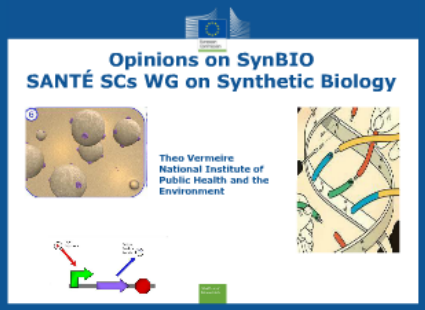
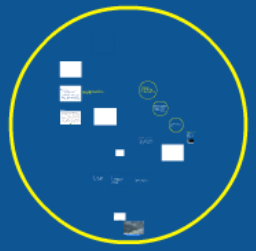
Introduction to the SCs and WG

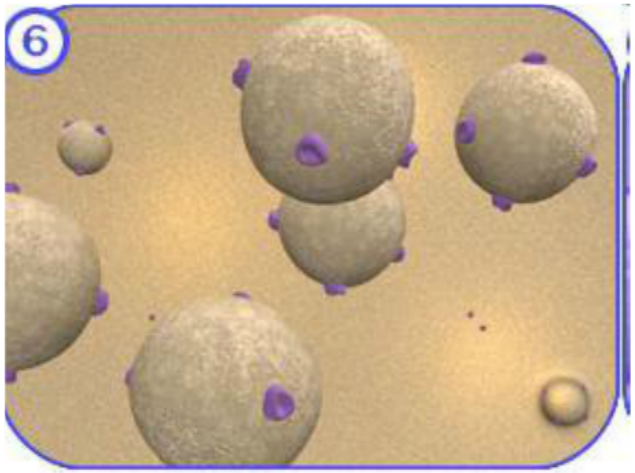


The Mandate

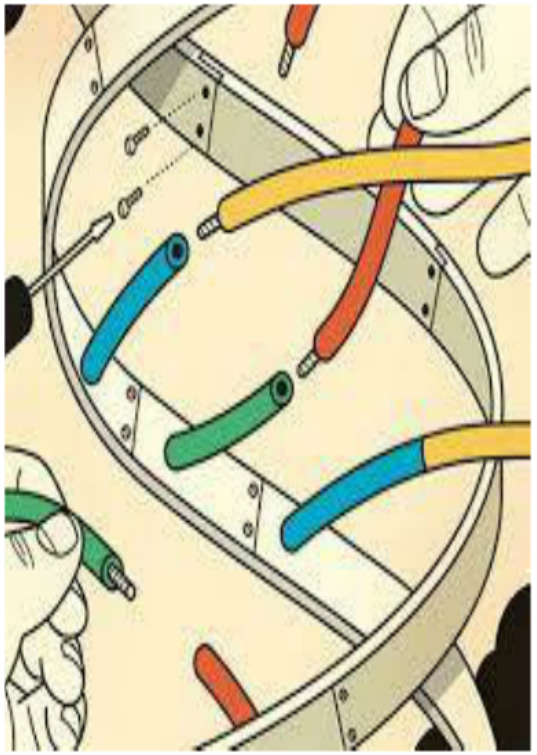
Opinion I

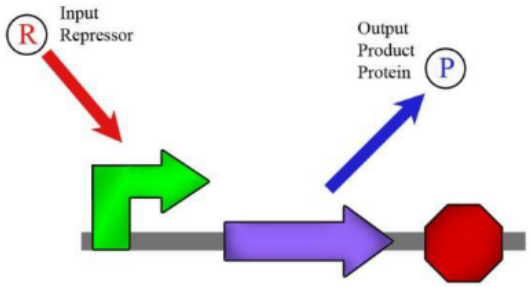


Opinions on SynBIO
SANTÉ SCs WG on Synthetic Biology



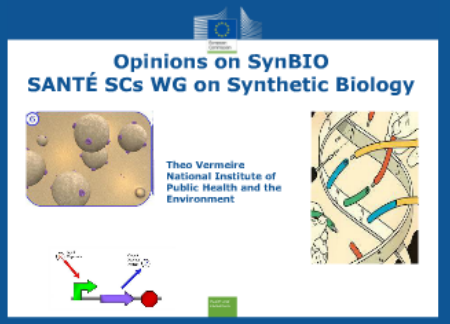
Theo Vermeire
National Institute of Public Health and the Environment



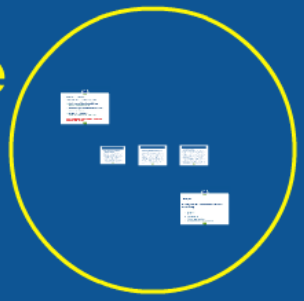


Health and Consumers

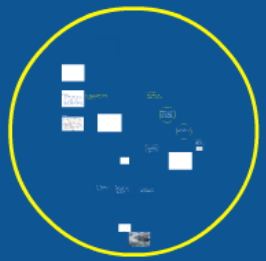
Introduction to the SCs and WG



The Mandate



Opinion I



Introduction to the SCs and WG

Introduction to the EC non-food Scientific Committees (SCs)

DG SANTE - Health Information and Scientific Committee Unit

Health and Food Safety

SCIENTIFIC COMMITTEES

The three independent non-food SCs (SCCS, SCHER, SCENIHR) ensure systematic assessment of risks, based on best practice for EU policy needs on health, consumers and environment.

Other EU risk assessment bodies:

- **European Food Safety Authority (EFSA)**
- **European Medicines Agency (EMA)**
- **European Centre for Disease Prevention and Control (ECDC)**
- **European Chemicals Agency (ECHA)**

SC on Emerging Newly Identified Risks SCENIHR

Mandates on:

- Emerging risks
- Newly identified risks
- Complex or multidisciplinary issues requiring comprehensive assessment
- Issues not covered by other bodies

SC on Health and Environmental Risks SCHER

Mandates on:

- Toxicity and eco-toxicity of chemical, biochemical and biological products
- Chemicals in toys
- Waste
- Environmental contaminants
- Drinking water quality
- Indoor and ambient air quality
- Endocrine disrupters

European Commission

SC on Consumer Safety SCCS

Mandates on:

- Risks related to consumer products (non-food)
- Cosmetics, Toys, Textiles, Clothing
- Household products
- Non-chemical risk: mechanical, physical, biological
- Consumer services: tattooing, tanning devices, etc.

Health and Food Safety

Health-EU newsletter 144 - Focus

Email version

Scientists examine the potential – and the risks – of Synthetic Biology

by Theo Vermeire, Head of Department Nanotechnology, Occupational Health and Transport Safety Centre for Safety of Substances and Products, RIVM, The Netherlands. Chair of the Scientific Committees Working Group on the SynBio Opinions

SCENIHR, SCHER and SCCS Opinions on Synthetic Biology

Synthetic biology (SynBio) has already delivered important products to the market such as yeast-synthesized artemisinin and biodegradable plastics produced from sugars. There is a potential for substantial contributions to medicine, materials, chemistry, food, nutrition, energy, sustainability, waste treatment, and safety. Yet, like for many new and emerging technologies, there is controversy leading to fierce debates on SynBio's potential for societal benefit, or risks.

The UN Convention on Biological Diversity held its 12th Conference of the Parties (COP 12) October, 6-17, 2015 in Pyeongchang, Republic of Korea. In a special session on SynBio, the Parties were urged "to take a precautionary approach ….when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology". The COP urged Parties to approve organisms resulting from SynBio techniques for field trials only after appropriate risk assessments are carried out. This recommendation was an important goal for the EU, ensuring a good balance between the potential of SynBio and the need for precaution on the issue. The EU had a middle position and provided an important scientific contribution to the development of definitions through a joint preliminary Opinion from its Scientific Committees SCENIHR, SCHER and SCCS.

This first Opinion, adopted by the SCs on September 26, 2014, answered questions from the European Commission on the scope and definition of SynBio. In late December 2014, the European Commission Scientific Committees issued a draft second opinion on whether existing risk assessment methods are adequate for SynBio. Early 2015, it will be followed by a third opinion on research priorities for risk assessment. These three opinions, which are written by an interdisciplinary Working Group of 20 experts from Europe and the United States, could significantly contribute to develop a European and global SynBio policy. Although security issues concerning SynBio are important, the terms of reference

WG SynBio

European Commission

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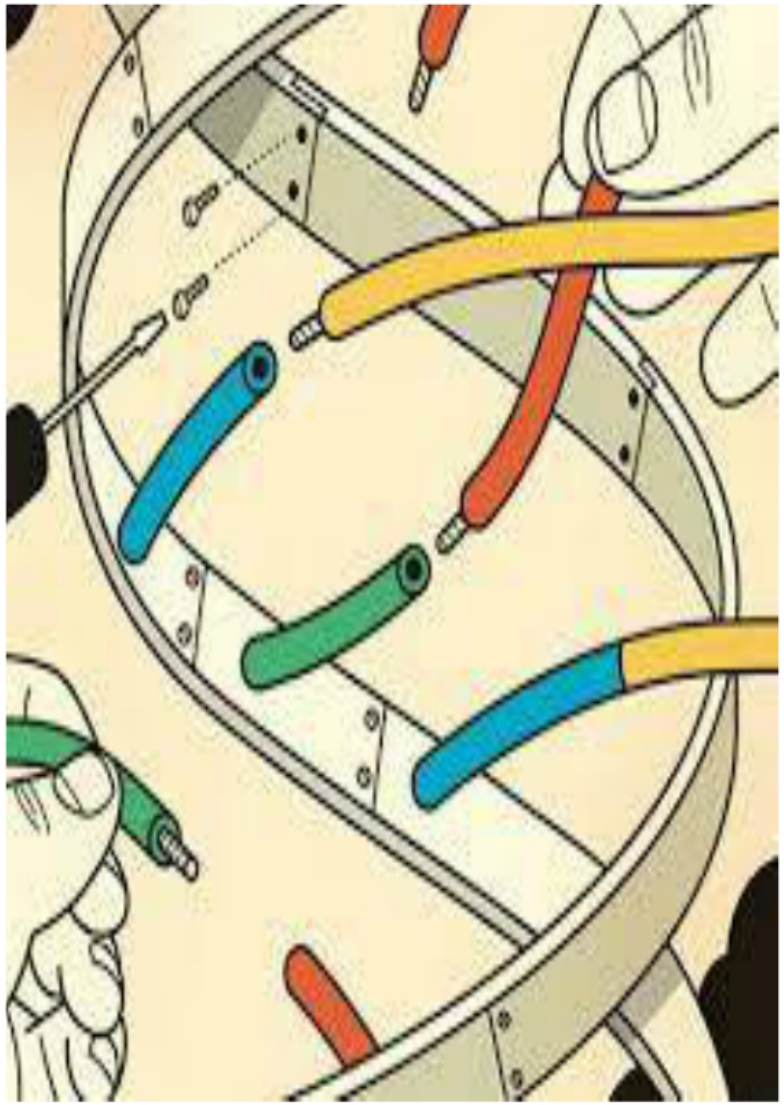

Health and Consumers

The Mandate

- Based on 11 questions
- Subdivided into 3 Scientific Opinions

1. **Definition of Synthetic Biology**
   (adopted September 26, 2014)
2. **Methodological and safety aspects**
   (adopted May 4, 2015)
3. **Research Priorities**
   (will be adopted by the end of the 2015)

http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm

European Commission

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?

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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?

Health and
Food Safety

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. 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.

Scope

Safety for the Foreseeable future excluding

- Security
- Social
- Governance
- Ethical implications
- Human embryonic research

Opinion I

Mandate Opinion I

Scope and definition of the phrase "Synthetic Biology"

European Commission

Mandate Question 1

Opinion I

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

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Genetic modification: the processes leading to the alteration of the genetic material of an organism in a way that does not occur naturally by mating and/or natural recombination

Introduction

- SynBio is currently encompassed within genetic modification as defined in the European Directives 2001/18/EC and 2009/41/EC and will likely remain so in the foreseeable future
- Existing definitions of SynBio emphasise modularisation and related engineering concepts as the main drivers
- But for risk assessment, an operational definition of SynBio derived from the working understanding of SynBio as a collection of conceptual and technological advances aiming to enable faster and easier design and manufacturing of GMOs is needed

Opinion I

European Commission

SynBio is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms.

- No focus on conceptual ideas like modularisation or standardisation
- For the risk assessment, an operational definition of SynBio is provided, which is derived from the working understanding of SynBio as a collection of conceptual and technological advances that aims to enable faster and easier design and manufacturing of GMOs. SynBio is seen as an extension of GM.
- It acknowledges the large existing body of regulations, RA and safety guidelines for biological and genetically modified material
- It also acknowledges that these guidelines need periodic updates due to the rapidly advancing nature of GM technologies.
- It therefore supports the need for on-going updates of risk assessment methods, addressed in Opinion II. Gaps in Opinion III.

Discriminating SynBio from GM

- SynBio is currently under the existing risk assessment and regulatory frameworks for GM
- Not clear how SynBio will go beyond the current GM framework
- Not clear what gaps will occur in the current risk assessment procedures for SynBio
- The basis of distinguishing SynBio and GM must be quantifiable with measurable inclusion and exclusion criteria

Criteria for discriminating SynBio from GM

SynBio covers any organism, system, material, product, or application resulting from introduction, assembly, or alteration of the genetic material in a living organism

Criteria do not deliver clear cut-off points or thresholds that scientifically discriminate SynBio from GM

Alone or in combination *these* are unable to differentiate SynBio from GM

- Complexity of the genetic modification
- Speed by which modification was achieved
- Number of independent modifications
- Degree of computational design methods used

Incl/excl Criteria: *not quantifiable/measurable*

Criteria discussed	Challenges
A considerable/substantial proportion of the resultant genetic material has been chemically synthesised	Although quantification of the amount or proportion of chemically synthesized genetic material is possible, any threshold would be arbitrary
The resultant genetic material or a part of it is newly designed	Although quantification of the amount of newly designed genetic material is possible, any threshold would be arbitrary
A significant proportion of the genetic material has been intentionally removed to develop a minimal functioning genome and/or a production chassis	Although quantification of the amount of removed material is possible, any threshold would be arbitrary
Standardised modular genetic parts have been utilised to rationally (re)design and assemble new or altered biological functions leading to new products; for example when a foreign pathway or genetic circuit has been introduced into a species in which it did not exist before	A limited number of standardised modular genetic parts have already been used in the past in GE. While SynBio tries to enhance this approach there is no agreed-upon parameter measuring the degree of standardisation.
A genetic construct that contains non-canonical heritable material	This criterion may be suited to discriminate xenobiology from other fields of SynBio, but does not help discriminating SynBio and GM.

European Commission

Mandate Question 2

Opinion I

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.

Health and Food Safety

1

The term ‘operational definition’ is understood as a working definition, meaning that the SynBio's definition is based on present knowledge and understanding of the field. However, this definition may evolve as the understanding of SynBio concepts, tools and applications evolves.

2

SynBio includes any activity that aims to modify the genetic material of living organisms as defined in the Cartagena Protocol on Biodiversity, i.e. “any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids” and in Article 2(1) of the Directives 2009/41/EC and 2001/18/EC (Annex V). Of course, this does not exclude the consideration of non-viable, non-reproducing goods and materials generated by or through the use of such living GMOs.

3

GM involves the modification of living organisms with heritable material, independent of the chemical nature of the heritable material and the way in which it has been manufactured. SynBio uses all available technologies for genetic modification, but in particular aims at the acceleration and facilitation of the process, which includes increasing its predictability.

European Commission

Mandate Question 3

Opinion I

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?

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1

Does not exclude the application to SynBio of the relevant and large body of Risk Assessment and safety regulations developed over the past 40 years for GM

2

Does not exclude extensions that account for recent technological advances, e.g.,

- Standardised genetic parts combined with circuit libraries and engineering methods
- Protocells Minimal cells and designer chassis
- Xenobiology
- Large-scale DNA synthesis
- Whole-genome editing

3

This definition allows for the rapidly advancing nature of GM technologies and need for ongoing updates of risk assessment methods

When talking to regulators and the public, synthetic biologists tend to emphasize "continuity with the past" and safety; when talking to prospective funders, they emphasize novelty (Tait 2009, 150).

Even within scientific communities, there are differences of opinion whether synthetic biology is revolutionary or an incremental advancement of biotechnology (Zhang et al. 2011).


THANK YOU
NEXT: SC SYNBIO OPINION II

Incl/excl Criteria: *not quantifiable/measurable*

European Commission

Criteria discussed	Challenges
A considerable/substantial proportion of the resultant genetic material has been chemically synthesised	Although quantification of the amount or proportion of chemically synthesized genetic material is possible, any threshold would be arbitrary
The resultant genetic material or a part of it is newly designed	Although quantification of the amount of newly designed genetic material is possible, any threshold would be arbitrary
A significant proportion of the genetic material has been intentionally removed to develop a minimal functioning genome and/or a production chassis	Although quantification of the amount of removed material is possible, any threshold would be arbitrary
Standardised modular genetic parts have been utilised to rationally (re)design and assemble new or altered biological functions leading to new products; for example when a foreign pathway or genetic circuit has been introduced into a species in which it did not exist before	A limited number of standardised modular genetic parts have already been used in the past in GE. While SynBio tries to enhance this approach there is no agreed-upon parameter measuring the degree of standardisation.
A genetic construct that contains non-canonical heritable material	This criterion may be suited to discriminate xenobiology from other fields of SynBio, but does not help discriminating SynBio and GM.