What if injections weren't needed anymore?

Synthetic biology is expected to design, construct and develop artificial (i.e. man-made) biological systems that mimic or even go beyond naturally-occurring biological systems. What are the benefits of this emerging field? Are there any ethical and social issues arising from this engineering approach to biology?

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The interdisciplinary field of synthetic biology is one of the fastest developing and most promising emerging technologies. It brings together individual parts that can be readily synthesised and combined in different biological arrangements. As such, it touches upon many different fields of enquiry, including molecular biology, evolutionary biology, systems biology, biophysics, electrical engineering, genetics, chemistry, computer sciences and bioinformatics. In view of its dynamic and open-ended character, the scientific committees of the European Commission have recently provided a rather broad definition of this emerging technology as the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms. Synthetic biology is expected to permit scientists to design entire new living organisms, biological parts, devices and systems that cannot be found in nature and to enhance the qualities of existing ones via the use of synthesised parts. The eventual findings of synthetic biology are expected to improve disease detection and treatment, facilitate cell transformation, produce medicines with enhanced qualities, remediate environmental pollutants and provide new energy sources such as biofuels. At the same time though, synthetically designed organisms raise a range of social, economic, ethical and legal issues, and question the adequacy of the EU legal framework in terms of controlling or containing the relevant human health and environmental risks.

Expected impacts and developments

According to a new market report published and authored by Transparency Market Research, the global market for synthetic biology products and applications is estimated to reach a market worth of USD 13.4 billion in 2019. The first products on the market include pharmaceuticals, biofuels and biomaterials.

Scientific advances in synthetic biology are expected to provide the foundations for realising the full innovation potential in fields such as renewable energy, as well as red and white biotechnology and nanotechnology. Health applications may include the production of novel types of proteins and pharmaceuticals, which will be more efficient, safer, cheaper and more environmentally-friendly than current ones, such as artemisinin, an anti-malaria drug, and a range of anti-microbial drugs.

It has also been argued that the successful deployment of synthetic biology applications will include the production of new types of vaccines and the development of micro-organisms with optimised synthetic metabolic pathways for the production of biofuels. Regarding the environment, progress is being made in relation to the development of biosensing systems that can detect hazardous environmental contaminants (such as heavy metals or toxins) and the engineering of micro-organisms which could eliminate these contaminants in biodegradable ways.

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Unexpected impacts and safety/ethical concerns

In addition to the benefits of synthetic biology, there are scientific uncertainties associated with the development of synthetic life, cells or genomes and their potential impact on the environment, the conservation and sustainable use of biological diversity and human health. The development of synthetic biology could entail a series of undesired impacts. For instance, the dual use potential of synthetic biology or even biohacking, that is the application of IT hacks to biological systems, could become a serious threat to safety and security, via the copying of the mechanisms used to produce pharmaceuticals in order to redesign harmful pathogens.

The distributed and diffuse nature of synthetic biology makes it difficult to track, regulate, or mitigate potential biosafety and biosecurity concerns. In fact, it is anticipated that the terrorist/criminal misuse potential will be strengthened. We must also consider the bioethical implications of current synthetic biology and its future ramifications. Does synthetic biology blur the distinction between life and non-life and under which terms should we interfere with nature? Where should we draw the line between what is open or not for synthetic design? The discussion of biosafety and ethical concerns has benefited from a series of projects that have been funded by the European Commission.

Anticipatory law-making

As technologies such as synthetic biology advance very fast and are becoming more widely accessible and easier to use, the role of law is becoming a crucial parameter. It raises unique and boundary-challenging regulatory questions regarding the source of genetic material or the introduction of transgenes into an organism by methods that do not necessarily fall under the current definition of genetic engineering. The primary role of law in that respect should be in developing proportionate pre-assessment tools and guiding risk assessment criteria in the fields of biosecurity, biosafety and the management and distribution of genetic resources.

The regulatory oversight of such an emerging technology is a challenging process given the novel character of synthetic biology, its dynamic epistemic boundaries and the high scientific uncertainties. In many shapes, synthetic biology challenges the adequacy of existing rules in various fields such as the production of biofuels, civil liability for damages, the potential dual use effects and the equitable distribution of benefits deriving from its exploitation. A discussion is currently taking place in the frame of the Nagoya Protocol and the Cartagena Protocol, about whether synthetic biology is captured through the concept of derivatives (products derived from biotechnology) and sufficiently controlled by the current risk assessment and intellectual property rules. In fact, the Scientific Committees of the European Commission suggest several improvements to ensure continued safety protection proportionate to risk, while enabling scientific and technological advances in the field of synthetic biology.

The governance of synthetic biology, either as a whole or following a product-based approach, would require a legal acknowledgment of its inherent complexity and a nuanced application of the precautionary principle through self-governance, institutional oversight and risk analysis tools. The COP12 (Conference of the Parties to the Convention on Biological Diversity) decided to urge parties to take a precautionary approach, when making use of synthetic biology techniques and to establish effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques.

Therefore, it is time for regulators to take a closer look at synthetic biology, not only in terms of coping with its sui generis challenges, but also in relation to accommodating the vast range of ethical concerns relevant to the effects or even permissibility of (re)designing of nature and the adequacy of the traditional risk analysis framework in facing the structural challenges of this unchartered scientific field.