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
Genome edited plants

2. Potential positive and potential negative impacts on the three objectives of the Convention
a. Conservation of biological diversity

CRISPR/Cas gene scissors, in particular, have the potential to alter gene functions and plant characteristics in ways that would not be expected through conventional breeding (Kawall, 2019). The plants obtained by NGTs can escape the boundaries of the characteristics of the individual species, even without the insertion of additional genes (Kawall 2021a; Kawall 2021b).

Risks for biodiversity can emerge from the intended and unintended genetic changes and effects that go along with it (Koller & Cieslack 2023). These effects may be caused by individual LMOs or cumulative effects and interactions of several LMOs within a shared environment (see gaps in risk assessment) (Koller et al., 2023).

b. Sustainable use of its components
Since sustainability comprises many levels of complexity, clear and transparent criteria for an adequate technology assessment are needed before conclusions can be made on potential benefits of specific traits (see Testbiotech 2023).

c. Fair and equitable sharing of the benefits arising out of the utilization of genetic resources
Patents applied for plants obtained by Synbio might be expanded to biological resources that are needed for conventional breeding and for example were found in centers of origin (see the example the usage of genes from *S. pimpinellifolium*, to gain resistance to the Tomato Brown Rugose Fruit Virus or the use of wild relative species in breeding of the soybeans against Asian soy rust (see: No Patents on Seeds, 2022)

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

Risk assessment:
Unintended effects that go along with the intended and unintended changes have to be examined case by case and step by step. Adequate methodology (including omics) for genome analysis, plant composition and reactions to environmental stressors (under contained conditions) should be examined in detail before any conclusion is made on the amount of data needed before field trials could be allowed.

If released, not only the risks of the individual events have to be considered, but also the interactions of NGT plants within shared environments.

Risk Management:
Measures should be taken for tracking, tracing, monitoring, avoiding uncontrolled spread and enabling the assessment of systemic adverse effects onto the ecosystems (tipping points).

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

Patents should be restricted to the technical processes, biological material that is needed for conventional breeding, should not be monopolized.

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.

Kawall, K. (2019) New possibilities on the horizon: genome editing makes the whole genome accessible for changes. Front Plant Sci, 10, 525. https://doi.org/10.3389/fpls.2019.00525

Kawall, K. (2021a) Genome-edited Camelina sativa with a unique fatty acid content and its potential impact on ecosystems. Environ Sci Eur, 33(1), 1-12. https://doi.org/10.1186/s12302-021-00482-2

Kawall, K. (2021b) The generic risks and the potential of SDN-1 applications in crop plants. Plants, 10(11), 2259. https://doi.org/10.3390/plants10112259

Kawall, K., Cotter, J., Then, C. (2020) Broadening the EU GMO risk assessment in the EU for genome editing technologies in agriculture. Environ Sci Eur, 32(1), 1-24. https://doi.org/10.1186/s12302-020-00361-2

Koller, F., Schulz, M., Juhas, M., Bauer-Panskus, A., Then, C. (2023) The need for assessment of risks arising from interactions between NGT organisms from an EU perspective. Environ Sci Eur, 35(1), 27. https://doi.org/10.1186/s12302-023-00734-3

Koller & Cieslak (2023) A perspective from the EU: Unintended genetic changes in plants caused by NGT – their relevance for a comprehensive molecular characterisation and risk assessment. Front. Bioeng. Biotechnol. 11:1276226.

Testbiotech (2023) Genetic engineering in agriculture: between high flying expectations and complex risks, The use of genetic engineering in agriculture requires a comprehensive technology assessment, Testbiotech report, https://www.testbiotech.org/node/3044

No Patents on Seeds! (2023) The future of plant breeding is under threat in Europe, Current interpretation of patent law is insufficient to stop patents on conventional breeding, https://www.no-patents-on-seeds.org/en/report2023

No Patents on Seeds (2022) Patents on genes and genetic variations can block access to biological diversity for plant breeding, https://www.no-patents-on-seeds.org/en/report2022

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