

Statement from the Research Field Health of the Helmholtz Association of German Research Centers

Re: Convention of Biological Diversity (CBD) Notification 2021-031

## **Draft Update of the „CBD Technical Series No. 82“ on Synthetic Biology**

The Helmholtz Association is Germany's largest research organization substantially supporting biomedical research in its research programs within the Research Field Health and its participating centers: *Cancer Research* at German Cancer Research Center (DKFZ) and Helmholtz-Zentrum Dresden-Rossendorf (HZDR), *Environmental And Metabolic Health* at Helmholtz Zentrum Munich (HMGU), *Systems Medicine and Cardiovascular Diseases* at Max Delbrück Center for Molecular Medicine (MDC), *Infection Research* at Helmholtz Center for Infection Research (HZI) and *Neurodegenerative Diseases* at German Center for Neurodegenerative Diseases (DZNE). The Helmholtz Health Centers have helped to develop some of the tools described in the CBD report on Systems Biology, and routinely deploy them to improve human health and well-being.

As scientists routinely using the genetic engineering tools outlined in this report on synthetic biology, we are aware of our obligation to ensure that research is used safely for the benefit of humanity. A key value we share with the CBD is to ensure that our research is performed ethically and safely, while minimizing its impact on the environment. In all of our research institutes, significant regulatory infrastructures have long existed to ensure that our work is performed to minimize its potential for impacting the environment and biodiversity. For instance, in response to concerns on genetically engineered organisms and their potential impact on the environment if released, we have in place stringent internal licensing structures for performing any research involving genetically modified organisms (GMOs). To this end, we have dedicated Biosafety offices that advise and mediate between the overseeing governmental authorities and research scientists.

Our experience in undertaking biomedical research has convinced us that an open and flexible approach towards scientific research results in the best outcome for society and for the environment. Open science includes principles where proscriptions on specific protocols only exist when clearly necessary due to specific identified risks, where the re-useability of research results is encouraged to maximize societal benefit, and where the exchange of biological samples and reagents is encouraged. Blanket regulations which may impact these principles should be slowly considered and undertaken, with all stakeholders including the researchers themselves consulted carefully and repeatedly. Especially, internationally binding treaty restrictions must be carefully balanced between scientific risks and rewards, as there is considerable risk of damaging the benefits deriving from research.

Regarding the current draft, we have concerns regarding the intention, structure, and conclusions of the circulated draft. Most prominently, the scope and definition of synthetic biology in this document is not well defined, as the authors themselves state (P8L9-12). There is a lack of clarity regarding what techniques and organisms should be considered synthetic biology, and why. Many of the examples described are already controlled closely as they are GMOs or techniques for creating such (CRISPR-cas9), for which there are considerable regulations already in place legally and within our institutions. It will be imperative for any

revised draft to clearly delineate how their definition of synthetic biology differs from GMOs, and why it will require additional controls.

We welcome an informed discussion on the societal and environmental impacts of recent developments in genetics, genomics, and synthetic biology. Here, however, we are concerned that a lack of definitional clarity has resulted in a list of techniques of interest to the CBD that is so broad it covers aspects of almost any modern biomedical research effort. Enacting binding restrictions on even a subset of these techniques could significantly impact our efforts to combat human disease.