Part I. Endorsement of submission Name of Country/Organization: Testbiotech

Name of CBD National Focal point/Head of Organization endorsing: Christoph Then

Signature of the CBD National Focal Point/ Head of Organization:

Date: 24 November 2023

### Part II. Submission of information

In submitting information, kindly provide the following information on one or more of the 12 trends and issues in synthetic biology as follows:

#### 1. Trend and issue in synthetic biology chosen

Microbiome engineering for non-medical purposes

### 2. Potential positive and potential negative impacts on the three objectives of the Convention

### a. Conservation of biological diversity

The microbiome is a common network of life, circumventing and closely interacting with plants, animals and humans. These networks are thought to co-evolve with their hosts and develop a mutualistic relationship that benefits both the host and microorganisms. It acts at the interphase between the organisms and their environment and is considered to be key for human, animal and plant health. Several attempts are made, to engineer the microbiomes or its specific parts and elements by Synbio approaches (Batool et al., 2023, Bai et al., 2023).

In regard to the conservation of biological diversity, several areas have to be taken into account such as the microbial communities of the intestines, the surfaces (skin, cuticula, etc), the soil (including mycorrhiza) as well as specific endophytes (such as living in plant cells).

In this context, the concept of the 'holobiont' was introduced to show that the biological characteristics of organisms, such as plants, insects or mammals, cannot be considered separately from their associated microbiomes. The concept of the holobiont is also relevant for Synbio applications, as the approach of 'paratransgenesis' shows: Instead of genetically engineering the host, the intended traits are introduced via the associated microorganisms, as it for example can be explored in case of honey bees and their microbiome. Researchers at the University of Austin (Texas) genetically engineered the genome of bacteria found in the gut of honey bees and bumble bees to make them produce additional biologically active molecules (non-coding ribonucleic acid, ncRNA). The ncRNA molecules are meant to be taken up from the gut and thus spread to other parts of the honey bee, including their central nervous system (Leonard et al., 2020). If honey bees with such microbes were to be released, there is no way of preventing the bacteria from infecting the gut of other honey bee colonies or wild relatives, such as bumble bees. Moreover, their synthetic genes can also be transferred to other species of bacteria.

More generally, if Synbio microbiomes are released into the environment, there are many risks of disrupting existing ecosystems and their future evolutionary dynamics. Synbio microbiomes may become a source of further destabilization of threatened species and the conservation of biological diversity.

b. Sustainable use of its components

c. Fair and equitable sharing of the benefits arising out of the utilization of genetic resources

# **3.** Potential gaps or challenges for risk asssessment, risk management and regulation, including availability of tools for detection, identification and monitoring

In 2020, a document published by European Food Safety Authority (EFSA, 2020), called attention to the role of the microbiome in environmental risk assessment and food and feed safety. As EFSA states, the soil microbial community represents the greatest reservoir of biological diversity in the world. The collective genome of the rhizosphere microbiome is referred to as 'the plant second genome' which has a crucial function for the plant, ranging from the recruitment of essential nutrients to boosting its defensive capacity against pathogens. The balance within soil microorganisms is considered to be directly related to plant health and soil fertility. The preservation of its integrity is of high relevance in environmental risk assessment. Similar reasons for concern have to be taken into account in regard to other microbiomes, such as in the gut of humans and animals.

However, according to EFSA, clarification is still needed on how current environmental risk assessments and possible indirect effects of plant and soil microbiomes on soil fertility and plant health could be captured. According to EFSA (2020), there are still no standardised approaches to characterise healthy soil from a microbiome perspective. Furthermore, the fungal, viral and archaeal diversity of the plant microbiome still cannot be evaluated in its entirety. Similar limits of knowledge occur in regard to other microbiomes, such as in the gut of humans and animals.

In the light of these many unknowns and uncertainties, measures should be taken to prevent the release of Synbio microbiomes.

4. Additional relevant considerations (e.g., socioeconomic, ethical, cultural, human health, intellectual property, liability and redress, IPLCs, public engagement, among others)

5. Timeframe to commercialization or release into the environment

6. Potential linkages to the Kunming-Montreal Global Biodiversity Framework and potential contribution to other internationally relevant goals and targets

## Submission of supporting documentation:

For any publication that you may want to share as part of your submission, kindly include: 1. Name of publication(s), author, date and DOI or URL link.

Batool, M., Carvalhais, L.C., Fu, B., Schenk P.M. (2023) Customized plant microbiome engineering for food security, Trends in Plant Science https://doi.org/10.1016/j.tplants.2023.10.012.

Bai, Xiaowu, Huang; Ziyu Duraj-Thatte; Anna M. Ebert et al (2023) Engineering the gut microbiome, Nature Reviews Bioengineering, https://doi.org/10.1038/s44222-023-00072-2

EFSA (2020) Editorial: Exploring the need to include microbiomes into EFSA's scientific assessments. EFSA J, 18(6):e18061. https://doi.org/10.2903/j.efsa.2020.e18061

Leonard, S. P., Powell E., Perutka J., Geng P., Heckmann L. C., Horak R. D., Davies B. W., Ellington A. D., Barrick J. E., Moran N. A. (2020) Engineered symbionts activate honey bee immunity and limit pathogens. Science, 367, 573-576. https://doi.org/10.1126/science.aax9039

2. Attach in pdf format any publication you have listed above.