Project title:

# Investigating the biosafety and risk assessment needs of synthetic biology in Austria and China

Principal investigators

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| **Dr. Markus Schmidt**<br>Organisation for International Dialogue and Conflict Management<br>Biosafety Working Group<br>Vienna, Austria<br>email: markus.schmidt@idialog.eu | **Dr. Wei Wei**<br>Institute of Botany,<br>Chinese Academy of Sciences<br>Beijing,<br>PR China<br>Email: weiwei@ibcas.ac.cn |

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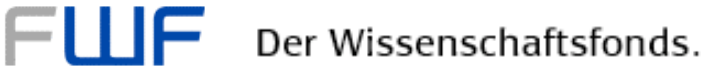

# Introduction

Fast becoming one of the most dynamic new sciences and engineering fields, synthetic biology has the potential to impact many areas of society. Synthetic biologists may use artificial molecules to reproduce emergent behaviour from natural biology, with the goal of creating artificial life or seek interchangeable biological parts to assemble them into devices and systems that function in a manner not found in nature. Approaches from synthetic biology, in particular the deliberate synthesis of complex, biological systems, have the capacity to change the way we approach certain key technologies and applications in biomedicine (e.g. in-vivo synthesis of pharmaceuticals, vectors for therapy), biochemistry (e.g. extension of the genetic code, non-natural proteins, bio-orthogonal reporters), environment (e.g. bioremediation, GMO biosafety), energy (bio-hydrogen production), defence against biological weapons, or materials science (e.g. for information technology, biosensors). Its potential benefits, such as the development of low-cost drugs or the production of chemicals and energy by engineered bacteria are enormous. There is, however, also the possibility of deliberate or accidental damage to humans, agriculture or the environment.

The possibility of laboratory synthesis of select agents (dangerous pathogens) raised important questions on biosecurity (i.e. the intentional misuse) that synthetic biology will have to face in the future, especially as the technology becomes cheaper, more powerful and more widely available. In response to this challenge for synthetic genomics, first self-regulation attempts and options for governance have been developed by science and industry.

Most comments and papers on potential risks of synthetic biology from the US focus on security aspects. We think, however, that it is necessary to start focusing on the safety issues involved, especially when keeping in mind the negative public reactions towards GMOs in Europe. This is why we foresee that concerns in Europe and possibly China – in contrast to the US – could focus more about safety issues than security issues of synthetic biology. In order to ensure a vital and successful development of this new science and technology field it is absolutely necessary to gather information about these risks and to devise possible strategies to minimize them.

In contrast to potential biosecurity implications in synthetic biology, only few papers discussing biosafety have been published so far, although frequent calls to address safety issues in synthetic biology voiced at conferences[1], meetings etc. by scientists and non-scientists, as well as research funding agencies.

[1] e.g. at the Synthetic Biology 2.0 (Berkeley) and 3.0 (Zurich) conference. See: http://pbd.lbl.gov/sbconf/ and http://www.syntheticbiology3.ethz.ch/

## *Aims*

Synthetic biology can be understood as the application of engineering principles to biology. Whereas in "genetic engineering" the term engineering is used as a metaphor, in synthetic biology it is a methodology. In a sense synthetic biology is the next development step after genetic engineering. Our objective is to provide better scientific insight into the challenges synthetic biology addresses in the field of biosafety and risk assessment. This objective – we think- is best tackled from an international perspective, including a central European (Austria) and Chinese approach.

We will pursue our objectives in three different steps:

1) analysing the current developments in synthetic biology and its different subfields; with a special focus on (central) Europe and China
2) investigating the biosafety (and to a lesser extent security) implications of synthetic biology;
3) review current biosafety regulations and prepare recommendations to improve existing biosafety assessement frameworks

The community has recognized the need to address safety concerns in synthetic biology, but up to now discussions are only fragmentary and rather limited to few groups in Europe and the US. Our project aims to stimulate an international debate by contributing to the establishment of a (European) - Chinese network of researchers investigating the biosafety aspects of synthetic biology.

Synthetic biology is becoming one of the hottest new fields of biology, with the potential to no less than revolutionize the way we do biotechnology today. By applying the toolbox of engineering disciplines to biology, a whole set of potential applications become possible ranging very widely across scientific and engineering disciplines. In order to ensure a vital and successful development of this new scientific field - in addition to describe the potential benefits - it is absolutely necessary to gather information also about the risks and to devise possible biosafety strategies to minimize them. Also, security issues of synthetic biology just start being explored, with hardly any researcher in Europe or China specifically focusing on the area of synthetic biology. While few undertakings on safety and security have recently started in the US, only one pilot project (SYNBIOSAFE) in has been carried out on a European level to investigate these aspects and – to our knowledge - not a single project has been carried out in China. Our project is the first European - Chinese project that focuses particularly on the safety (and security) concerns and tries to facilitate a successful and socially acceptable development in synthetic biology.

## Relevance to the research area

Most comments and papers on potential risks of synthetic biology from the US focus on security aspects. We think, however, that it is necessary to start focusing on the safety issues involved, especially when keeping in mind the negative public reactions towards GMOs in Europe and the lacking approval of GM rice for markets in China (even though large investments were made to develop these GM varieties). This is why we foresee that in Europe – probably in contrast to the US – the general public, the media, NGOs and most scientists could be more concerned about safety issues than security issues of synthetic biology.

Also recent analyses of the biosafety framework in China have shown that the Chinese and European biosafety regulatory systems (including risk assessment, labelling) have much more in common that either of both have with the system in the US. Following Tucker and Zilinskas (*The New Atlantis* 2006: 31) three categories of potential risks from developments in synthetic biology have to be distinguished.

> *"First, synthetic microorganisms might escape from a research laboratory or containment facility, proliferate out of control, and cause environmental damage or threaten public health. Second, a synthetic microorganism developed for some applied purpose might cause harmful side effects after being deliberately released into the open environment. Third, outlaw states, terrorist organizations, or individuals might exploit synthetic biology for hostile or malicious purposes."*

The likelihood of these risks materializing will in part depend on the degree of diffusion of SB knowledge and skills. Given the de-skilling agenda - or in other words to make it easier for non-professional biotechnologists to produce novel life forms - it would seem prudent to expect large-scale diffusion and conceptualize governance measures accordingly so as to prevent the above risks from becoming reality.

From an Austrian, a European and a Chinese governance perspective, several questions need to be addressed in order to prevent the most serious risk, in order to enable a sustainable and safe development.

## *Work- and timetable*

Based on the recently finished project SYNBIOSAFE - a SSA FP6-NEST project working to identify new ethical and safety aspects in synthetic biology –coordinated by Markus Schmidt, the proposed project aims to find similarities and differences in the way new biosafety challenges are tackled by Chinese and European scientists and regulatory boards.

## Workplan

We divide our work into several work packages (WP):

**WP 0: Coordination and management of project**

In this WP we will carry out regular coordination and management tasks for the project, including the organisation of regular project meetings between the Chinese and Austrian partners.

**WP 1: Analyse latest developments in synthetic biology**

This WP analyses the current developments in synthetic biology and its different subfields; with a special focus on those ongoing in (central) Europe and China.

**WP 2: Investigate the safety implications of synthetic biology;**

Based on WP 1 we will identify and analyse new safety issues in SB, in other words those not present in traditional biotechnology and recombinant DNA work. Also we will look into risk assessment practices and analyse its shortcomings towards their application in synthetic biology.

**WP 3: Review current biosafety regulations**

Based on WP 2 we will review current biosafety regulations to find out to what extend they can handle the latest cutting-edge developments of synthetic biology and their potential applications.

**WP 4: Prepare recommendations**

In this WP we will summarize the results from the previous WPs and prepare our conclusions and recommendations on how to improve existing biosafety and risk assessement frameworks in order to handle the next generation biotechnologies spearheaded by synthetic biology.

**WP 5: Dissemination and Communication**

We will set up a website to inform about our work, including an interactive section to discuss these issues with a broader audience. We will provide information on European and Chinese synthetic biology initiatives, and on biosafety and risk assessment experts to provide a comprehensive overview of key stakeholders in this field.