



## Book Review

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### **Emerging Policy Issues in Synthetic Biology**

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Synthetic Biology is an emerging technology that has received attention on account of its potential and the risk factors that are perceived to be associated with it. According to a report from Royal Academy of Engineering (2009), Synthetic Biology has been defined as “Synthetic Biology aims to design and engineer biologically-based parts, novel devices and systems as well as redesigning existing, natural biological systems”. This raises many questions such as are we playing God and how natural are these systems and how are natural biological systems redesigned, can their behaviour and response be fully controlled or predicted.<sup>1</sup> The Inter Academy Panel – a global network of science academies has acknowledged the potential of synthetic biology and suggested that “we must collectively ensure that policy development worldwide is sufficiently flexible to encourage research and manage innovation, including those applications not yet envisaged, while suggesting sensible practices to mitigate any risks”.<sup>2</sup>

From a public policy perspective while lessons learnt from regulating biotechnology are necessary for regulating synthetic biology, the newness of synthetic biology raises many concerns. For example, biosafety and biosecurity issues are far more important in synthetic biology as the potential to develop novel organisms through synthetic biology for biowarfare cannot be dismissed as fantasy. Hence, in the recent years many organisations including Royal Society, Presidential Commission on Bioethics, International Risk Governing Council have published studies and reports on policy issues and regulation of synthetic biology. OECD being an inter-governmental organisation that has been involved in technology regulation issues for many years is also working on regulating synthetic

biology and hence a publication from OECD on synthetic biology is apt.

This book has seven chapters with two annexes. The chapters deal with *inter alia*, application and potential uses of synthetic biology, investment patterns in synthetic biology, intellectual property issues, governance and risk regulation, and, national policies on synthetic biology. The report rightly points out that reduction in costs of DNA synthesis is vital as inexpensive and accurate DNA synthesis is important for future of synthetic biology. It argues that technical difficulties and hurdles have to be overcome and at the same time there are biosecurity concerns as sequence designs can be sent across countries or transferred easily and used elsewhere. In fact this modularity of this technology is a big challenge for enforcing biosafety and biosecurity. The dilemma here is that as costs decrease access to the technology and materials is likely to increase resulting in wide spread application/experimentation involving them and regulating this is not easy. In case of building research infrastructure while USA and Europe are leading others like China, South Korea and Japan are also devoting financial and human resources in this and venture capital is also playing an important role. But the challenge lies in avoiding duplication and fragmentation and developing a clear cut road map for this technology. UK has established a road map and has increased its funding for synthetic biology

Given the multi-disciplinary nature of synthetic biology education in synthetic biology will have to give importance to develop relevant human resources and training besides establishing centers and groups where multi-disciplinary research is possible. In terms of applications that are being developed, biofuels, and health dominate although R&D in synthetic biology is addressing many themes. As in case of other emerging technologies the role of intellectual property in this technology is important. This book points out the challenges in synthetic biology in terms of intellectual property rights and suggests that open innovation, open source models, patent pools, and patent clearinghouses can offer many interesting options. It also discusses the Biobricks model and licensing models and agreements. The debate on intellectual property rights in synthetic biology have gone beyond patenting vs. open source divide and this book suggests that synthetic biology can learn from semiconductor industry in handling intellectual property.

Regarding governance and regulation the chapter in the book describes

the current developments and the evolving regulatory regime for synthetic biology. It points out the importance of public engagement and rightly cautions that the negative reaction to GM technology in Europe might affect realising the benefits of synthetic biology in Europe. The discussion in this chapter could have been more extensive and issues related to risk perception and governance could have been given more space. While lessons from regulating GM technology and biotechnology are relevant synthetic biology is different from both in many aspects. Defining synthetic biology is a challenging task.

According to a report from three Scientific Committees of European Commission (Scientific Committee on Health and Environmental Risks, Scientific Committee on Emerging and Newly Identified Health Risks and Scientific Committee on Consumer Safety), “From a purely risk assessment perspective, the principal purpose of defining SynBio is to assist the identification of processes or products that, because of their nature, scale and/or application, might require a substantial change from the current risk assessment procedures. However, deciding upon a precise definition for SynBio is a challenging task, because it is a rapidly expanding science in which new processes and products may be introduced and derived that are not currently envisaged.” (Opinion on Synthetic Biology I, European Commission, 2014: 25).

Thus regulating synthetic biology raises many new questions and I am sure that OECD will address them in its work on synthetic biology. This book provides a good but brief analysis of national level policies and plans on synthetic biology and notes the development of roadmaps in synthetic biology.

This book provides a good overview of the policy issues in synthetic biology and identifies major issues that have to be addressed by policy makers. Its comprehensive approach covers almost all policy issues related to synthetic biology. The report discusses the implication of synthetic biology for agriculture, bioeconomy and its role in addressing climate change. More discussion on transnational regulation of synthetic biology, synthetic biology, biodiversity and Convention on Biodiversity and Do It Yourself (DIY) synthetic biology could have enhanced the utility of the book.

Although the literature on ethical, legal and social aspects of synthetic biology is expanding and many projects have been funded to address them not much literature is available on policy issues in synthetic biology and on linking developments in synthetic biology with policy issues. This book meets that need well. Hence I would strongly recommend this as a must read for anyone interested in understanding public policy issues in synthetic biology.

**-K. Ravi Srinivas**

RIS

ravisrinivas@ris.org.in

### Endnotes

<sup>1</sup> See, for example, Schmidt *et al.* (2010)

<sup>2</sup> IAP (2014). See also National Academy of Engineering and National Research Council (2013).

### References

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