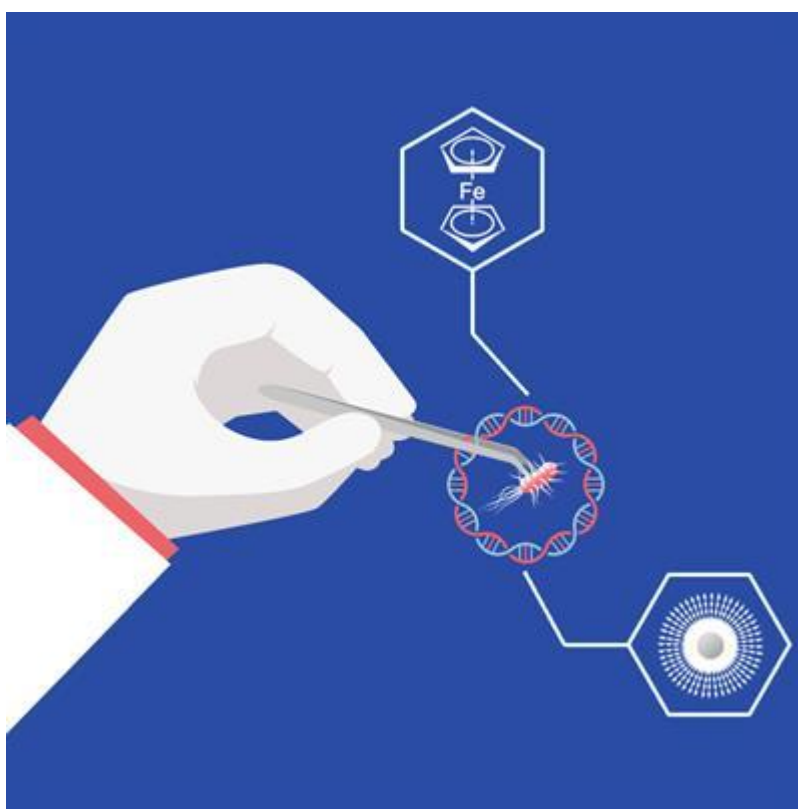


Report of Webinar Series

Science-Policy-Society Interface : Synthetic Biology



(Source: Frontiersin.org)

Science-Policy-Society Interface : Synthetic Biology

Background

As per estimates from the industry and investors, the synthetic biology investments have gone up from USD 9 billion to USD 46 billion between the first quarter of 2020 and the first quarter of 2021¹. This unprecedented growth in support of applications of synthetic biology, ranging from manufacturing of vaccines to pharmaceuticals to chemicals is an indication of not just the potential of this technology, approach and science in the future but also the economic impact of the sector on the society.

Parallely, the policy and regulatory discussions on this branch of science, under the Convention on Biological Diversity (CBD), with 196 countries as Parties to the Convention are ongoing since 2010, where the Conference of the Parties (COP) to CBD has discussed potential impacts from synthetic biology organisms, products and components on the objectives of the Convention and its Protocols.^{2, 3, 4, 5}.

Supported by a small number of reviews on the potential links between synthetic biology, the policy and regulatory needs, a number of stakeholder groups, including indigenous people and local communities (IPLCs) have started to focus on the impact of this science on society in terms of socio-economic implications, including those related to intellectual property issues, issues of equity and benefit sharing^{6, 7}.

The Need

Given the potential implications of decisions made by the COP, regarding implementation of the CBD, and the need for improved science and society focus in dealing with synthetic biology by the 196 countries that are Parties to the CBD, there is an urgent need to bring practitioners of science, policy makers and investors and representatives of the society on to a common platform to discuss various issues so that decisions related to policy and regulatory issues related to synthetic biology can be made based on appropriate information and clear background, expectations.

Webinar Series on Synthetic Biology

In support of the above, the United Nations Environment Programme (UNEP), in collaboration with the industry, academia and policy makers, organized two webinars focusing on science, industry

¹ <https://synbiobeta.com/q1-shatters-previous-synthetic-biology-investment-record-signals-projected-2021-investment-of-up-to-36-billion/>

² <https://www.cbd.int/doc/c/514a/7182/942934bf394fc171a9a2800a/sbstta-24-l-05-en.pdf>

³ <https://www.cbd.int/doc/c/3e39/ab14/44325f0e632fa1cc0eeb80fd/sbstta-24-04-rev1-en.pdf>

⁴ <https://www.cbd.int/doc/c/851a/4ca2/96f2124eeb52d82e2a0c08cf/sbstta-24-inf-19-en.pdf>

⁵ <https://www.cbd.int/doc/c/2074/26e7/a135b1b57dabe8e8ed669324/synbio-ahteg-2019-01-03-en.pdf>

⁶ Sachin Sathyarajan, Balakrishna Pisupati, Neeraj Varma and pawan Dhar (2020) Policy and research planning for synthetic biology. JNU & FLEDGE, India.

⁷ <https://www.iucn.org/theme/science-and-economics/our-work/other-work/synthetic-biology-and-biodiversity-conservation>

perspectives in synthetic biology (including the nature of investments) and policy and regulatory perspectives on 8th February 2022 and 8th March 2022.

These webinars brought together about 230 interested individuals representing academia, industry, governments, civil society, youth and women's organizations with experts sharing experiences of dealing with science policy issues related to synthetic biology and expectations from the policy making side. Details of the panellists and respondents are presented in the annexure to this report.

Key issues shared and discussed during the webinars include:

- Synthetic biology has evolved more rapidly during the past decade with myriad applications focusing on both development of products and organisms.
- Investments in synthetic biology products and organisms has increased tremendously during the last two years, where the investor-friendly environment created due to advances in technologies such as the use of mRNA technology in vaccine production and others have helped the peaking of investments.
- It is expected that the industrial application of synthetic biology products and organisms will continue to grow and new applications in a number of areas such as health sciences, environmental sciences and others are expected to increase.
- During the last year (2021) industry has started to focus on developing synthetic biology based organisms more rapidly than before.
- Since 2010, supported by the discussions under the Convention on Biological Diversity (CBD) discussions on policy and regulatory aspects in managing synthetic biology products and organisms has increased and it is expected that the forthcoming Fifteenth Conference of Parties to the CBD (CBD COP 15) will make decisions on how to proceed regarding the “new and emerging issue analysis”, and a horizon scanning process on synthetic biology.
- The science-policy interface (SPI) and practice in synthetic biology serves as a good case study for further strengthening the science-policy-practice links, including by UNEP since UNEP has committed to strengthening the future of SPI.
- Noting that policies can either promote or block new technologies such as synthetic biology, participants suggested the need to pursue technology-neutral position and support investigation of all solutions., ensure informed participation and transparency in discussions related to policy and regulatory developments, including collaboration with diverse stakeholders to address any concerns and get technology accepted in the market, support consideration of more perspectives and viewpoints and agree to fail quickly and move on.
- Citing examples of approaches by consortia such as the Engineering Biology Research Consortium (EBRC), suggestion was made to undertake assessments on scientific, social, community and policy impacts of synthetic biology.
- Considering a confluence of factors that are contributing to develop and deploy transformative technologies at scale, the need to collaborate with nature was highlighted as potential for future of sustainable development.
- Suggesting synthetic biology as an approach rather than an enabling technology, participants discussed on how Parties have “considered” the operational definition of synthetic biology with discussions under the CBD are broader as they cover organisms, products and components. Though the AHTEG has concluded that so far organisms developed through synthetic biology are LMOs and there within the scope of the CP, some participants wished more clarity on this issue.
- Focusing on how synthetic biology is being considered across other multilateral processes, such as under the Biological Weapons Convention, the World Health Organization and

others, the participants recognized the need for synergies in approaches to dealing with the science and applications using synthetic biology and prompted the need to have inclusive considerations of emerging issues within organizations and processes to have clear national frameworks to manage the synthetic biology products and organisms.

- With international movement of technological applications, their adoption and deployment participants felt the need to have approaches to policy and regulatory aspects that are consistent, predictable and transparent to support collaboration and technology transfer. Currently, such actions are not guided by any policy framework(s) in many countries.
- As discussions progress on policy and regulatory aspects of synthetic biology under the CBD, participants were reminded about the governance issues related to synthetic biology including on the need to consider ethics and diverse interests in applications and regulatory aspects related to the technology.
- Hearing experiences from countries that are considering use of principles and approaches in regulatory synthetic biology products and organisms akin to those of living modified organisms and the school of thought that seem to support such considerations under the Cartagena Protocol, the participants focused on the rationale of such decisions by countries.
- Considering the discussions during the webinars, the participants recognized the urgent need to have a final and agreed definition of synthetic biology, at least in the context of the CBD and its discussions on synthetic biology. Any more delays in this decision will undermine our ability to deal with the technology with its increasing applications, deployment and adoption at various levels around the world.
- Participants also suggested focus on strengthening the discussions under the CBD and its Protocols on biosafety and access and benefit sharing (the Nagoya Protocol)
- Discussing the issue of reaching out to policy makers to help understand the science-policy aspects of synthetic biology, the participants discussed the options for inclusive discussions and need for capacity development and awareness raising on opportunities and impacts of synthetic biology.

Concluding the discussions, the United Nations Environment Programme (UNEP) that organized the sessions indicated the interest and availability of UNEP in supporting science-policy practice issues related to synthetic biology and support discussions in preparation for CBD COP 15.

For more information

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Annex

Webinar 1 – 8th February 2022

Understanding synthetic biology : Academic and industry perspectives

Panelists :

- Ms. Felicity Keiper, Expert, Global Regulatory Affairs, BASF
- Ms. Nicole Richards, Chief Executive Officer, Allonnia
- Mr. Michael Koepke, Vice President, Synthetic Biology, Lanzatech
- Mr. Mathias Cousin, Managing Director, Monitor Deloitte

Respondents :

- Ms. Ntakadzeni Tshidada, Deputy Director, Biosafety, Department of Environment, South Africa
- Mr. Sachin Sathyarajan, National Law School of India University, India

Webinar 2 – 8th March 2022

Recent developments in policy and regulatory issues related to synthetic biology

Panelists :

- Ms. Marianela Araya Quesada, Programme Management Officer, Secretariat to the Convention on Biological Diversity
- Ms. Ntakadzeni Tshidada, Deputy Director, Biosafety, Department of Environment, South Africa
- Dr. Balakrishna Pisupati, Programme Manager, UNEP
- Dr. Tim Strabala, Principal Scientist, Environmental Protection Authority, New Zealand

Respondents :

- Ms. Nicole Richards, Chief Executive Officer, Allonnia
- Ms. Marina von Weissenberg, Ministerial Advisor, Ministry of Environment, Finland