Preface

This discussion material is the result of a collaboration between the The Danish Board of Technology and the Danish Council of Ethics on synthetic biology taking place between April 2010 to April 2011. The intention was to highlight the synthetic biology debate in Denmark within a wider audience than that of the academic research environment.

Through dialogue with experts and other stakeholders with knowledge and interest in the subject, it has been the project´s aim to elucidate a new area of development in biotechnology and genetic engineering. We find it important to discuss the prospects for synthetic biology, while research herein is still in its infancy.

With this project we wish to convey:
1) Knowledge of how synthetic biology is characterized
2) Examples of potential applications of synthetic biology
3) Dilemmas and challenges associated with synthetic biology within research priorities, ethics, democratic management, risk assessment and regulation

The Council of Ethics and The Danish Board of Technology has established a working group for the project consisting of experts in biology, physics, chemistry, philosophy, risk communication and science communication. This group has defined the project's themes, contributed their professional knowledge and written drafts of the discussion material. In January 2011 the Council of Ethics and The Danish Board of Technology held a workshop on synthetic biology, where participants contributed to this discussion material.

This material is intended to initiate a debate, while offering suggestions on how we can handle further work on synthetic biology in a Danish context. The material does not contain any final assessments of potential and societal challenges related to synthetic biology.

The material is to be disseminated widely to various research groups, to businesses and to government agencies with a potential interest in synthetic biology. Since a major issue regarding the perspectives for synthetic biology is whether there is a need for new and specific legislation on this matter, the political sphere, as well as the authorities, is also targeted by the project. Moreover, the material is to be sent to participants in the project workshop, and to a broad group of existing contact institutions within The Danish Board of Technology and the Council of Ethics.

The working group on synthetic biology within the Council of Ethics has provided comments on various versions of this material. However, the material as such has not been reviewed by the Council of Ethics. The Council of Ethics and The Danish Board of Technology would like to thank the project's working group for a very committed effort, and for their major contribution to the formulation of discussion material.

Working Group Composition:
Birger Lindberg Møller, Faculty of Life Sciences, KU-LIFE
Gunna Christiansen, the Council of Ethics
Jacob Vedelsby, freelance journalist
Maja Horst, Department of Organization, CBS
Steen Rasmussen, the Faculty of Science, Southern Danish University
Sune Holm, Department of Media, Cognition and Communication, University of Copenhagen
Thomas Breck, Center for Risk Communication

Summary

The working group's rating of synthetic biology and approaches to advancing the debate:

The 21st century is characterized by a strong focus on new research within biotechnology and visions for, among others, a bio-based society including a number of potentially useful improvements for everyday life. It is expected that through biotechnological advances it will be possible to develop new or improved medicines, new sustainable materials, substitutes for harmful chemicals and new energy sources that are not based on fossil resources and which can control and reduce pollution. In addition, there is an ambition to obtain new fundamental knowledge of the "building blocks of life."

Meanwhile, the 21st century has been marked by a critical attitude to certain areas within biotechnology, based on experiences from the past decades' development of e.g. GM plants as well as research which some have perceived as ethically questionable. Biotechnology, genetic engineering research and development may not lead only to improvements and new sustainable solutions. They can also create negative consequences for humans, nature and the environment, and may reflect that a positive role of science and technology in society can not be taken for granted.

In all modesty it is hoped this discussion material will contribute to an open debate at an early stage in the development of synthetic biology, involving the positive expectations of that which research could ultimately result in, as well as new knowledge of the smallest units and basic functions of life. However, this material is also intended to present a more critical slant on synthetic biology. Including both positions is essential to avoid polarized society debates. This is also important when striving to attain socially robust research applications, strong research priorities and an informed societal position on research.

Synthetic biology can be described as an encounter between different disciplines. Currently, synthetic biology has much in common with traditional gene and biotechnology. However, it is driven by a vision to build living or lifelike structures that are designed to solve specific tasks, similar to the way engineers today build computers and machinery. Through the realization of these visions, molecular biologists and geneticists meet with e.g. nano-technologists, computer scientists and chemists. The result is not only the creation of technology and applications, but also the creation of fundamental knowledge about life. The vision of constructing living organisms from non-living elements has always been fascinating. So far it has only achieved success at the idea level - within a science fiction framework.

In summary, the working group behind this paper assesses:

• Synthetic biology is at such an early stage of development that there are ***good opportunities to be proactive in this area. This provides an opportunity to promote a broad interdisciplinary dialogue on the prospects for synthetic biology*** between

different researchers in the field, companies, authorities and grass root organizations - to create an open dialogue between private and public parties and stakeholders as well as between converging views and knowledge

• ***There is a need for an open interdisciplinary dialogue on synthetic biology***, focusing on:

- Increased opportunities for cooperation within Danish research.
- Potential applications of synthetic biology - within environment, energy, health, agriculture etc.
- Environmental and human health, ethical, legal and social aspects of synthetic biology - including the need to continually assess whether current regulation is appropriate.
- Prioritization of research funding based on Denmark's role in the international research community - the mapping of international research activities.

• ***There are limited risks associated with research in synthetic biology at its present stage, and that there is no need for new specific regulation in this area***.

• ***It is important to work toward a responsible management of research and development*** within synthetic biology - with vigilance on the part of individual researchers, institutions and authorities - to ensure the responsible development of new synthetic biological products.

• ***There must be an ongoing evaluation of the balance between the need for regulation and the need to pursue new research and development potentials***, as a way to maximize utility and minimize damage. It may be useful to have clear guidelines to achieve security and safety in biotechnology research and development, but these should not unduly impede researchers' development or impede their creative potentials.

• ***The general public is a key stakeholder, and should be continuously involved in the ethic and value debate*** - for example, on what synthetic biology should and should not be used for, to what extent it should be supported with public funding, on which risks are acceptable and on the social and cultural significance of synthetic biology.

• ***Synthetic biology will have global implications. It is essential that each country assumes responsibility for an international cooperation***, where synthetic biology's potential and necessary regulation will be a shared duty. The objective should be to attain transparency, information sharing, shared practices and coordination.

• ***Collaboration between researchers, developers, patent holders, businesses and governments must be encouraged*** in order to create synergies and strategies for innovation.

• ***Risk assessment should be more integral to biotechnology research*** - and not only presented in specific forums outside research. Additional specific tools capable of

controlling and regulating damage and risks related to synthetic biology research and development should be developed.