



Federal Ministry
of Health



State of discussion regarding synthetic biology in Germany

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Some of the notes presented may reflect my personal views and do not necessarily reflect the perspective of the MoH nor of the Federal Government.



Characteristic of synthetic biology

SynBio is a typical example of a

hope -

– many hopes are linked to it (currently more or less theoretically).

hype -

– some of these go far beyond what will be possible in the near future and seem to ,hype‘ the field.

fear -

– due to the enormous (theoretical) possibilities of intervention in organisms as well as to its dual use character, synthetic biology is associated with fears.

technology.



High potential for medical innovations

Example 1: *E. coli*-strain engineered to make protein which binds specifically to *Pseudomonas aeruginosa*, binding activates 1) toxin production within *E. coli* cells and 2) protein generation which causes *E. coli* cells to burst and set free the toxin against *P. aeruginosa* (*Mol. Syst. Biol.* 7, 521 (2011)).

Example 2: Opium synthesis: production of a key intermediate from glucose by engineered *Saccharomyces cerevisiae* (*Nat. Chem. Biol.* 11, 465 (2015)).

Example 3: Alterations in A/H5N1-virus making them virulent to humans by airborne transmission (*Science* 336, 1534 (2012)).

Example 4: In vitro synthesis and characterisation of the 1918 Spanish Influenza Pandemic Virus A/H1N1 (*Science* 310, 77 (2005)).

Examples 3 & 4:  **Dual use research of concern (DURC)**



Conflicting priorities regarding synthetic biology

research,
development,
production



freedom of sciences:
article 5, basic law for FRG

accidental release,
protection of
researchers and
environment



biosafety

conflicting priorities

deliberate misuse,
maintain public health



biosecurity



Supranational legal provisions

- Cartagena Protocol on Biosafety
- Convention on the Prohibition of the Development, Production and stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction
- Regulation (EC) No1829/2003 (GMO food and feed)
- Directive 18/2001/EC (deliberate release of GMO)
- Directive 2009/41/EC (contained use of GMO)
- Regulations (EC) No 428/2009 and 388/2012 (Dual use)
- Directive 2000/54/EC (Protection of Workers from Risks Related to Exposure of Biological Agents at Work)

- Directive 2001/83/EC (Pharmaceuticals)
- Regulation (EC) No 1394/2007 (Advanced Therapies Medicinal Products)
- ...

Important to note: Current discussion under Convention on Biological Diversity



Legal provisions in Germany

- Gentechnikgesetz (Act on Genetic Engineering)
- Biostoffverordnung (Biological Agents Regulation)
- Kriegswaffenkontrollgesetz (War Weapons Control Act)
- Außenwirtschaftsgesetz (External Trade and Payment Act)
- Infektionsschutzgesetz (Act on the Prevention and Control of Infectious Diseases in Man)
- Tierseuchengesetz (Epizootic Disease Act)

- Arzneimittelgesetz (Medicinal Products Act)
- ...



Policies/Codes of Conduct

Industry

International Gene Synthesis Consortium: *Harmonized Screening Protocol* (2009)

Industry Association Synthetic Biology: *Code of Concuct for Best Practices in Gene Synthesis* (2009)

BIO Deutschland: *Positionspapier Biosicherheit – die Dual-Use-Problematik* (2008)

...

Research organisations

Deutsche Forschungsgemeinschaft (German Research Foundation, 2008/2013),

Max Planck-Society (2010), Leibniz-Association (2012), ...

Institutions

Robert Koch Institute (governmental body for safeguarding public health), ...



Public debate

The hope, hype and fear about synthetic biology has lead to a public debate on its

(chances,)

risks and

regulation.



Central Committee on Biological Safety

Opinion *First Monitoring Report* (2012):

- projects on synthetic biology conducted in Germany so far fall into the scope of the Act on Genetic Engineering (exemption: synthesis of nucleic acids).
- these projects do not reveal a biosafety risk which differs from that of 'conventional' genetic engineering experiments.
- This risk can be addressed by the provisions of risk assessment and risk management laid down in the Act on Genetic Engineering.



German Ethics Council

Opinion *Biosecurity – Freedom and Responsibility of Research* (May 2014):

- the legal provisions in force are directed mainly to biosafety issues,
- no coherent (international) legal system exists for preventing misuse of DURC.



German Ethics Council

Inter alia:

- raising the level of awareness for questions of biosecurity in the scientific community
- **elaborate a national biosecurity code of conduct for responsible research defining what constitutes a responsible manner of dealing with biosecurity questions**
- fund only scientists complying with the code of conduct
- **appoint a central DURC commission at national level**
- **legally define DURC**
- establish the obligation to consult the DURC Commission prior to commencement of DURC
- set up a world wide, uniform and as far as possible binding definition and classification of DURC under international law.



German Bundestag – Committee on Education, Research and Technology Assessment

Hearing on Scientific Responsibility (Nov. 2015),
seven invited experts:

- dual use is not a specific problem to life sciences but to science in general
- decisions can only be made on a case by case basis
- the scientists are responsible for their experiments**
- responsibility/awareness raising should be part of education and training
- establishment of commissions on ethics in research at local level**
- establishment of a central commission on DURC which deals with high impact projects**
- not possible to comprehensively legally define DURC**
- therefore, close monitoring is recommended
- ...



Office of Technology Assessment at the German Bundestag

Final report: *Synthetic Biology – next step in biotechnology and genetic engineering*
(to be published soon),

- scientific-technological questions
- issues related to ethics,
 - >biosafety,
 - >biosecurity,
 - >intellectual property rights,
 - >governance and regulation,
 - >public perception,
 - >communication matters.



Summary

Synthetic biology holds high potential for innovations in medicine.

Synthetic biology comprises dual use research of concern.

Currently, the legal provisions including Codes of Conduct in force seem to cover ongoing research.

Opinions by organisations, institutions and committees are important contributions to the debate in Germany.

So far, it is premature to draw conclusions from this ongoing open discussion.