

Statement

Response of German Life Science Association (VBIO e. V.) concerning the public consultation on the “Preliminary Opinion on Synthetic Biology I – Definition“, launched by the European Commission.



Background

German Life Science Association acknowledges that the European Commission has initiated a comprehensive discussion on Synthetic Biology. This discussion is aimed to find the position of EU to this complex field of research and possible application. It partly interferes with other fields of modern biology which are highly disputed within society. Therefore, the issue of Synthetic Biology (SynBio) should be discussed with sense of proportion, taking the time which is needed.

We recognize that the EU Commission has already defined three milestones: Opinion 1 (definition), opinion 2 (risk assessment methodology, safety aspects) and opinion 3 (research priorities). Nevertheless the milestones are likely to interfere and we would like to strengthen the process character of the discussion. As Synthetic Biology is evolving very fast, any kind of definition (opinion 1) will remain preliminary (see also p. 5 28ff). This should be recognized in later stages of the discussion on opinion 1 and the following debates on opinion 2 and 3.

Opinion

We doubt, that the proposed definition (“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 to alter living or non-living materials.”) meets the predefined benchmark to provide an “operational definition of Synthetic Biology“. In our view it lacks discrete, scientific criteria which distinguish Synthetic Biology from conventional gene technology. Therefore in practice it does not allow to distinguish a certain research activity as practicing Synthetic Biology or not. But at least at the point of risk assessment (opinion 2) or defining research priorities (opinion 3), a strict and clear definition is a prerequisite.

Moreover: This lack of accuracy might lead to define research activities as „Synthetic Biology“ which are already regulated by other EU legislation. This kind of double coverage has to be avoided. (see also p. 15 39ff „Although SynBio is a relatively new field, the existing regulations applicable to biological, chemical or genetic modification research and products are also applicable to SynBio research, applications and products and Annex IV).

Our recommendations for further discussion

- The definition of Synthetic Biology should be modified to make it more specific and usable. To reach this objective an enhanced further dialogue with practitioners from academia (and industry) is strongly recommended to provide a selective, reliable and thus operable definition for Synthetic Biology.
- Definition (and in the long run possibly regulation) should focus on the construction of completely new pathways using multiple genes from different species or de novo synthesis of living entities.
- Whatever definition will be the outcome: All activities, which fall under this definition but are already regulated by other EU Regulations need no special regulation under the head “Synthetic Biology“. In particular organisms or natural products that are generated by gene technology need not to be covered and vice versa. In case emerging tools of gene technology challenge the existing regulations of gene technology the latter ones might be adapted within its separate rationale.

German Life Science Association will follow the ongoing process of definition, risk assessment and research priorities in the field of synthetic Biology. We are willing to bring in the expertise of our members and member societies.

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