

**TEMPLATE FOR PEER REVIEW COMMENTS
TECHNICAL SERIES ON SYNTHETIC BIOLOGY**

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Comments on the Technical Series on Synthetic Biology		
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<p>General</p>	<p>0</p>	<p>VBIO, the German Life Sciences Association (www.vbio.de), represents the interests of professional societies in the life sciences, including teacher associations, with over 25,000 members of all life sciences backgrounds.</p> <p>GASB, the German Association for Synthetic Biology (https://www.synthetischebiologie.org), represents over 100 scientists and university students in the field of synthetic Biology.</p> <p>We advocate not only for the freedom of life science research, but also for its ethical, safe and secure conduct, as well as compliance of all stakeholders to all respective regulations.</p> <p>1. Definition of Synthetic Biology</p> <p>VBIO and GASB have already commented on the topic of Synthetic Biology in the run-up to SBSTTA in 2018 (https://bch.cbd.int/database/record.shtml?documentid=113239). Regrettably we have noticed that, in the last three years, no observable progress towards a clear definition of Synthetic Biology was made. A clear distinction between methods and applications is missing throughout the text and both are subsumed under the generic term Synthetic Biology. In this regard, we consider the IUCN Assessment of Synthetic Biology and Biodiversity Conservation (https://www.iucn.org/theme/science-and-economics/our-work/other-work/synthetic-biology-and-biodiversity-conservation/development-iucn-policy-synthetic-biology/iucn-assessment-synthetic-biology-and-biodiversity) a more concise starting point for defining Synthetic Biology.</p> <p>Without a clear definition, a rigorous assessment of the claims and statements within this document is impossible. We are very much aware of the difficulties in finding a common definition. We take note that varying definitions and terminologies are used in different countries. At the same time, we are also aware that the insistence on a generally agreed definition, as well as the argument that synthetic biology is not definable at all, are in themselves strategies to block the political process from moving forward.</p> <p>A possible way ahead and a lesson learned can come from the topic of Digital Sequence Information (DSI). At the last AHTEG on DSI (https://www.cbd.int/doc/c/ba60/7272/3260b5e396821d42bc21035a/dsi-ahteg-2020-01-07-en.pdf), four potential definitions for DSI were taken up as a starting point for discussions. Having several potential definitions, ranging from the narrowest to the broadest, would help to avoid inadmissible equivalencies being drawn (e.g., genome editing with gene drives), without the need to decide on a final definition. It could then be assessed for every definition whether Synthetic Biology is a New Emerging Issue and whether and what type of further regulation is needed.</p> <p>2. Gene drives</p> <p>Gene drives can be a new tool to support conservation efforts, but at the same time they pose the highest risks for biodiversity. Defining what constitutes a Gene drive and what does not is difficult, but Alphey et al. provide a very good starting point (https://doi.org/10.1073/pnas.2020417117) that should be elaborated upon.</p> <p>In any case, gene drives are only one very specific tool of Synthetic Biology, even in the narrowest definition. A clear distinction should be drawn here, especially towards methods of industrial biotechnology that take place in contained settings. It may even make sense to separate the topics of Synthetic Biology and Gene drives, due to the large differences.</p>
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9 (11)	31f	<p><i>“.... those likely to fall under regulation will be subject to a thorough analysis of their different potential impacts on biodiversity-related issues as well as cultural, social, ethical and economic considerations.”</i></p> <p>That is certainly correct. In our understanding a specific risk assessment is necessary for each single product (see p56, c43). Keeping that in mind – due to the lack of a proper definition in this text – a wide range of methods and application will be covered; we doubt that this broad assessment approach will be feasible in practice and can meet the requirements adequately.</p>
9 (11)	34f	<p><i>“The potential of the synthetic biology toolbox is boundless, and so are the opportunities for synthetic biology to have an impact in an unprecedented manner.”</i></p> <p>The potential of the synthetic biology toolbox is expanding - but it is certainly not “boundless”.</p> <p>The impact of synthetic biology might be significant – but the impact of low-tech approaches can be even bigger. For example, the global use of concrete for construction, a low-tech product several centuries old, has increased dramatically over the last decades and we just experience in an “unprecedented manner” its impact on CO2 emissions and climate.</p> <p>↪ <i>We suggest rewriting the statement avoiding the terms “boundless” and “unprecedented”</i></p>
10 (12)	1ff	<p><i>“The value of the synthetic biology market has increased exponentially.”</i></p> <p>From the fact that the market for synthetic biology products has grown, a special need for action or regulation is derived. This is an unjustified linkage and not convincing. However, this section is particularly misleading and gives a wrong impression, as the definition of Synthetic Biology in this market analysis differs significantly from the topics addressed in this document. The markets and applications in the cited study focus on closed-system applications. These applications neither utilize biodiversity nor have any impact on biodiversity specific to synthetic biology, if already existing regulations are met.</p>

10 (12)	23	<p><i>„Despite its potentially global deployment, research and development in synthetic biology mostly occurs in a limited number of countries “</i></p> <p>We agree that the potential of Synthetic Biology is not fully used by every country and that this gap needs to be filled. As a positive example, we want to name specifically the iGEM competition (https://igem.org/Main_Page), which helps greatly to disseminate Synthetic Biology around the globe.</p> <p>At the same time, however, we note that, in some countries, the total R&D in Synthetic Biology comes down to a single iGEM team made of university students. Whilst acknowledging the differences in structure and amount of funding, we would like to point out that the mentioned gaps often result from divergent political priority settings, too. Some countries could certainly put in more effort, both in terms of funding and policy, to support the deployment of Synthetic Biology in their country.</p> <p>However, the cited figures would be more convincing if comparative figures on the distribution of research funds and projects from other areas of the life sciences were provided, as well as the total amount on funds spent for R&D projects. The figures seem to reflect the general disparity in research funding between countries, and more efforts towards technology dissemination and scientific collaboration are certainly needed.</p> <p>↪ <i>We suggest that the special funding asymmetry in the field of synthetic biology be supported by a comparison with corresponding key figures from the field of life science research. Furthermore, an overview of national funding strategies and roadmaps for synthetic biology could be helpful</i></p>
11 (13)	28ff	<p><i>Communication, engagement and transparency</i></p> <p>We recognize the need for early involvement of stakeholders and transparency. And, as scientists, we have to acknowledge that societal expectations can change and do not always harmonize with our views. However, what we do expect is a fair and open dialogue based on scientific facts and mutual respect.</p> <p>Issues of biosecurity and dual use certainly must be considered in overall regulation as well as in communication. However, there must be differentiation according to their impact level - e. g. for gene editing versus gene drives. Such differences should be communicated more clearly, and the paper CBD Technical Series No. 82, with its general lack of differentiation, does not reflect this demand.</p> <p>↪ <i>We suggest addressing the question of a fact-based dialogue and the necessary preconditions for a mutually respectful dialogue. It may be worth keeping in mind that according to the possible impact of the methods and approaches of synthetic biology different approaches of communication might be desirable.</i></p>

12	34-38	<p><i>“Often, international and national regulatory regimes tend to focus on biosafety risks rather than a more holistic approach that takes into account a range of public interest issues related to the biosecurity, ethics, societal, cultural and economic implications of synthetic biology more broadly, as well as potential benefits related to biodiversity conservation and sustainable use. In this sense, a new paradigm for regulating synthetic biology applications is needed that looks beyond just biosafety.”</i></p> <p>We agree that the focus of regulatory regimes is predominantly on biosafety. The potential positive benefits towards matters with high societal priority (e.g., climate change, economic development, public health, biodiversity conservation) are often not considered. We would appreciate a more holistic approach in the sense that the impacts of using a technology are weighed against the impacts of not using it.</p> <p>However, we would like to point out that a holistic approach must be very carefully placed into the context of weighted according to the local circumstances and interests on the ground. Such a case-by-case assessment will lead to very specific assessments and regulatory consequences. Thus, there seem to be a certain contradiction with respect to the demand of uniformity of a comprehensive and strict regulation.</p> <p>According to the lack of a proper definition of synthetic biology, we expect a multitude of single cases to which a costly holistic approach will be applied. We doubt that this kind of broad regulation can be practicably implemented and efficiently imposed by any international body.</p>
13/14	Table	<p>We appreciate that this table provides a first attempt to distinguish between contained and released applications, showing that the vast number of current applications take place in completely contained settings. However, the examples of “Part(s), devices, and systems” are confusing, as they can refer to the genetic changes made in cells to obtain all the products mentioned in this part of the table. Part(s), devices, and systems are a general description, whereas the other examples are concrete applications by using/creating such parts, devices and systems.</p> <p>Furthermore, it would be helpful to distinguish between examples that are planned to be transferred from the research stage to commercial exploitation. For example, there is no intention of making the horsepox virus commercially available.</p> <p>↪ <i>We suggest that the example “Part(s), devices, and systems” be removed</i></p>
65ff	18ff	<p><i>“E. SYNTHETIC BIOLOGY GOVERNANCE AND REGULATORY PERSPECTIVES 7.The Governance and Regulation of Synthetic Biology”</i></p> <p>In our view, the current vagueness of definition is not a good basis for deriving any regulatory consequences. This necessarily requires a prior definition of the subject of regulation.</p> <p>↪ <i>We propose to postpone governance and regulatory perspectives (chapter E; pg. 65 to 120) until a mutually accepted definition, or several workable definitions, of synthetic biology are available.</i></p>

132	48f	<p><i>As the field continues to advance and more applications become available, there is a growing pressure towards achieving clarity.</i></p> <p>We fully agree that clarity about concept und definition of synthetic biology is a precondition for any regulation and notice the lack of clarity.</p> <p>We want to emphasize that, in our view, a clear, mutually agreed definition of what falls under the term “synthetic biology” is the precondition for any discussion on specific regulations. We hope that the upcoming discussion will focus on defining synthetic biology within the CBD and its Protocols in order to move the discussion forward.</p>
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