Statement

Synthetic Biology II Risk assessment methodologies and safety aspects

Verband | Biologie, Biowissenschaften & Biomedizin in Deutschland

Background
In December 2014 the European Commission (DG Health and Food Safety) and its Scientific Committees have launched a public consultation on the preliminary opinion on Synthetic Biology II– Risk assessment methodologies and safety aspects.
German Life Science Association (VBIO e. V.) participated in the following Public consultation as documented here.

References
http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_26_en.htm
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_048.pdf

3.1 Introduction

Page 11, line 30ff

The SCs preliminary opinion discusses risk assessment classified as „technologies and methods (mostly) evolved from genetic engineering“. Given this background structure, the inclusion of Citizen Science (e.g. Do-It-Yourself Biology - DIY Biology) seems misguiding as it is neither a technology nor a method of engineering. Citizen Science is specified by the Person doing Science (Synthetic Biology) in a certain framework of facilities apart of professional research infrastructures. We agree that DIY Biology raises questions on training, safety, security, compliance and supervision that need to be addressed. But as a matter of rigidity we recommend to include all special consideration concerning Citizen Science under 3.2 Risk governance (page 14ff).

3.2 Risk governance

Page 14, line 29ff

The preliminary opinion states that “Risk governance can be at the level of authorities, but also ´self-governance´ should be recognised as an important contribution toward safety”. We agree with the opinion. However, we wish to indicate that both approaches might be in fragile relationship to each other. In fact, bureaucratic procedures issued by authorities may not enforce self-governance structures.

Page 14, line 43/44

As biosecurity issues are not the main scope of the SCs, we understand that the SCs in its preliminary opinion focused on biosafety. Still, we would like to encourage the SCs and its members to actively participate in future discussions on biosecurity aspects potentially associated with Synthetic Biology. The SCs profound knowledge of Synthetic Biology will be needed there, too. In case of formal obstacles that prevent SCs to take part in the biosecurity discourse in EU bodies, we ask you to ensure that evidence-based scientific knowledge on Synthetic Biology will be carefully considered.

Page 15, line 5ff
As we agree with the statements given on page 14, lines 7 - 16, we support the idea that „those involved in SynBio must be proactive in explaining both the pros and cons of particular novel important developments“. However, we disagree with the following apodictic statement that „it is best to have a process that is *independent* of Synthetic Biologists (…)“. In our opinion, the process of explaining pros and cons must be based on topical scientific evidence provided by Synthetic Biologists, who are involved in it, directly or indirectly. In addition, excluding Synthetic Biologists from that process will heavily undermine the claim in line 4 („those involved in SynBio must be proactive in explaining both the pros and cons of particular novel important developments“).
We kindly suggest revising this phrase to ensure that biological evidence has to be included in the process.

Page 15, line 16ff
Amongst others the preliminary opinion recommends to give consideration „to relevant education in schools“. We certainly understand that school curricula are national or federal matters. In terms of promoting best practice we would nevertheless recommend that the Commission supports suitable educational programs. This is beyond the scope of the SCs, but we would appreciate if the SCs would consider and advocate such a commitment in future discussions within the EU Commission.

Page 15, line 20ff
Synthetic Biology is quickly evolving and we support the opinion that this has to be reflected by academic education as well as by professional training. Courses should be accessible and affordable to a growing audience (also including DiY biologists). Training can be integrated into on-campus programs or offered as MOOCs, which will be suitable tools to ensure sufficient spread of knowledge. Within the framework of self-governance MOOCs might serve as an important tool. Considering the rapid developments within Synthetic Biology (and the corresponding MOOCs) it will hardly be possible for individual MOOCs to undergo a complex accreditation process. We alternatively suggest that the SCs encourages the initiation of a project to develop a set of minimal criteria for communication via MOOCs, or for training in the field of Synthetic Biology.

Page 16, line 1-4
We support the opinion that the mentioned issues are „frequently raised following a major technological development and none of these individual concerns is unique to SynBio“. For us, the summation of these considerations does not justify a ‘unique’ ethical concern for issues related to Synthetic Biology.

3.3 Implications of SynBio
Page 16, line 16
The SCs considers the assessment of risk guidance documents such as those issued by the GMO panel and/or the GMO unit of the European Food Safety Authority (EFSA). We recommend that existing risk guidance, e.g. for genetically modified organisms (GMOs) such as plants, animals and micro-organisms as well as environmental risk assessment of medicinal products should be evaluated and updated first, wherever and whenever appropriate. This process should be based on current scientific evidence. Any new risk guidance on SynBio – if necessary at all – therefore needs to refer to already existing relevant guidance, whenever possible, in order to provide a distinct European policy and legislation that is clear for all those implementing it.
We are concerned that the lack of clear indication of where the guidance is different from already existing assessments will put legislative and executive bodies on national level at risk of unintentional non-compliance.

Page 16, line 34ff
We agree with the SCs that „reasonable estimations of future developments are difficult“ and support the proposal to revisit „risk assessment methodologies for SynBio at regular intervals“. For these regular reassessments as well as for the general evaluation in 10 years from now, we suggest an open process, encouraging all relevant stakeholders to contribute.

3.4 Risks related to SynBio Tools, Technologies and Methods
Page 27, line 11-13:
We support the idea to „streamline and standardise across EU member states the methods for submitting genetic modification data and genetic parts information to risk assessors“. A maximum of transparency is desirable. However, it has to be considered that a forced complete disclosure might discourage scientists to submit confidential business information to the risk assessors.

4 OPINION
Page 45, line 39-40:
We encourage a product- rather than a process-based approach since it is the characteristics of the product which determine its risk, not the techniques which led to the product.

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