg, and nurturing a pregnant elephant to give birth to an engineered woolly mammoth calf.

The precautionary principle should find application within the realm of de-extinction efforts. The consideration of international agreements becomes imperative for delineating measures to regulate and safeguard de-extinct species. Notable among these agreements are the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Convention on the Conservation of Migratory Species of Wild Animals, the Convention on Biological Diversity, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, the Patent Law Treaty, and various other international accords.

As strides are made toward the advancement of de-extinction endeavours, the global community should contemplate the wide-reaching legal ramifications inherent in de-extinction. An approach steeped in precaution should be embraced, steering discussions on how to oversee and safeguard species that have undergone de-extinction. Even if the specific invocation of the precautionary principle is not explicitly embedded within distinct international treaties, the foundational notion of early intervention encapsulated within this principle should guide responses to the myriad challenges that de-extinct species introduce.

To ensure the enduring survival of de-extinct species and preclude their re-extinction, proactive safeguards must be instituted. Anticipatory adjustments to the international legal frameworks safeguarding existing species could contribute to this objective. Essential regulations need to be established ahead of the introduction of de-extinct species into their natural environments, shielding against potential unintended repercussions akin to the narrative of Frankenstein's monster.

The stewardship and governance of de-extinct species could be achieved through the amendment of prevailing international treaties and agreements. Alternatively, the creation of fresh resolutions or analogous documentation within existing frameworks could also serve this purpose. It may even necessitate the formulation of a completely new treaty or agreement dedicated to the oversight and regulation of de-extinct species.

The most effective strategy likely involves a blend of these possibilities. Initially, proposing new resolutions to existing treaties might offer a viable route, while over the long term, crafting a dedicated treaty could be indispensable. Of course, there are country-specific issues that have to be looked into (Kuriakose, 2022).

Acknowledging that some nations might be hesitant to initiate profound adjustments due to the nascent nature of de-extinction, the discourse on this matter should commence without delay. While the future trajectory of de-extinction remains uncertain, the importance of acting preemptively cannot be overstated; erring on the side of early action is unequivocally preferable to responding belatedly.

B. Synthetic Meat

Cultured meat, also known as Synthetic meat or lab-grown meat, is a type of meat that is produced by culturing animal cells in a laboratory rather than by traditional animal farming methods. It is an emerging technology in the field of cellular agriculture, which aims to produce animal products without the need for raising and slaughtering animals. The aim is to deliver the sensory experience, meet nutritional requirements, and generate environmental sustainability without slaughtering animals.

Estimates indicate that >80 billion animals are globally slaughtered every year for food generating more than 40 per cent of global methane emissions, leading to climate change deforestation, and water scarcity.

Cultured meat technology has the potential to meet the key UN Sustainable Development Goals (2 and 13) of eliminating hunger, achieving good health, ensuring sustainable consumption and production, and combating climate change.

To feed millions of people and meet their dietary requirements, the livestock sector has been expanding incessantly significantly contributing to global warming. Estimates indicate that for the last six decades, global meat production has risen three times and is expected to reach 300 million tons by the year 2020 (Alexandratos & Bruinsma, 2012).

Overall, it seems the global demand for food production may increase by 70 per cent (latest UN estimates) due to population growth.

Given the highly connected world that we live in, meat produced in one country can easily find its place on the supermarket shelves of another country. Due to this reason, suitable global regulatory guidelines need to be developed to assess the environmental impact (energy consumption, waste management, water usage), Intellectual Property Rights (patent protection, licensing, technology transfer), International Harmonisation (global trade practices, food security diplomacy), standardisation of process, meat quality and manufacturing practices. Of paramount importance is the safety of the cultured meat (potential risks of contamination, unintended toxins and residues showing up in the cultured meat, presence of antibiotics). So regulation at national, regional and international levels to regulate these aspects is essential.

Given that cultured meat is far less polluting than farm-based, suitable carbon credits may be discussed with the possibility of exchanging them among countries.

The India Initiative

From the Indian perspective, probably the first step in synthetic biology was taken when Indian teams presented their designs at the iGEM competition (MIT) in 2006.

Towards the end of the decade, the first synthetic biology conference (Biodesign India) was held at the Centre for Systems and Synthetic Biology, University of

Kerala in October 2010 to identify the emerging synthetic biology community in India. This conference crystallized an interest group "SynJeevani" from State universities, Central universities, IITs, and National Research Labs. The second synthetic biology event was held in Dec 2012 at Jawaharlal Nehru University with representation from the University of Washington and the US National Science Foundation. The outcome of this event was an appreciation of an urgent need to start academic and research programs in synthetic biology. In 2014, a major DBT and NSF (USA) sponsored Indo-US conference and workshop on Synthetic and Systems Biology was organized at JNU. This event brought together speakers from the US and India, a large student and scientific community from India. Several exciting collaborative ideas were discussed between the US and Indian synthetic biology communities. A special DBT brainstorming session was held (during this meeting) to explore the road ahead for India, leading to a concrete future action plan. In 2017, an International Biological Engineering Meeting was held at JNU with support from NIPER Kolkata.

In 2018, DBT awarded the project "*Policy and Research Planning for Synthetic Biology*" to Jawaharlal Nehru University. The outcome of the project was an 85-page foresight document submitted to DBT for further deliberations and for building a comprehensive synthetic biology policy for India (Dhar & Balakrishna, 2020; Sathyarajan *et al.*, 2021).

In 2022, a new iGEM India League was initiated to make iGEM competition more accessible to students, academicians, professionals, and institutions. Focused on the Indian Subcontinent, the League aims to develop the Synthetic Biology Infrastructure and Education ecosystem.

Broadly speaking, in the context of Indian science, synthetic biology research has begun a bit slowly. Frequent interactions among scientists, students, and funding managers are needed to improve India's position in this sector globally. India needs to launch major scientific and education programs in synthetic biology, along with a dedicated DBT task force on synthetic biology.

This vision is recognized in the 2011 Report of the Planning Commission constituted a task force on synthetic and systems biology resource network (SSBRN) which states that: "In India the Synthetic and Systems Biology is at a nascent stage… The timing is suitable for a well-supported 'push' into synthetic biology, both from the point of view of enabling technologies as well as looking toward practical applications. The immediate goal should be to build a base of research expertise and infrastructure in Synthetic and Systems Biology. Citing this, Srinivas pointed out that addressing regulatory, ethical, legal, and social issues is crucial to harness Synthetic Biology effectively (Srinivas, 2014).

Two recent key developments have emerged from India in the Synthetic Biology space. One is India joining the **Global Biofoundry Alliance** (Panda & Dhar, 2021a, 2021b) and the second is starting the **lab-grown meat** initiative (Dhar, 2023).

The Biofoundry India drive is an attempt to build a national maker space for building tools, standards, and applications in biological engineering. Using high throughput technology and automated workflows, it would be possible to test thousands of strain edits in parallel and select the right design for further development. Currently, there are no regulations regarding developing and operating Biofoundry. In the future it would be useful to plan along these lines, to ensure responsible innovation.

The cultured meat initiative has led to the commercial production of animal culture medium that does not require the addition of Fetal Bovine Serum (Gautam *et al.*, 2023). Clear Meat Pvt. Ltd. is the first Indian startup in this sector that has taken an early lead in this direction. Academia and Industry are waiting for the Government's clearance to manufacture lab-grown meat that is affordable, environment-friendly, nutritious, and ethical. The cultured meat technology has the potential to be a disruptor to feed the world and can be a good opportunity for multilateral diplomacy.

Moving to the future there is little debate that India's potential in using science for diplomacy remains under-utilized.

- India needs to commission detailed foresight/technology landscaping studies within the country and at the global level (QUAD, BRICS, ASEAN, Asia Pacific) to understand environmental and biosecurity challenges in synthetic biology. Globally regulatory guidelines specific to synthetic biology are lacking. It's time to bring the stakeholders from academia, industry, and society on a common platform and build a robust regulatory framework to ensure the protection of good science within a responsible innovation framework.

- The connotation of '*emerging technologies*' has shifted from its meaning three decades ago when it pertained to the early Internet. In contemporary times, it includes artificial intelligence, quantum computing, biotechnology, space technologies, and blockchain. These emerging technologies are pivotal to India's expanding domestic economy and digital landscape. However, they also bring along potential security vulnerabilities. As we find ourselves in an era of rapidly advancing technological frontiers, it becomes imperative to collaborate with experts, diplomats, and skilled professionals to formulate relevant policies. This collaborative effort serves to bridge the critical gap in terms of national security and domestic interests. It also involves a comprehensive assessment of the capabilities and potential applications of these technologies.

In this context, the New, Emerging, and Strategic Technologies (NEST) division within the Ministry of External Affairs (MEA) assumes a vital role.

The NEST division is instrumental in comprehending the strategic implications of disruptive and dual-use technologies on foreign policy and the associated international legal dimensions. This is achieved through dialogues with foreign governments and coordination with domestic ministries and departments. While India could face new security challenges due to these advancements, it's essential to recognize their potential as economic and geostrategic assets. These technologies can significantly transform livelihoods and governance. We suggest that NEST should explore the linkage between Science Diplomacy and Synthetic Biology and use Science Diplomacy imaginatively.

Future Pathways

1. There is a need for an international framework that defines the boundary conditions of synthetic biology toward safe and effective research. India can use Science Diplomacy to develop an international framework. For this India has to develop a coherent policy and strategy on Synthetic Biology with a focus on external engagement and initiatives to contribute to the global development of regulation of synthetic biology including standards and addressing biosafety and biosecurity issues.

2. *Convention of Biological Diversity (CBD):* The Ad Hoc Technical Expert Group (AHTEG) of CBD on synthetic biology has produced multiple reports but has yet to come up with a robust assessment and recommendations. There is a need for stakeholders from Academia, Industry, Government, and Social Interest groups to come together and collectively decide the way forward. The CBD process in Synthetic Biology has to be taken forward. The reports prepared so far can be assessed for their relevance for India and how India can use them in its international strategy on Synthetic Biology. After reviewing the developments in CBD and elsewhere on regulating Synthetic Biology, Weiss argues that the Precautionary Principle will be useful in regulating Synthetic Biology. (Weiss, 2020, p. 201). Given the developments under CBD, the best option would be to use CBD to develop suitable guidelines to regulate Synthetic Biology, with or without a separate Protocol.

3. The Self-regulation by people in academia/industry/hobbyists in the form of soft standards is neither binding nor legally enforceable so Synthetic Biology must be stringently regulated. However as the experience in biotechnology and other emerging technologies proves, the regulatory frameworks and priorities in regulation are not likely to be universal. India can take the lead by developing a robust, science-risk-potential-based regulatory framework that can be a good model to be adopted/adapted.

4. The de-extinction of organisms needs to be deliberated assessed for its impact on biological diversity and ecosystems. Its long-term impacts on ecosystems have to be a key consideration.

5. India can take a global lead in building an open-access system in synthetic biology. Open Science is a movement to make science more accessible, inclusive, and equitable for the benefit of all. The concept of open science calls for designing a system where research data, lab notes, and other research processes are freely available, under terms that enable the reuse, redistribution, and reproduction of the research and its underlying data and methods. In the spirit of Open Science, the world needs Synthetic Biology Commons a polycentric, multi-stakeholder alliance to ensure free access to a vast array of scientific data generated worldwide, similar to Genomic Commons (Contreras &

Knoppers, 2018). Building upon the experience with Genomic Commons as described by Contreas and Knoppers and other similar commons-based initiatives a Synthetic Biology Commons can be envisaged.

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Endnotes

[1] For details, see https://blogs.lse.ac.uk/europpblog/2022/05/20/war-in-ukraine-highlights-the-enduring-myths-of-science-diplomacy/.

[2] Visit https://www.sciencediplomacy.org/editorial/2022/emerging-technologies-and-science-diplomacy.

[3] See, https://www.cbd.int/synbio/current_activities/ahteg/.

[4] Details available at https://agrifutures.com.au/wp-content/uploads/publications/16-035.pdf.

[5] For details, visit https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXI-10&chapter=21&clang=_en.

[6] More details at https://colossal.com/mammoth/.