**Statement of scientific members of the Max Planck Society
on CBD Technical Series No. 82 “Synthetic Biology”**

The manuscript draft highlights correctly that deployment of genetically modified organism should be accompanied by careful assessment of benefits and risks. As scientists involved in the use, as well as the development of genetic engineering and synthetic biology, we are very aware that we have a deep obligation to accompany and support this process to ensure that science is used safely for the benefit of mankind. This of course includes not endangering the biological diversity and ecosystems of the planet we all live on. However as written, the document has several very serious deficiencies that are discussed in the following:

1. **Lack of clear definition of the term “synthetic biology” and motivation to differentiate from existing regulatory processes.**

A fundamental weakness of the document is that it neither does precisely define synthetic biology nor does it make a clear case, why it should be regulated differently from genetic engineering processes, such as genome modification, genome editing, or gene drives that are already widely discussed by regulators. This lack of definition is for instance reflected in the many synthetic biology examples listed that are in reality just products of classical genetic modification methods (e.g., a single-gene disruption by CRISPR does not qualify as synthetic biology). Because synthetic biology does not represent a single unified discipline, as outlined in the text, a general regulatory framework aimed at governing all aspects of synthetic biology is likely to severely hinder progress and discovery of fundamental principles underlying the functioning of biological systems as well as the exploration of their potential for application.

1. **Need of a clear statement on the regulation of synthetic biological applications.**

Another difficulty is the absence of a statement on the evaluation of synthetic biological applications. However, taking a clear stand on the crucial question, whether the methods of creating a genetically modified organism or the final product of this process should form the basis for a risk assessment will be imperative to develop any legally relevant rules. Instead of aiming to regulate the “process of synthetic biology”, any regulations should be focused on the individual products and their specific risks. For instance a risk assessment of gene drives will be very different compared to that of single nucleotide mutations, which are also naturally occurring and were generated by genome editing.

1. **Lack of commitment to objective, fact-based decision-making for regulatory affairs.**

Another big concern is the lack of a clear commitment to scientific theory and fact-based argumentation as guiding principle for decision-making. We agree that there is a need for scientific bodies to continuously engage in dialogue with the public and to increase the quality of that dialogue, as well as a need to promote transparent information sharing. However, there also needs to be an in-principle agreement on the possibility of attaining an objective definition of risk. We would strongly caution against bringing broader policy and societal issues into regulatory issues related to synthetic biology and instead strongly favour an evidence-based approach, including evidence-based decision-making guided by the scientific community on a case-by-case basis to avoid violating biodiversity and sustainability goals.

1. **Weighing risks and benefits fairly, including discussion of alternatives during decision-making**

While we agree that it is important to consider societal and ethical concerns relating to synthetic biology research and applications, we find it also important that potential and realized benefits to society and environment are widely publicized for an informed discussion in the public. Considering the polarized and emotionalized discussion on the generation and release of genetically modified organisms in the past, we deem it essential to fairly weigh risks and benefits based on a scientifically informed discussion to prevent the ban of technologies that hold significant promise to solve societal and ecological problems. We also would like to stress that any discussion on technologies needs to incorporate considerations of potential alternatives and their benefits and risks (e.g., the use of pesticides versus specifically designed biocontrol agents). Finally, we would also like to highlight that many of the risks discussed in the text are not related to the specific technology of “synthetic biology”, but rather to broader social practices, such as aggres­sive monopoly business models.

1. **Limitations of scientific freedom and open science through overarching regulations.**

A strong concern is the creation of overarching regulatory frameworks that will stand in diametric opposition to the freedom of science. We support the goals of commendable, equitable benefit sharing including collective funding to support the Convention on Biological Diversity. Never­theless, the concrete policy implementation has proven very often impractical for basic science, lead to de facto research bans and seriously impeded cataloguing and global tracking of biodiversity. This is contrary to open science principles and a concrete problem, as without such knowledge, biodiversity cannot be understood and protected. It would be more helpful and goal-oriented to classify research approaches along the question, whether the research is for profit or not for profit and whether it has specific aims beyond investigating, characterizing or cataloguing biodiversity? Our concerns also include extension of the Nagoya protocol onto Digital Sequence Information (DSI), which would have far-reaching negative consequences, could severely damage scientific research progress in the fields of environmental and life sciences and biodiversity, and would particularly threaten international research cooperation within these fields.

1. **Economic considerations impeding basic science.**

We strongly oppose to any efforts that aim at legislating research based on unreliable economic predictions. This would not benefit developing economies and would only serve to prevent basic research efforts. It is completely unjustified that researchers cannot identify and study the enzymatic transformations of a given molecule because of the (very small) possibility that such basic research efforts may in many years time have some impact on the economy of a country? A more productive, pragmatic and realistic solution is to foster mutually beneficial international collaborations with developing countries. For example, researchers from the Western world freely collaborating with growers of medical plants in Asia in a manner that is not legislated or constrained by third party regulations and is mutually beneficial for both parties.

1. **Intransparent review process and lack of participation of experts**

Last, but not least, we are very much concerned that the writing and reviewing process of this document did not systematically involve scientific expertise and institutions. This includes the Max Planck Society, one of the leading basic science organizations in Europe that is very active in developing novel genetic engineering and synthetic biology methods. We would have considered a fair and transparent participation as indispensable to create a document that provides accurate definitions of the term “synthetic biology” and potential risk assessment, clearly commits to evidence-based decision making, discusses the consequences of potential regulatory frameworks for basic science and their limits for open research and innovation in a world facing the challenge of climate change and the dramatic loss of biodiversity.

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