Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
in association with
Scientific Committee on Consumer Safety (SCCS)
Scientific Committee on Health and Environmental Risks (SCHER)

request for a joint scientific opinion:
on Synthetic Biology

1. Background

1.1 General introduction

Synthetic Biology (SB) aims at designing biological systems that do not exist in nature using engineering principles or re-designing existing ones to better understand life processes, to generate and assemble functional modular components, and to develop novel applications or processes[1]. This tends to lead to products that mainly produce, absorb or detect chemical substances of interest.

Therefore, Synthetic Biology offers the potential to create a group of major new industries. The development of these industries will likely have profound implications for the future of the European Union and other major economies. At the same time, there is scientific uncertainty on the development of such products associated with synthetic life, cells or genomes and their potential impact on the environment, the conservation and sustainable use of biological diversity and human health. In this context, a precautionary approach is required when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, in accordance with domestic legislation and other relevant international obligations.

Just as advances in synthetic chemistry had a major impact on the shaping of modern societal and economic structures in the 19th and 20th centuries, Synthetic Biology comes with promises of substantial benefits for health, the environment, resource management and the economy, when fully based on a precautionary approach and avoiding any harmful impact on the environment, the conservation and sustainable use of biological diversity and human health. Even though biotechnology has become an integral part of the modern chemical industry, the introduction of Synthetic Biology entails uncertainties and potential risks that deserve scrutiny.

1.2 Legal background

In December 2008, an EU Member States expert working group was established to analyse a non-exhaustive list of techniques (synthetic genomics included) for which it is unclear whether they would result in a genetically modified organism as defined under Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) and Directive 2009/41/EC on contained use of genetically modified (GM) micro-organisms. The Report of this group was finalized in December 2011. Given the fact that synthetic genomics (and more generally synthetic biology) is a fast-evolving field with a potential for very new developments as compared to what can be achieved with gene modification techniques currently listed in the Directives, the Working Group felt that the subject was too broad to discuss in the context of the working group.

[1] http://www.tessy-europe.eu/public_docs/TESSY-Final-Report_D5-3.pdf

1.3 Scientific background

The European Commission has been supporting research on the scientific and societal implications of Synthetic Biology as well as engaging stakeholders and promoting the exchange of information with and within the SB community via its Framework programmes for Research and Technological Development.

The multi-disciplinary nature and breadth of Synthetic Biology makes the assessment of the state-of-the-art, developments in and outside of the lab as well as the nature of foreseen applications and their time to market particularly challenging. Still, significant insights can be gained from a series of projects and reports. These projects and reports include

a) The outcomes of the NEST, FP6 and FP7 projects in the field of Synthetic Biology, funded by the European Commission. These projects involve variety of synthetic biology engineering approaches (e.g. minimal genome, standardisation, gene transcription, cell membrane), and applications (e.g., biocatalytic processes, diagnostic, drug development delivery, energy, bioremediation), but also embrace training, regulatory and societal aspects as well as governance and ethics. Please find a list of key FP6 and FP7 projects in the Annex.

b) The recommendations from the European Group of Ethics (EGE) outlined in its opinion on the ethical aspects of Synthetic Biology[2] -adopted on 17 November 2009 upon request from the President of the European Commission- on the need of risk assessment studies on current risk assessment procedures in the EU, including a survey of relevant bio-safety procedures.

c) The discussions held at the 5th meeting of Chairs and Secretariats of the EU Commission and Agency Scientific Committees and Panels involved in Risk Assessment, organised by DG SANCO in Brussels on 18-19 November 2009.

d) The conclusions of the workshop on Synthetic Biology: "From Science to Governance", organised by DG SANCO on 18-19 March 2010, that there is a need for an appropriate risk analysis and a systematic consideration of the relevant safety aspects, in order to facilitate a comprehensive assessment of this new technology.[3]

e) The increasing information on Synthetic Biology techniques, tools and applications published in the general press and in peer-reviewed journals, citing just as an example the recent announcement of the creation of a bacterial cell controlled by a chemically synthesized genome[4].

f) The international symposium on “Opportunities and Challenges in the Emerging Field of Synthetic Biology” held in July 2009 in Washington, DC, under the auspices of the United States National Academies, the Organisation for Economic Co-operation and Development and the Royal Society.[5]

g) Other relevant available scientific information from various stakeholders e.g.

[2] http://ec.europa.eu/european_group_ethics/docs/opinion25_en.pdf
[3] http://ec.europa.eu/health/dialogue_collaboration/events/ev_20100318_en.htm
[4] D.G. Gibson et al, Science. 2010 May 20. Epub ahead of print: http://www.sciencemag.org/cgi/rapidpdf/science.1190719v1.pdf
[5] http://www.oecd.org/document/28/0,3343,en_2649_34537_43106012_1_1_1_37437,00.html

European Molecular Biology Organisation.

2. Terms of reference

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is requested to answer the following questions through a joint opinion in association with SCHER and SCCS and if relevant other European Community bodies *e.g.* European Environmental Agency(EEA) and European Food Safety Agency(EFSA):

2.1 Scope and definition of the phrase "Synthetic Biology"

1. What is Synthetic Biology and what is its relationship to the genetic modification of organisms?

2. Based on current knowledge about scientific, technical, and commercial developments, what are the essential requirements of a science-based, operational definition of "Synthetic Biology"? These requirements should comprise specific inclusion and exclusion criteria, with special attention given to quantifiable and currently measurable ones.

3. Based on a survey of existing definitions, to which extent would the definitions available meet the requirements identified by the Committee as fundamental and operational?

2.2 Methodological and safety aspects

4. What are the implications for human and non-human animal health and the environment of likely developments in Synthetic Biology resulting or not in a genetically modified organism as defined in the Directive 2001/18/EC?

5. Are existing methodologies appropriate for assessing the potential risks associated with different kinds of activities, tools, products and applications arising from Synthetic Biology research?

6. If existing methodologies are not appropriate to assess the potential risks associated with activities related to and products arising from Synthetic Biology research, how should existing methodologies be adapted and/or completed?

7. How, when, and to what extent can safety (safety locks) be inherently built into products of Synthetic Biology?

8. The SCENIHR, SCHER, SCCS are asked to draw the blue print of a general procedure/strategy for designing inherently safe applications of Synthetic Biology.

2.3 Research priorities

9. The SCENIHR, SCHER, SCCS are asked to review the state of the scientific knowledge concerning specific risks to the environment and synthesise it following the procedure and the requirements mentioned in the Decision XI/11 of the Convention of Biodiversity and include the synthesis in its opinion.

10. Thematic workshops should be organised with relevant stakeholders in order to review the data and scientific knowledge synthesised and mentioned at point 9 in relation to particular risks or to broad risk assessment issues.

11. What are the major gaps in knowledge which are necessary for performing a reliable risk assessment in the areas of concern?

12. SCENIHR, SCHER, and SCCS are requested to provide research recommendations on the main scientific gaps identified in question 3. The recommendations should also include methodological guidance on the experimental design and on the requirements of the proposals, in order to ensure data quality and comparability, as well as the usability of the results for risk assessment.

3. Requesting services: SANCO, RTD, ENV, ENTR

4. Deadline

October 2014

ANNEX

FP6 and FP7 DG Research and Innovation have financed 27 Synthetic Biology projects.

FP6

SYNBIOLOGY: A European perspective on synthetic biology

BIOMODULARH2: Energy project promises a new biotechnology

TESSY: foundations for a European synthetic biology

SYNPLEXITY: Dynamics and complexity in synthetic protein networks (MOBILITY)

CELLCOMPUT: – Biological computation built on cell communication systems (NEST)

SYNBIOSAFE: Safety and Ethical Aspects of Synthetic Biology

FP7

KBBE-2007-3-3-01 Synthetic Biology for the Environment (CSA-CA): Targeting environmental pollution with engineered microbial systems a la carte (TARPOL)

KBBE-2009-3-6-05: Synthetic biology for biotechnological applications (CP-FP): Bacterial Synthetic Minimal Genomes for Biotechnology (BASYNTHEC)

KBBE.2011.3.6-03: Towards standardisation in Synthetic Biology (CP-IP): Standardization and orthogonalization of the gene expression flow for robust engineering of NTN (new-to-nature) biological properties (ST-FLOW)

KBBE.2011.3.6-04: Applying Synthetic Biology principles towards the cell factory notion in biotechnology (CP-FP): Products from methanol by synthetic cell factories (PROMYSE) and Code-engineered new-to-nature microbial cell factories for novel and safety enhanced bio-production (METACODE)

KBBE.2011.3.6-06: Synthetic biology – ERA-NET. Call FP7-ERANET-2011-RTD: Development and Coordination of Synthetic Biology in the European Research Area (ERASynBio)

SiS-2008-1.1.2.1: Ethics and new and emerging fields of science and technology: SYNTHETICS and SYBHEL

SiS.2012.1.2-1. Mobilisation and Mutual Learning Action Plans; Acronym: SYN-ENERGY