

Part I. Endorsement of submission

Name of Country/Organization: Brazil/Ministry of Agriculture and Livestock

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

Luiz Eduardo Andrade de Souza (Ministry of Foreign Affairs,
Biodiversity Division)

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

Date: 24/11/2023

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:**
 - b. **Sustainable use of its components**
 - c. **Fair and equitable sharing of the benefits arising out of the utilization of genetic resources**

Synthetic Biology-enabled biomanufacturing could help replace petrochemically-derived chemicals, fossil fuels and materials. This has the potential to improve sustainability by reducing reliance on petrochemicals, thus reducing greenhouse gas emissions associated with production. Biomanufacturing solutions are also being developed that aim to utilize CO₂ as a feedstock (e.g. engineered algae and cyanobacteria), which could enable carbon-negative manufacturing. Synthetic biology may have success targeting higher margin applications where there are limited low carbon alternatives, such as the production of energy dense fuels for aviation. Undoubtedly, Brazil considers that Synthetic Biology could play an important role in the conservation of biological diversity as well as the sustainable use of its components.

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

Brazil's Biosafety Regulatory System, including the existing risk assessment and management framework, is appropriate to address the current synthetic biology applications.

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

It is also important to emphasize as part of the assessment at the horizon scanning process that benefits of the technologies should be considered. As biomanufacturing, for instance, can be used to produce biofuels, synthetic biology may enable efficient conversion of more sustainable feedstocks such as agricultural waste and CO₂, thus having a significant and positive impact on a circular carbon economy.

5. **Timeframe to commercialization or release into the environment**

Many applications are already on the market, some examples are presented bellow:

- A) **Microbial metabolic engineering for contained use, including for high value fine chemical production and petrochemical precursors:** production of high-value compounds from the shikimate pathway, a metabolic pathway widely used by organisms in nature (e.g. bacteria, fungi and plants) to synthesize the aromatic amino acids (AAAs) phenylalanine (Phe), tryptophan (Trp) and tyrosine (Tyr)
Reference: Carbonell, P., Jervis, A.J., Robinson, C.J. et al. An automated Design-Build-Test-Learn pipeline for enhanced microbial production of fine chemicals. *Commun Biol* 1, 66 (2018). <https://doi.org/10.1038/s42003-018-0076-9>;
- B) **Biofuel production:** Increasing concerns of environmental impacts and global warming calls for urgent need to switch from use of fossil fuels to renewable technologies. Biofuels represent attractive alternatives to fossil fuels and have gained increasing attention. Through the use of synthetic biology, it has become possible to engineer microbial cell factories for efficient biofuel production in a more precise and efficient manner.
Reference: Liu Z, Wang J, Nielsen J. Yeast synthetic biology advances biofuel production. *Curr Opin Microbiol.* 2022 Feb;65:33-39. <https://doi.org/10.1016/j.mib.2021.10.010>. Epub 2021 Oct 29. PMID: 34739924.
- C) **Engineered algae:** microalgae bear immense potential as bio-cell factories in terms of producing key chemicals, recombinant proteins, enzymes, lipid, hydrogen and alcohol. The microalgae are gaining much attention for use as a potential feedstock by virtue of its high carbohydrate and lipid content, rapid growth rate and resistance to fluctuating environmental conditions
References: Jagadevan, S., Banerjee, A., Banerjee, C. et al. Recent developments in synthetic biology and metabolic engineering in microalgae towards biofuel production. *Biotechnol Biofuels* 11, 185 (2018). <https://doi.org/10.1186/s13068-018-1181-1>;
Samuel J. King, Ante Jerkovic, Louise J. Brown, Kerstin Petroll, Robert D. Willows, Synthetic biology for improved hydrogen production in *Chlamydomonas reinhardtii*, *Microbial Biotechnology* (2022) 15(7), 1946–1965, <https://doi.org/10.1111/1751-7915.14024>
- D) **Synthetic biology for CO₂ fixation:** Studies suggests that some of the proposed synthetic pathways could have significant quantitative advantages over their natural counterparts, such as the overall kinetic rate. One such cycle, which is predicted to be two to three times faster than the Calvin–Benson cycle, employs the most effective carboxylating enzyme, phosphoenolpyruvate carboxylase, using the core of the naturally evolved C₄ cycle.
Reference: Gong, F., Cai, Z. & Li, Y. Synthetic biology for CO₂ fixation. *Sci. China Life Sci.* 59, 1106–1114 (2016). <https://doi.org/10.1007/s11427-016-0304-2>
- E) **Fine and Commodity Chemicals:** Biomanufacturing can be used to produce chemicals from renewable feedstocks. This has the potential to improve the sustainability or efficiency of chemical production processes. Novamont’s (ITA) Mater-Biotech plant produces industrial scale butanediol using biomanufacturing (fermentation) for use in bioplastics.
Reference: Novamont (2021) Mater-Biotech. Viewed 13 Nov 2023, <<https://www.novamont.it/eng/materbiotech/>>.

F) ***Biomanufactured materials:*** Biomanufacturing can be used to produce polymers, proteins and other materials more sustainably or with novel characteristics for use in diverse markets. The Bolt Threads (US) has demonstrated commercial production of spider silk proteins using engineered yeast, and Zymergen (US) uses biomanufacturing to produce novel transparent polyimide films for electronic device screens. References: Bolt Threads (n.d.) Microsilk. Viewed 13 Nov 2023, <<https://boltthreads.com/technology/microsilk/>>. Zymergen (n.d.) Hyaline Z2. Viewed 13 Nov 2023, <<https://www.zymergen.com/products/electronics/hyaline/hyaline-z2/>>.

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

The microbiome engineering has potential to support the GBF Target 10. Besides that, due to the characteristics of Synthetic Biology, the technology should contribute directly to the Sustainable Development Goals 7, 9, 12, 13, 15.

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

Template for submitting information on additional trends and issues that were identified and prioritized by the multidisciplinary AHTEG for information gathering

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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:** Synthetic biology applications for bioremediation, biodegradation or biomining
- 2. Potential positive and potential negative impacts on the three objectives of the Convention**
 - a. 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**

Bioremediation uses microorganisms to degrade organic contaminants by using them as an energy source for growth, or to convert inorganic contaminants to less harmful forms. Synthetic biology can be used to engineer enzymes and microbes that are more efficient in remediating environmental contaminants. Therefore, Brazil considers that the nature of clean-up activities using Synthetic Biology can contribute to the conservation of natural resources, biodiversity and enhance the quality-of-life in the surrounding communities.

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

Brazil's Biosafety Regulatory System, including the existing risk assessment and management framework, is appropriate to address the current synthetic biology applications.

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

It is also important to emphasize as part of the assessment at the horizon scanning process that benefits of the technologies should be considered. In this sense, bioremediation using synthetic biology toolkits, such as engineered enzymes to remove oil spills, could be one of the most important alternative due to its cost-effectiveness and adaptability to different local conditions.

- 5. Timeframe to commercialization or release into the environment**

No current commercial examples of bioremediations has been identified so far. However, it is expected that, from five to ten years from now, the Synthetic Biology remediation of per- and polyfluoroalkyl substances (PFAS) could be a valuable opportunity due to the absence of effective alternatives.

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

The Bioremediation based on Synthetic Biology would support the implementation of different Sustainable Development Goals, such as life below water (SDG- 14), life on land (SDG-15), biological systems in a changing climate (SDG-13), sustainable consumption and production (SDG-12), sustainable cities and communities (SDG-11), industry, innovation, and infrastructure (SDG-9), clean water and sanitation (SDG-6), sustainable agriculture and phytoremediation (SDG-2), and affordable and clean energy (SDG-7).

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

Brazil is of the view that Genome Edited Plants should not be considered under Synthetic Biology discussions, as they are used in plant breeding to generate mutations that are equivalent to those achievable through conventional tools. The genome editing is an enabling tool that can be used to achieve several outcomes and, when these outcomes relate to GMO/LMO plants, they fall under the scope of existing regulatory frameworks such as Cartagena Protocol.

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**

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

Brazil understands that engineered bacteria for nitrogen-fixation and fertilizers generate positive impacts related to the second objective of the Convention on Biological Diversity - sustainable use of its components -, as they provide an alternative to the application of chemical fertilizers, which can cause the eutrophication of aquatic environments when applied in excess. Those benefits include *inter alia*: less use of nitrogen fertilizers, which results in savings for producers; self-supply of nitrogen used for plant formation, minimizing the impacts of nitrogen on the environment. The use of legumes as efficient green manures for Biological nitrogen fixation (BNF) provides nitrogen to the soil and improves its physical, chemical and biological properties, including through increased productivity, especially in nitrogen-deficient soils.

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

From Brazil's perspective, there are no gaps for risk assessment, risk management and regulation to engineered bacteria for nitrogen-fixation and fertilizers, as there is great experience accumulated with the use of the comparator, i.e, that natural biological nitrogen fixation (BNF) which was discovered by Beijerinck in 1901.

In Brazil, for instance, 80% of the soybean planted area uses microorganisms to fix nitrogen. This has had a very large positive environmental impact, as it is estimated that 430 million tons of CO₂ equivalent have not been released into the atmosphere thanks to the use of nitrogen-fixing bacteria.

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

From Brazil's perspective, there are no additional relevant considerations, as the examples given are not part of the GMO risk assessment.

5. Timeframe to commercialization or release into the environment

The Brazilian research sector has been active in the search for new bacteria and genes that can expand the use of biological fixation. The development of biological fixation strategies in cereals – corn, wheat, barley, etc. – has been extensively studied and commercial releases are expected in a short term.

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

This trend could contribute with the implementation of the Soil Conservation Strategy (FAO, CBD and SDG-2).

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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:** Transient modification of agricultural plants, pests and pathogens using RNAi or nanomaterials
2. **Potential positive and potential negative impacts on the three objectives of the Convention**
 - a. **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**

Brazil understands that transient modification of agricultural plants, pests and pathogens using RNAi or nanomaterials generate positive impacts related to second objective of CDB, sustainable use of its components, as they provide an alternative to the application of pesticides with high toxicity and can offer additional alternative for farmers to species-specificity crop protection, as well as to improve productivity. It is also important to highlight that, with climate change, FAO estimates the reduction of productivity in many crops in the next decades and, therefore, the development of new tools is essential to ensure global food security.

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

From Brazil's perspective, there are no gaps, as the existing risk assessment frameworks on biosafety related to LMOs and for the safety of the pesticide and its registration, including the assessments undertaken by the Ministry of Agriculture and Livestock, Ministry of Health and Ministry of Environment and Climate Change, already address other relevant aspects related with the RNAi approval.

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

No relevant considerations as they are part of the decision making and not the risk assessment.

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**

Besides Target 7, this trend could contribute with the implementation of the Soil Conservation Strategy (FAO, CBD and SDG-2).

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