

The Societal Aspects of Synthetic Biology: A Priority Paper

First draft

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Because it deals with living products, Synthetic Biology (SB) develops as a branch of biotechnology with a high impact on society. As a result, the ethical and societal aspects of this discipline are becoming increasingly prominent. While these are still early days to assess the full social impact such a technology might have, it is crucial that the ethical and societal dimensions develop side by side with the field, engaging all stakeholders, including scientists, other experts and society.

The following paper has arisen from the first 1,5 years of our project SYNBIOSAFE (www.synbiosafe.eu), studying the ethical and safety aspects of synthetic biology. Based on an extensive literature search, interviews with scientists, social scientists, IP experts, NGO's and finally on a four week long public e-forum¹, the authors of this paper have compiled what they believe are priority topics in SB for the months and years ahead.

The points collected below are meant to encourage all stakeholders to react to the various issues presented, engage in the prioritisation of these issues and participate in a continuous dialogue, with the ultimate goal of providing a basis for the multi-stakeholder governance of the field.

We will present and discuss this priority paper at the Synthetic Biology 4.0 conference in Hong Kong in the session "Towards A Consensus Paper for Synthetic Biology", taking place at 12 October, session D roundtable, 4:00 – 5:30 pm. We would like to invite you to comment and discuss the priority paper, by sending us an email (comment@synbiosafe.eu) and/or joining our SB 4.0 session.

Ethics

- Creating and engineering life being central to the vision of SB, further societal discussion is warranted on the definition of life and of living organisms, as well as the effect various conceptions of life may have on the ethical implications of SB
- An open and engaged ethical debate is needed on the various applications of SB, particularly regarding the interaction of natural and synthetic organisms and its consequences for the environment, as well as the applications either related to human health or using cells of human origin.

¹ Schmidt M, Torgersen H, Ganguli-Mitra A, Kelle A, Deplazes A, Biller-Andorno N. 2008. SYNBIOSAFE e-conference: online community discussion on the societal aspects of synthetic biology. *Systems and Synthetic Biology* (online first). <http://dx.doi.org/10.1007/s11693-008-9019-y>

- Further discussion should be encouraged on the possible effect of the distribution of SB products on various aspects of social justice and the current global divide.

Safety

- Careful attention must be paid to the way SB skills diffuse (biohacking etc.). The consequences of further deskilling biotechnology are not clear and should be monitored.
- A discussion is warranted on whether we need new methods to conduct risk assessments on novel issues, such as new biocircuits or alternative biological systems, and if so, what such methods may look like.
- An important task of a safety discussion may involve exploring how SB itself may contribute towards overcoming biosafety problems.

Security

- Biosecurity awareness among synthetic biology practitioners is generally low and needs to be increased through enhanced communication and cooperation between the synthetic biology and biosecurity communities.
- In addition to such an enhanced dialogue and cooperation, science and engineering curricula should incorporate dual-use issues related to their fields, i.e. should explicitly address the fact that many beneficial discoveries and technologies can be misused for nefarious purposes.
- The question of oversight of synthetic biology from a biosecurity perspective needs further deliberation. While some fear undue restrictions resulting from an oversight system, others point to the beneficial effects such a system or organisation might have.

Intellectual Property

- Given that SB leads to novel types of inventions based on living organisms, solutions to deal with upcoming intellectual property issues have to be found. Two main questions need to be addressed:
 - 1) Should access be open or not? If open access is considered adequate, what model would be appropriate?
 - 2) Should inventions be protected by patents or by copyright?

Public perception and engagement

- Although some lessons can be learned, the analogy to past debates, e.g. on genetic engineering may have its limits. It seems, however, that scientists would certainly be well advised to adopt an open approach towards the public and engage in ethical discussions that go beyond factual information about scientific and technological advances.
- Regulation is no guarantee for public acceptance. Although imminent safety and security issues must be taken seriously, nanotechnology provides examples that in certain contexts flexible forms of governance may be more appropriate than strict regulation.