G20 INSIGHTS

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POLICY AREA:
2030 Agenda for Sustainable Development

Consolidated G20 synthetic biology policies and their role in the 2030 Agenda for Sustainable Development

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Abstract

Synthetic biology has the potential to drive significant advances in numerous industry sectors, including electronics, energy, biomedicine, food and agriculture. Synthetic biology can potentially address many of the SDGs, but there are myriads of scientific, social, commercial and legal issues, which policymakers must address. In this brief, we urge G20 member states to (a) develop effective and safe practices for commercialization of synthetic biology products; (b) develop frameworks and protocols for clinical and environmental trials in synthetic biology; (c) clarify and assign responsibility for failed or dangerous synthetic biology developments; (d) revise and adapt existing intellectual property law to meet challenges posed by synthetic biology; (e) establish governance, regulation and risk management procedures; (f) develop consolidated policies for development and application of synthetic biology among G20 member states; (g) tackle growing issues related to Do-It-Yourself synthetic biology, biohacking, and bioterrorism; (h) apply the precautionary principle to all new synthetic biology products.

Challenge

Due to the relative immaturity of the field, many synthetic biology products are still in the early stages of development. Despite this, scientists hope to use synthetic biology approaches to develop many useful types of products. (*1, 2*) This includes but is not limited to the following technologies:

- Synthetic biological mechanisms: artificial biochemical and cellular pathways created *in vitro* using natural and synthetic biomolecules and their component materials. (*1, 3*)
- Nucleic acids used for information storage and transfer; where digital information is encoded employing nucleotide sequences of synthetic RNA and DNA molecules. (*1, 2, 4*)
- Semi-artificial organisms; where part of, or even an entire, genome is integrated into a living cell to invoke desired new functions and capabilities. (*2, 3*)
- Biosensors; biosynthetic devices capable of sensing and reporting some ambient phenomenon such as brain activity or presence of toxins in the environment. (*3*)

- Synthetic custom-designed proteins; novel protein structures with new or improved functions. (*1, 4*)
- Biosensors; biosynthetic devices capable of sensing and reporting some ambient phenomena such as brain activity or presence of toxins in the environment. (*2, 3*)
- Last but not least, synthetic biology can be used for materials production; here living cells function as microscopic molecular foundries to produce materials with desired, genetically encoded, properties.
- These technologies have both benefits and dangers, which are too numerous to completely cover in this document. Instead, further discussion will focus on ways to facilitate and regulate this field at large for current political and governing bodies that have become engaged in this issue and highlight the respective policies under way. (*1-3*)

It is important to recognize that the topics explored in this field are not fully understood, and therefore a precautionary principle should be applied when inventing, manufacturing, using, and disposing of products brought about by synthetic biology. Synthetic biology and its effects on the environment and human health are still poorly understood and inappropriate use and disposal of synthetic biology products may lead to long-term, and even irreversible, consequences. (*1, 6-10*) We propose that additional environmental and toxicity studies should be performed before synthetic biology is applied in various fields of industry. Environmental and health policies need to adapt and address all the rapidly multiplying aspects of this emerging field before further development and advancement, in order to protect the existing ecosystems, biodiversity, and human health. (*1, 3, 7-9*)

Synthetic biology is heralded as a technology that will provide numerous significant opportunities for virtually every industry sector. This includes the development of biofuels, value-added chemicals, drug delivery, and protein therapeutics among other things. (*1-4*) However, just like any new development, synthetic biology doesn't come challenge free and is currently almost unregulated. The lack of standards and regulations regarding those who can practice synthetic biology and how it can be applied is about to become an issue. (*3*) Together with defining safe uses and disposal, synthetic biology raises numerous questions and worries among citizens, scientists, experts, policy makers and governments alike. There are many stakeholders and to add to the mix there is also a growing movement of Do-It-Yourself (DIY) synthetic biologists, citizen scientists, and other homegrown practitioners. (*3, 5, 6*)

Do-It-Yourself Synthetic Biology is a rapidly evolving and emerging social biotechnology movement, in which individuals, community groups, and small organizations study biology and life science using the same or similar methods as traditional research institutions. DIY Synthetic Biology is primarily undertaken by individuals with extensive research training from academia or biotech and pharmaceutical corporations, who then mentor and supervise novice DIY biologists with little or no formal training. Other terms are also associated with this newly emerging and unregulated field. Commonly used terms *biohacking* and *wetware hacking* emphasize the connection to hacker culture and the hacker ethos, while the term *bio-punk* emphasizes the techno-progressive, political, and artistic elements of the movement. The above terms, just like their archetypal counterparts, emphasize the intellectual challenge of creatively overcoming limitations of biological systems to achieve novel and clever outcomes, but at the same time the terms indicate unregulated and potentially damaging or harmful nature of these activities. In recent years, maker spaces and community Do-It-Yourself Synthetic Biology labs have been opening up across the globe, to harness an interest in learning and working in non-academic settings. (*6*)

Additional description is required to specify the context for the apparent controversy with regulation and promotion of DIY Synthetic Biology. The value and promise of such DIY movement is three-fold:

- it boosts creativity and conditions minds of creative amateur bio-experimenters with engineering mindset;
- it produces added value proof-of-concept prototypes, stimulating synthetic biology and bio-discovery at large with no extra spending by governments, major research charities, or research councils; and
- allows for the evaluation of the risks and their mitigation and catastrophe prevention.

Moreover, unlike nuclear energy domain, complete control of the synthetic biology is impossible (due to the availability of the minimal kit for experimentation). Therefore synthetic biology resembles IT sector developments. In this regard, it is important to nurture the creative spirit and foster international cooperation at the high school level. At the same time transparency and registration of the citizen synthetic biologists, viral and novel trends in this field, registry of the synthetic parts, good international relations, and risk evaluation here are as vital as in the case of the weapons and IT control, and therefore so called bio-hackers should become traceable. We suggest that to effectively inform and regulate and fine-tune the DIY Synthetic Biology policy, we should boost active interaction between all citizens including teenagers, teachers, and researchers, and promote interdisciplinary exchange.

This document discusses opportunities and challenges in the rapidly growing synthetic biology field, urging policy makers to regulate the field before its irreversible advancement is beyond management.

Proposal

Synthetic biology is a multidisciplinary field of study, and as such it requires the involvement of various stakeholders and experts to cover its multidisciplinary aspects, including policy and biosafety. There are numerous aspects of synthetic biology that require urgent action. However, various experts fail to address them focusing strictly on environmental, health and biosecurity issues. Synthetic biology market is expected to grow to $11.8 billion in 2018 with a compound annual growth rate (CAGR) of 34.4% over the five-year period from 2013 to 2018. (*11*) This tremendous growth is sustained by the constant R&D developments in the field. However, to continue the growth at this pace, systematic and efficient education, communication and policy development are required. Commercialization pathways, as well as medical and environmental trails in relation to synthetic biology, are also poorly covered. Most of the currently used synthetic biology regulations have been adopted from policies and regulations developed for other technologies, and hence are often incapable of addressing full extent of the field. There are also issues related to intellectual property and responsibility for side-effects or by-products of commercial processes. These issues are typically addressed nationally but not coordinated across countries.

Most of these activities are performed on a national level. While a number of countries have realized the pressing need to form national synthetic biology agendas, to date, very few countries have reflected these agendas in their policy. However, the integrated approach required for this emerging opportunity comes with a challenge. Synthetic biology can potentially have disastrous effects on human health and well-being, environment and biodiversity. The complexity of the challenge is exacerbated by its molecular nature. The G20 member states are well placed to take the lead addressing all of these issues.

The work described in this brief builds on multiple reports, conferences and workshops attended by the authors, and aims to spark further debate among policymakers of G20 member states.

Proposal 1. The route from the laboratory to the market

The pathway for synthetic biology from the laboratory to the market is not as straightforward as for other emerging technologies. Current commercialization routes are significantly similar to commercialization paths of new drugs. However, the synthetic biology field is more complex and very different from pharmaceutical/drug industry. Some of the commercialization issues have already been described in this brief, such as intellectual property, medicine, and environmental considerations. However, there are also other problems preventing commercialization within this promising technology domain. Lack of education, community opposition, and ethical issues are among the top commercialization issues often mentioned for synthetic biology.

The current technology transfer procedures for synthetic biology have to be redesigned to maximize the impact of the technology while ensuring its safety. Currently, the route from the laboratory to the market can take up to ten and more years. With rapidly growing population, escalating climate change issues, food security etc., we cannot afford such timeline gaps for commercialization. Accelerated commercialization pathways for synthetic biology are in high demand, but these accelerated pathways have to ensure that safety standards are met before market release.

Proposal 2. Clinical and environmental trials in synthetic biology

The role of synthetic biology in addressing some of the most urgent world challenges, as well as SDGs (Sustainable Development Goals) has been emphasized. Currently, there are no specific regulations in regard to clinical, environmental and toxicity trials about synthetic biology. Most of the procedures are directly adopted, from Genetically Modified Organisms (GMO) or drug development frameworks. Recently, the U.S. Food and Drug Administration (FDA) quietly proposed regulations (*12*) that would require any genetically engineered organism to undergo a strict regulatory procedure. In essence, the FDA wants to define any organism that a scientist purposefully genetically modifies as a “drug,” and such development would have to pass strict and lengthy clinical trials to be approved. While the regulation proposed by FDA is a step forward, at the same time it doesn’t address the problem entirely. Synthetic organisms or any other synthetic biology developments are very different to drugs, with more complex and broader impacts, and hence require a more in-depth specialized solution. Synthetic biology involves a number of different sub-fields, uses various techniques, and hence each of these requires a specific approach.

Development of specialized clinical and environmental procedures related to synthetic biology must ensure that the technology is safe and commercially viable, while at the same time making sure that safety considerations don’t prevent technology from further development. Finding balanced approaches to clinical and environmental trials is a complex task that requires all stakeholders to work together to find the optimal solution. Scale, complexity, and importance of this work are such that they require the involvement of several governments to ensure its success, scalability, and applicability. Hence, G20 is perfectly positioned as a consortium of countries to lead this initiative.

A vast amount of funding is dedicated to synthetic biology developments, but not enough financial support is given to the evaluation of medical and environmental consequences of these events. Technology safety should be given equal importance as to further technology development. Hence,

we urge G20 members to revise their synthetic biology funding structures and redirect a deserved fraction of the funding towards safety measurements.

Proposal 3. Responsibility in synthetic biology

The party willing to implement a product containing new synthetic biology components should be responsible for ensuring the safety of the product before use. Producer should also be legally responsible for any harm or damage done to user or environment both intentionally and unintentionally by the product. Further on, in cases where the product is developed by a third party only for laboratory or proof-of-concept use and is intended to be commercialized or released by another organization, any legal claims become the responsibility of that organization.

Manufacturers and importers of synthetic biology molecules, proteins, altered DNA, genes or any other related synthetic biology products, should be obliged to make publically and commonly available Synthetic Biology Material Safety Data Sheet (further called SBMSDS). SBMSDS, just like broadly used Material Safety Data Sheet (MSDS) is a document that provides health and safety information about synthetic biology products, substances or synthetically altered compounds of biological origin that are classified as hazardous materials or dangerous goods.

Manufacturers and importers of dangerous goods and hazardous materials must be obliged to:

- prepare an MSDS for each of their products;
- provide the current MSDS to employers or occupiers of premises where the product is used or stored;
- review and revise each MSDS as often as necessary and at least every 3 years to make sure that the information is accurate and up to date.

SBMSDS's provide at least information on:

- the manufacturer or importing supplier;
- the product (its name, ingredients, and properties);
- how the product can affect your health;
- precautions for using or storing it safely.

Please note that SBMSDS is used only as an example for this brief, other terms and abbreviations can be developed for the future use.

Proposal 4. Intellectual property issues and synthetic biology

IP law has for decades been a difficult area for life sciences. The expansion of synthetic biology reveals some significant gaps between the field and intellectual property provisioning. Current synthetic biology frameworks and policies to some extent fail to address intellectual property issues related to this whole new area. The IP law is by default applicable and transferable to all new technology developments. However, IP law related to synthetic biology developments fails to address numerous issues posed by this new field. The patentability of living organisms is a complex matter between

science, law, and ethics. For example, a living organism is patentable only when the organism contains a newly found gene, which has been deliberately altered by genetic engineering or biotechnology to introduce or modify that gene. However, the Subsection 18(2) of the Patents Act 1990 expressly excludes human beings and processes for making human beings from patentability.

The global IP framework requires adaptation to new challenges of synthetic biology to cope with new developments. There are distinct roles for government policies and an urgent need for the development of more unified approaches to IP.

Proposal 5. Governance, regulation and risk management in synthetic biology

Most of the synthetic biology regulations developed and currently used by G20 member states, are indeed the regulations developed decades ago, they were designed to address issues of genetically modified organisms. Several G20 members to date have failed to introduce policies and regulations related to GMOs.

While numerous challenges of GMO and synthetic biology overlap and policies designed to address challenges of GMO can be transferable to synthetic biology, this is not always the case. Synthetic biology originates from developments in GMO. However, at the current stage of development synthetic biology is a superior and much more complex field than its prototype counterpart. Tools, procedures, and capabilities of synthetic biology have developed so much in the last few years and become so broad that their origins from GMO can be hardly traced back.

This is why outdated regulations developed for GMO fail to accommodate rapidly growing and changing needs of synthetic biology. This is another reason why synthetic biology requires entirely new approaches to governance, regulation and risk management. These new policy developments need science-based data-driven approaches, as burdensome regulations may suppress further research and development. Moreover, potential international regulatory and governance conflicts could have an adverse effect on international trade.

Further funding is required to identify any biosafety and biosecurity issues as soon as possible and to address them once identified.

Proposal 6. Consolidated policies for the development and application of synthetic biology

Policy development is in most cases a response to some urgent needs or an attempt to combat or prevent an unwanted occurrence. We have hardly learnt lessons from previous technology developments and we tend to implement policies when tackling an issue becomes a stiff challenge.

The lack of policy developments may suggest that synthetic biology is still a very young discipline, and it hasn't yet caused damage significant enough to entail specific policy developments or governance.

Various G20 member states take different approaches to synthetic biology developments. Some member countries take the opportunities and challenges of synthetic biology more seriously than others. However, joint and unified interdisciplinary approach is required among all member states to

pioneer the field. Consolidated laws and regulations in this rapidly growing area would be an advantage for international trade and technology transfer among all G20 countries.

Based on national synthetic biology reports, clearly many G20 members actively participating in synthetic biology developments believe that the next pre-policy development milestone is a development of national synthetic biology agenda or a roadmap. We believe that G20 requires common global agenda for synthetic biology. Further, we believe that such joint G20 agenda can be a key element enabling the integrated G20 synthetic biology policy.

Proposal 7. Do-It-Yourself synthetic biology

Do-It-Yourself (DIY) Synthetic Biology is a rapidly growing movement of individuals, often without any prior practical knowledge of the field, who use readily available DIY synthetic biology kits and online protocols to experiment and to alter living organisms. While practicing DIY synthetic biology as a hobby is not meant to be harmful, irresponsible use of this knowledge may result in hazardous situations, not only for users but also their surroundings. It can be even more harmful when readily available DIY synthetic biology is used for a purpose by terrorist groups.

Recent terrorist attacks in Europe and elsewhere, pushed German Government to remind grassroots synthetic biologists and biohackers of the Genetic Engineering Act (GenTG) that has been in place since 1990. The Federal Office for Consumer Protection and Food Safety of Germany (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) issued a statement prohibiting the use of DIY synthetic biology and genetic engineering kits outside of the specialized facilities and research institutions. Whoever disobeys the law by ordering a DIY kit and utilizing that equipment outside of the designated facilities will be liable to a penalty of up to 50,000 Euros in accordance with Section 38(1)(2) GenTG. Furthermore, if Genetically Modified Organisms (GMOs) are released due to the use of the DIY kits, offender can face imprisonment of up to three years or a fine as stated under Section 39(2)(1) GenTG.

This reminder is Germany's preventive response to this growing phenomenon. While the reasons behind the ban are clear, such actions can prevent or reduce further developments. Biohacking is often compared to its computing counterpart, where machine code is replaced with DNA sequences. However, back in the late 80s and 90s when the computer industry was rapidly growing no one prevented regular users from buying computers because they might be used for criminal or illegal purposes. Today we are surrounded by computers and digital applications, which support our work and everyday life.

We urge G20 member states to take leadership and regulate the field of Do-It-Yourself synthetic biology. But a blanket ban of DIY synthetic biology won't solve the problem. G20 can play a crucial role in this unfolding yet vital debate for synthetic biology.

Proposal 8. Application of Precautionary Principle

The precautionary principle should be applied at all times. The principle states that if an action or policy has a suspected risk of causing harm to the public, or to the environment, in the absence of

scientific consensus, the burden of proof that it is not harmful falls on those taking that action. Adverse effects may emerge in the long term and hence clinical and environmental trials won't be able to identify them.

An example of such problem has been reported recently in the similar field of nanotechnology. Titanium dioxide (TiO_2) widely used as an active additive to toothpaste, the main ingredient of sunscreen and sweetener broadly utilized by the food industry, has been proven to cause cancer. Reports on negative effects of titanium dioxide and its effects on human health emerged back in 2009 (*13*), however a recent independent study (*14*) confirmed previous suspicions. Moreover, a study from 2015 associates TiO_2 as a possible cause of brain damage (*15*).

Developed regulations should be continually updated, and coordination between the G20 Member States will be vital. The precautionary principle must play a fundamental role in addressing the threats to human health, biodiversity, and environment. Moreover, the precautionary principle must be essential in policy design and development. The precautionary principle in synthetic biology is a critical element of ethical debates and legal decision making and will help protect the human health and the environment from harm.

Conclusions

Regarding little-perceived controversy and the domain where the innovation in question is considered or employed, we propose that decisions should be made by special committees including specialists in synthetic biology, ethics, and biosafety.

The main safety concern in synthetic biology, undoubtedly, is that some of the man-designed biological systems may lead to unanticipated or ill-intended effects for existing biological life forms including humans. However, many of the future and current developments are likely to help mankind survive, control biological matter in general; and therefore shall work for the common good. While the detailed safety tests should fully apply to practical applications of all innovations in synthetic biology, there should be a fast-track for the developments vital for the population survival. Therefore, based on the urgent public debate, such proposals should be assessed and tested.

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Existing Agreements

Final Opinion on Synthetic Biology III: Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology

Opinion prepared by the European Commission and specifically EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Consumer Safety (SCCS).

Next steps for European synthetic biology: a strategic vision from ERASynBio

This Strategic Vision was published in April 2014 and is a result of a joint effort between the partners of the European Research Area Network for the development and coordination of synthetic biology in Europe (ERASynBio), and was supported by funding from the European Commission through the Seventh Framework Programme.

Existing Policies and Monitoring

German Genetic Engineering Act (Gentechnikgesetz)

The German Act on the Regulation of Genetic Engineering (GenTG) has been issued in 1990 and has been amended several times since. The Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittel-sicherheit or BVL) is authority responsible for enforcing the Act.

http://www.gesetze-im-internet.de/bundesrecht/gentg/gesamt.pdf *(Original German version of the Act)*

http://web.uni-frankfurt.de/si/gentech/GenTGengl10-95c.pdf *(Unauthorized English translation)*

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing (Council Directive 90/220/EEC)

http://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC_1&format=PDF

Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms

http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/dir_1990_219/dir_1990_219_en.pdf

Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity, XIII/17. Synthetic biology (CBD/COP/DEC/XIII/17), adopted 16 December 2016

https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-17-en.pdf

Guidance for Industry - Regulation of Intentionally Altered Genomic DNA in Animals

This guidance by the US Food and Drug Administration (FDA) is a revision of Guidance #187, "Regulation of Genetically Engineered Animals," which has been revised to update information concerning the products of different technologies used to produce intentionally altered animals.

https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf

Australian Gene Technology Act

The objectives of this legislation are to protect the health and safety of people and to protect the environment. The Act implements frameworks to identifying risks posed by gene technology, and managing those risks through strict regulations.

https://www.legislation.gov.au/Details/C2016C00792

Decree No. 304 of the State Council of the People's Republic of China

http://extwprlegs1.fao.org/docs/pdf/chn52814E.pdf *(English version of the Decree by FAO)*