Part I. Endorsement of submission

Name of Country/Organization: European Union/European Commission

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

Hugo Maria SCHALLY

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

e-signed

Hugo Maria Schally

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

      Genome editing in plants may be used to obtain a wide variety of traits, some of which may also be obtained using conventional breeding techniques or classical mutagenesis using chemicals or various forms of radiation. Any impact on the objectives of the Convention will be determined by the traits of a plant not by the technique used to generate this plant. Furthermore, concrete impacts on the conservation of biological diversity may be strongly influenced by the mode of agriculture and will thus not be exclusively attributable to a particular plant trait or genome modification.

      Potential positive impacts on the conservation of biological diversity could, for example, be realised through traits strengthening climate adaptation, pest resistance (thus reducing the use of plant protection products) or improving soil quality. Potential negative impacts on the conservation of biological diversity could, for example, be realised through traits enabling the broad-scale use of pesticides or changing the structural or nutritional composition of the plant in a way that renders it inaccessible or unsuitable for use by wild animals.

   b. Sustainable use of its components

      Considerations under 2.a are also relevant for the sustainable use of biological diversity.

   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

   The European Food Safety Authority (EFSA) concluded in multiple of their opinions that certain plants developed with new genomic techniques, including with applications of genome editing, do not give rise to different hazards than conventionally bred or mutagenized plants in relation to human and animal health and the environment. Furthermore, they concluded that the European

regulations and guidelines are broadly applicable to the risk assessment of genome-edited plants and that data requirements could, however, justifiably be reduced on a case-by-case basis[1].

The European Group on Ethics in Science and New Technologies (EGE) published in 2021 an opinion on the ethics of genome editing, which focuses on applications in humans, animals and plants[2]. Among its conclusions on plants, EGE recommends a systems approach to evaluate costs and benefits in any future use and regulation proportionate to the risk.

Regarding the detection and identification of genome-edited plants, the European Union Reference Laboratory (EURL) for genetically modified food and feed together with the European Network of Genetically Modified Organisms Laboratories (ENGL) in their report of 2023 confirmed that analytical testing is not feasible for all products obtained by targeted mutagenesis and cisgenesis. If the introduced modifications of the genetic material are not specific to the genome-edited plant in question, they do not allow the differentiation of the genome-edited plant from conventional plants. In such cases, analytical detection will need to be complemented by other enforcement measures[3].

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

Genome editing in itself constitutes a group of techniques that may be used in the development of synthetic biology applications. This does, however, not imply that all applications that have been developed using genome editing can be considered synthetic biology. On the contrary, genome editing, particularly as it is currently used for the improvement of crop plants, often results in products that are molecularly undistinguishable from products that can arise from conventional breeding or classical chemical or physical mutagenesis.

Genome editing in plants may be used to introduce agronomically and environmentally beneficial traits more efficiently than with other methods. Potential improvements include increases in yield, nutritional value, storage duration/shelf life, soil quality and tolerance to changing climatic conditions as well as reductions in the required use of pesticides and fertilisers in plant cultivation.

As regards intellectual property, it is important to ensure farmers' and breeders' access to patented techniques and material, so as to promote seed diversity at affordable prices and to safeguard breeding and cultivation of unpatented conventional and organic crops. At the same time, it remains important to also strongly support innovation in plant breeding by preserving

---

[1] European Food Safety Authority (EFSA), Panel on Genetically Modified Organisms, 2012. Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 10(2):2561; https://doi.org/10.2903/j.efsa.2012.2561

EFSA, Panel on Genetically Modified Organisms, 2020. Applicability of the EFSA Opinion on SDNs type 3 for the safety assessment of plants developed using SDNs type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 18(11):6299; https://doi.org/10.2903/j.efsa.2020.6299

EFSA, Panel on Genetically Modified Organisms, 2021. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology. EFSA Journal 2021;19(2):6301; https://doi.org/10.2903/j.efsa.2021.6301

EFSA, Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 20(10):7621; https://doi.org/10.2903/j.efsa.2022.7621.

EFSA, Panel on Genetically Modified Organisms, 2022. Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 20(10): 7618; https://doi.org/10.2903/j.efsa.2022.7618

[2] European Group on Ethics in Science and New Technologies, 2021. Opinion on the Ethics if Genome Editing. https://op.europa.eu/en/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1

[3] European Network of GMO Laboratories, 2023. Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis, Publications Office of the European Union, Luxembourg, JRC133689, https://publications.jrc.ec.europa.eu/repository/handle/JRC133689

investment incentives, such as through patents. In this context, the European Commission has announced a study to assess, as part of a broader market analysis, the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to genetic material and techniques and on availability of seeds to farmers as well as the overall competitiveness of the EU biotech industry. The Commission will report on its findings by 2026.

5. Timeframe to commercialization or release into the environment

   Several genome-edited plants are already cultured in context of experimental releases or after obtaining a market authorisation in different jurisdictions. A further increase can be expected.

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

   Genome-edited plants have the potential to contribute to achieving multiple of the Sustainable Development Goals (Goal 2: zero hunger, Goal 3: good health and well-being, Goal 9: industry, innovation and infrastructure, Goal 12: responsible consumption and production, Goal 13: climate action and Goal 15: life on land).