BRIEF OF THE SCIENTIFIC ADVISORY BOARD ON:

SYNTHETIC BIOLOGY

WHAT IS SYNTHETIC BIOLOGY?

Synthetic biology involves targeted engineering of genetic materials of organisms and biological systems to give them new characteristics and purposes.[1] It includes the techniques of DNA sequencing, genome editing, and the use of DNA in computers ("biocomputing").[2] While synthetic biology has been in use for decades, recent breakthroughs in nucleic acid synthesis, gene editing and convergence with AI are dramatically expanding potential applications in the fields of health, environment, agriculture, manufacturing, and computing.[3] Our rapidly growing ability to design and synthetically construct viruses and microorganisms opens up new avenues for studying life and delivering new benefits to humanity.[4]

WHY IT MATTERS?

Advances in synthetic biology are rapidly transforming a range of sectors, with increasingly global implications in the fields of health, security, environment, and human rights.

WHAT ARE THE LATEST DEVELOPMENTS?

• **MEDICINE:** DNA sequencing and synthesis was instrumental in the design and production of some COVID-19 vaccines. It has also been used to develop effective therapies for some forms of cancer.[5] Today, hundreds of medical start-ups are applying synthetic biology to cure diseases, develop vaccines, and improve diagnoses.[6] In early 2023, for example, the first CRISPR-based gene-editing treatment for sickle-cell disease was approved by the U.S. Food and Drug Administration (FDA).[7] The coming period is likely to see many more medical breakthroughs, including for neurological and metabolic diseases. Investments in DNA nanotechnologies for medical use are expected to reach $26 billion by 2031.[8]

• **ENVIRONMENT AND MANUFACTURING:** In 2024, artificial photosynthetic systems offered hope for new solar-to-fuel energy conversion.[9] Engineered textiles, dyes, and cosmetics are already transforming parts of the fashion industry.[10] Synthetic biology is being marketed as a method of "bioremediation" for making or digesting plastics in a carbon-negative manner.[11] Eco-engineered living organisms will consume large quantities of microplastics and other pollutants in our oceans and soil in the near future, with huge impacts on the manufacturing industry.[12]

• **AGRICULTURE:** The use of genetic modifications for improved food production is well-known and widespread. Recently, cellular agriculture generated products like cheese, meat, and other proteins without the use of live animals.[13] Breakthroughs involving improved nutritional quality and more resilient crops suggest a high potential for large-scale improvements in food security and sustainable agriculture.[14] "Gene drives" that alter the inheritable characteristics of plants and animals are increasingly used to eradicate pests and develop more resilient crops.[15] As a result, ecosystem-level changes are witnessing the creation of "synthetic microbial communities" that may be more productive and resilient than naturally occurring ones.[16]

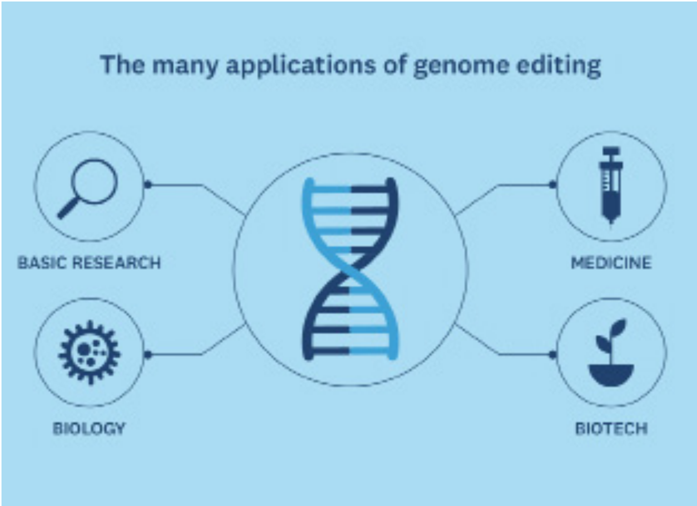
- **COMPUTING:** The field of "biocomputing" includes the use of synthetic DNA to create systems capable of handling large volumes of data more efficiently than traditional silicon-based microprocessors.[17] Examples include CRISPR systems for storing data in living cells; direct encoding of data in DNA strands; and the creation of "living computers" that can sense and respond to their environments.[18] While not yet on the market, the development of synthetic neural networks could offer massive increases in computing power by mimicking the efficiency and parallel processing capabilities of the human brain.[19]

WHAT ARE THE POTENTIAL RISKS?

Synthetic biology poses significant potential **environmental and food security risks** related to the unintended release of genetically modified organisms or the pollution of gene pools of domesticated or wild species. Genetic modifications may spread into the wild, contaminating or competing with populations, disrupting ecosystems, and causing biodiversity loss and environmental deterioration.[20] New or modified species can upset nutrient balances in soil and water, alter microbial communities, and interfere with a range of natural evolutionary processes, potentially destroying entire food systems.[21] Many agricultural communities have expressed concern that industries are already overly reliant on GMO crops, consolidating power in a few companies holding proprietary rights, decreasing food security, increasing socio-economic inequality, and reducing biodiversity.[22] Synthetic biology could accelerate these trends, but in many cases the potential effects are not yet well-known.

The dual-use potential for **synthetic biology products as weapons** is a growing concern, especially as technologies become more readily available.[23] While worst-case scenarios involving global deployment of deadly pathogens are unlikely in the short-term,[24] the rapid acceleration of biological technologies highlights the need for a better understanding of security risks, along with forums to deconflict and de-escalate.[25] Beyond the security realm, the **public health** implications of an unintentional release of new pathogens – including the unlikely possibility of a new pandemic – highlights the need for proactive health measures.[26]

A range of **social and ethical concerns** also have been raised.[27] Given the concentration of technological expertise in the Global North, the benefits of synthetic biology are likely to accrue to wealthier countries. The unauthorized use of biological information from developing countries – called "biopiracy" – can directly undermine the rights of Indigenous populations in particular.[28] And more generally, synthetic biology raises questions about the right of humans to interfere in naturally-occurring ecosystems that have evolved over millions of years.[29]



The many applications of genome editing

Many of these risks point to the inherent **uncertainty** of synthetic biology. While described in the language of engineering, the practice involves the manipulation of living cells, which may mutate or evolve within our environment and our bodies. This means that many of the alterations made to DNA or other living material cannot be controlled fully by synthetic biologists, while the impacts of introducing new organisms into the world are impossible to predict and difficult to regulate with typical slow-moving processes. At the same time, recent advancements in computational algorithms and artificial intelligence are significantly improving our ability to model these systems with increasing degrees of precision, allowing us to better weigh benefits and risks together.[30]

WHAT ARE THE IMPLICATIONS?

Synthetic biology offers a potentially transformative set of technologies that could drive sustainable agriculture and energy, eradicate global diseases, and accelerate progress on some of our most important global goals. In some scenarios, our ability to meet the sustainable development goals may hinge largely on the kind of leap forward offered by synthetic biology.[31] At the same time, the risks are now clearly reaching a global level, with potential cascade effects for every human on the planet.

Recognizing these profound risks, many countries have enacted targeted legislation on biosafety standards.[32] While regulations may manage the specific risks within a national context, they do not cover the harms that synthetic biology may cause globally, are limited by the uncertainties inherent in synthetic biology, and could limit innovations. Existing international frameworks may not be fully equipped to address the evolving risks. The 2003 **Cartagena Protocol on Biosafety to the Convention on Biological Diversity** provides guidance on the transboundary movement of living modified organisms, rather than on synthetic biology practices. The **Biological Weapons Convention** does include important prohibitions on the weaponization of biological processes, but further development may be needed to effectively manage the complexities of modern synthetic biology.[33] Most directly, the **Conference of the Parties to the Convention on Biological Diversity** has created a working group to consider the effects of synthetic biology, but has yet to develop any form of regulation or guidance.[34] As such, these are unlikely to address the kinds of risks that emanate from unintentional release of biological materials into the environment, new and emerging capabilities, or the broader consequences of manipulating genetic material in the longer-term.

WHAT ARE THE CONSIDERATIONS?

• AN INTERNATIONAL SYSTEMATIC RISK ASSESSMENT.[35] While there have been a wide variety of nationally and regionally-based risk assessments, the potential global impact points to the need for an international one.[36] Such an assessment would evaluate the wide range of potential impacts, including in public health, ecosystems, agriculture, military application, and computing. An inclusive and multidisciplinary assessment should include information about the social and developmental risks of growing inequalities caused by concentrations of biotech in the Global North.[37] It should also be balanced, offering an evidence-based assessment of the many benefits offered by synthetic biology, how advances in technology could mitigate risks, and options to harness its full potential.

• ETHICAL GUIDELINES. Global regulation of synthetic biology via treaty or other binding agreement is unlikely in the short term. Building on existing efforts by the Convention on Biological Diversity, there is a pressing need for an inclusive international process to develop ethical guidelines as a basis of good practice today, and more enforceable regulations in the future. Such guidelines should cover the areas of biosafety, biosecurity, data privacy, environmental protection, public health, social justice and equity, access and transparency, and responsibility/accountability.[38]

• TECHNOLOGY INVESTMENTS IN THE GLOBAL SOUTH. In 2007, sequencing a human genome cost roughly $10 million. Today the same process costs around $800. The use of synthetic genomes is set to bring prices down even further, while computational biology offers enormous potential for low-cost, high-impact research in the Global South. Yet the overwhelming bulk of synthetic biology research is conducted in a small number of wealthy countries, with the medical benefits flowing to a small minority. As demonstrated by the unequal rollout of the COVID-19 vaccines, failure to account for the Global South can have devastating consequences. We need greater involvement of Global South scientists in all phases of the "design-build-test-learn" process for synthetic biology.[39] Indeed, as the cost of establishing manufacturing facilities decreases, bio-foundries could be established in emerging economies.

• INCLUSION OF SYNTHETIC BIOLOGY WITHIN AI GOVERNANCE. AI convergence with synthetic biology promises to dramatically accelerate progress, including the establishment of "self-driving" labs run entirely by autonomous AI systems. This convergence could create risks that outpace current regulatory frameworks, both on the AI and biological sides.[40] While promoting the safe development of synthetic biology within the biological realm, it is crucial that national, regional, and international AI governance focuses on this convergence, looking to address risks within AI regulation as well.

• A CENTRAL REPORTING MECHANISM FOR SYNTHETIC BIOLOGY. Today's concentration of expertise in the Global North means there is a massive information asymmetry between developed and developing countries. Having a central data aggregation site that transparently records all significant advances in synthetic biology that are validated scientifically could drive more equitable advancements in this field.

• PUBLIC AWARENESS AND TRUST. One of the greatest challenges for synthetic biology is gaining public acceptance. To build trust in the field, it is essential to design and implement targeted public engagement and education campaigns. These initiatives not only foster informed perspectives but also play a vital role in securing the necessary funding to support and advance this field.

To foster global equity in synthetic biology, the Global North should strategically invest in capacity-building initiatives in the Global South, ensuring inclusive access to cutting-edge technologies, knowledge transfer, and collaborative research. This will empower sustainable development and innovation, addressing global challenges collectively.

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