

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**

Engineered bacteria for nitrogen-fixation and fertilizer

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

**a. Conservation of biological diversity**

There are massive gaps in our knowledge that impede our ability to thoroughly assess risks and to predict the consequences of releasing of Synbio microorganisms into the environment. Release of Synbio microbes has the potential to affect the environment in unintended ways (see FOE, 2023). This is especially relevant for Synbio microorganisms that are engineered to show higher efficacy in metabolic functions such as nitrogen fixation.

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 assessment, risk management and regulation, including availability of tools for detection, identification and monitoring**

In the context of Synbio microorganism that are engineered to show higher efficacy in metabolic functions such as nitrogen fixation, EFSA (2020) considers the following environmental risks to be relevant: *“Altered efficacy can be related to levels of exposure by e.g. 1) increased environmental survival and host colonisation, 2) increased invasiveness and, 3) increased competition in naturally evolved microbial communities due to enhanced fitness, thereby displacing beneficial microorganisms or disrupting, 4) altered metabolism, e.g. by changes in substrate utilisation opening new environmental niches; 5) altered lifestyle, e.g. by energy use (aerobic versus anaerobic) opening new environmental niches.*

*Wider future SynBioMs, including xenobionts, aimed for deliberate release into the environment, may lead to novel hazards compared to microorganisms developed with established genetic modification techniques, e.g. due to 1) new-to-nature organisms/products/constituents possibly with poorly understood interactions with its biotic and abiotic environment, 2) xeno-proteins with new enzymatic properties, i.e. modified substrate specificity or higher environmental robustness, and so opening new environmental niches and 3) substantial reduction of the genome could lead to unexpected interactions with other organisms (e.g. those that lead to evasion of the immune system). The assessment to identify novel hazards or risks should always be performed on a case-by-case basis.”*

EFSA (2020) suggested several activities in risk assessment methodology and research to overcome current gaps in research. However, uncertainties and unknowns will prevail in many cases, also caused by lack of spatio-temporal control. Therefore, cut-off criteria will be needed to come to reliable decision making in case of too high uncertainties and too many unknowns, resulting in inconclusive risk assessment.

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.

EFSA (2020) Scientific Opinion on the evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of microorganisms obtained through synthetic biology. EFSA Journal 2020;18(10):6263, 50 pp. <https://doi.org/10.2903/j.efsa.2020.6263>

FOE (2023) Genetically Engineered Soil Microbes: Risks and Concerns, [https://foe.org/wp-content/uploads/2023/08/GE\\_Microbes\\_Report\\_Final.pdf](https://foe.org/wp-content/uploads/2023/08/GE_Microbes_Report_Final.pdf)

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