

23 – 24 April 2012

Technology Assessment

Towards a European Policy for the Governance of Ethical and Legal Issues of Synthetic Biology and Human Health

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SYBHEL work packages



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Synthetic Biology and Human Health: Ethical and Legal Issues

www.sybhel.org (2009 – 2012)

- SynBio and the definition and creation of life (WP2)
- What should a 'SynBio-ethics' for human health look like? (WP3)
- SynBio for human health and well-being (WP4)
- Commercialisation and regulation of SynBio (WP5)
- Public policy on SynBio for human health (WP6)

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How can issues raised in other WP's be translated in (European) policy options?

European Workshop: April 2011

SynBio experts, policymakers, regulators, patient associations, ethicists, social scientists

- Identify prospective human health applications in SynBio
- Describe ELSI-issues pertaining to these SynBio health applications
- *Explore the existing approaches to govern these issues within the European context*
- *Formulate policy options*

Global Workshop: February 2012

policy experts from different regions in the world

- Identify potential contributions of SynBio to global public health
- Discuss necessary conditions for the realisation of these options

Potential future SynBio health applications



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- New pharmaceutical production processes: in vivo synthesis of complex naturally or non-naturally occurring compounds
 - **Artemisinin** (anti-malaria drug)
 - anti-cancer drugs
 - anti-biotics
 - vaccins
- New kinds of therapeutic products
 - molecular devices for tissue repair
 - tumor fighting bacteria ('living therapeutics')
- Biosensors
 - environmental biosensor detecting arsenic concentrations in drinking water
 - mammalian biosensors
- Targeted drug delivery
- New platforms for identification of disease mechanisms and drug targets

Issues specific for SynBio health applications



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SynBio Applications	ELSI issues of synbio health applications				
	Bio-safety and efficacy of SynBio health products	Dual-Use & Bio-Security Issues	Patents and Intellectual Property	Fundamental ethical questions about engineering (human) life	Other?
<i>New pharmaceutical production processes</i> (synthesis of natural bioactive compounds e.g. artemisinin)					
<i>New kinds of therapeutic products</i> (e.g. engineered viruses and bacteria)					
<i>New kinds of diagnostic products</i> (e.g. biosensors or improved immunoassays)					
<i>New forms of targeted delivery</i>					
<i>Development of pharma products</i> (e.g. synthetically attenuated virus for new vaccines)					

European governance 'tools'



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ELSI issues	Tools for SynBio governance				
	<i>Laws, Regulations & Directives</i>	<i>Research Ethics, Evaluation & Funding</i>	<i>Norms, Values & Codes of Professional Conduct</i>	<i>Public Debate & Involvement.</i>	<i>Other?</i>
Horizontal gene transfer from accidental release of engineered bacteria or viruses					
Long and short-term safety & efficacy of SynBio products					
Dual use of synthetic virus engineering					
Overly narrow or broad patents on essential SynBio building blocks, stifling health innovation					
Moral legitimacy of patenting life (forms)					
Human enhancement & life extension					

Major governance challenges



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International Risk Governance Council (IRGC 2011): Appropriate risk governance for synthetic biology

Challenge 1

We don't know where SynBio will lead us in terms of health applications (problem of uncertainty)

Challenge 2

We don't know to what extent current regulations will be adequate to deal with future developments in the field of synbio and health (limitations of 'hard' law)

Challenge 3

We need to go beyond legal regulation to secure a socially robust development of synthetic biology (potential of 'soft' governance)

Challenge 4

We need to overcome antagonisms between technology and morality (limitations of ELSI approach)

Governance challenge 1



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We don't know where SynBio will lead us in terms of health applications

- SynBio as a combined development of (genetic and metabolic) platforms and specific trajectories of application, suggesting different innovation strategies
- Regulation as an important factor that will co-shape the field: indication that established practices of regulation – and perceived regulatory hurdles – are driving synbio in particular direction

Recommendation

European innovation policies need to be more strongly informed by the regulatory challenges and the strategic choices encountered by researchers in the field

Governance challenge 2



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We don't know to what extent current regulations will be adequate to deal with future developments in the field of SynBio and health

- Health related research in SynBio implies a move in cellular engineering from bacteria and plants to animals and humans, potentially undermine in a fundamental way the current paradigm of GMO risk assessment
- Health related research in SynBio will also strengthen current move to biologicals in medicinal product development, creating new challenges for regulation of medicinal products

Recommendation

European policies in GMO safety regulation and medicinal product regulation should address in an anticipatory mode new challenges resulting from future SynBio health applications, involving relevant regulatory agencies in these fields

Governance challenge 3



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We need to go beyond regulation to secure a socially robust development of synthetic biology

- How to govern a dynamic scientific world in which things are constantly changing? Should we rely (more) on self-regulation, based on a SynBio code of conduct?
- Role of research ethics committees in governing SynBio. Need for broader forms of feed-back of research ethics evaluations beyond individual projects
- How to move from narrowly defined discourse of 'risk' to broader public concerns about SynBio challenging deeply rooted conceptions and values in society?
- Need to shift away from technology-specific discussions about risks and concerns to a broader discussion of the societal goals that should drive research

Recommendation

Need for experiments contributing to the general aim of 'responsible research and innovation' (supporting iGEM community?!)

Governance challenge 4



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We need to overcome antagonisms between technology and morality

- Bioethicists as 'guardians' protecting the life sphere from technology rather than 'mediators' of the interaction between technology and ethics, thus reproducing a long-standing division of labour between technologists pushing innovation and ethicists putting a break on technology
- How to address the complexities of future techno-moral change in a way which fosters productive interaction between technology and ethics, also looking for ways in which technology might be helpful in achieving important societal (health) goals

Recommendation

Critically discuss ways in which synthetic biology might address important problems and goals of (global public) health and the conditions needed to achieve these aims