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Convention on Biological Diversity

Subsidiary Body on Scientific, Technical and Technological Advice
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Item 5 of the provisional agenda*
Synthetic biology

Additional prioritized trends and issues in synthetic biology**

Note by the Secretariat

I. Introduction

1. At its first meeting held in July 2023, the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology agreed on a process for the first cycle of broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology. The process for the 2023–2024 intersessional period consisted of both multidisciplinary expert-driven submissions by members of the multidisciplinary Expert Group and a literature review conducted by the Secretariat.

2. In line with the request from the multidisciplinary Expert Group, the Secretariat produced a revised list of trends and issues in synthetic biology ("the provisional selection list") based on the 2019 report of the Ad Hoc Technical Expert Group on Synthetic Biology (CBD/SYNBIO/AHTEG/2019/1/3), the Open-ended Online Forum on Synthetic Biology convened from 20 to 31 March 2023, the submissions of information in response to notification No. 2023-006 and the publication "Technical Series No. 100: Synthetic Biology".

3. Following the compilation of the provisional selection list, the members of the multidisciplinary Expert Group were invited to select up to five items from the list or submit new items for consideration that in their expert opinion would be the most prominent issues to consider for the first cycle of broad and regular horizon scanning, monitoring and assessment using an electronic submission form. In performing their selection, the experts were requested to provide information on the potential impacts on the three objectives of the Convention on Biological Diversity, additional relevant considerations (e.g. socioeconomic, cultural or ethical), the estimated timeframe for release or impact of the selected item and relevant documentation to support their selection. Submissions were received from 31 August until 18 September 2023.

4. At their virtual meeting from 10 to 13 October 2023, the members of the multidisciplinary Expert Group prioritized a list of 17 trends and issues in synthetic biology for assessment at the next physical meeting of the Group. Five of the trends and issues in synthetic biology were selected for a more detailed assessment and forwarded to the Open-ended Online Forum on Synthetic Biology for

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** The present document is being issued without formal editing.

further information gathering. At the second meeting of the multidisciplinary Expert Group, these items were assessed and made available in the report of the meeting (CBD/SYNBIO/AHTEG/2024/1/3).

5. Regarding the additional 12 trends and topics in synthetic biology, they were selected to undergo a less detailed assessment. To support their assessment, an additional submissions of information process occurred from 26 October to 24 November 2023, to gather supplementary information to support these 12 items. However, owing to time constraints, the members of the multidisciplinary Expert Group were unable to conduct an assessment of these 12 trends and issues in synthetic biology but recommended to make the information compiled on these 12 trends and issues available.

6. Thus, this present document represents a compilation of the multidisciplinary expert-driven submission process of the additional prioritized 12 trends and issues in synthetic biology originally designated for a less detailed assessment. All bibliographic references shared during the process can be found in the annex and is organized by trend or issue.

II. Additional trends and issues in synthetic biology prioritized by the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology

A. Use of synthetic biology in wild organisms in the context of resilience in threatened species

7. The use of synthetic biology in wild organisms in the context of resilience in threatened species aims to assist conservation efforts for endangered or threatened species by introducing or reinforcing genetic diversity and conferring resilience to biotic and/or abiotic pressures. Approaches could entail engineering protected species, precision conversation strategies and assisted evolution.

8. Some specific examples of applications could include:

- Engineered American chestnut trees for blight resistance;
- In vivo germ-line genome editing directly into wild bird populations for disease resistance (e.g., malaria resistance in Hawaiian honeycreepers);
- Inheritable immunity to sylvatic plague in critically endangered black-footed ferrets;
- Enhanced thermal tolerance in coral and kelp species;
- Engineered chytrid resistance in frogs;
- Cane toad toxin resistance in Northern Quolls, Australia; and
- Modification of honeybee microbiome for greater pest resilience.

9. Synthetic biology approaches to improve resilience in threatened species might be relevant for the goals and targets of the Kunming-Montreal Global Biodiversity Framework, such as Targets 9 (Manage wild species sustainably to benefit people), Target 10 (Enhance biodiversity and sustainability in agriculture, aquaculture, fisheries, and forestry) and Target 17 (Strengthen biosafety and distribute the benefits of biotechnology). Particularly, for Target 17, further strengthening of biosafety measures might be required to account for gaps in risk assessment and risk management.

1. Timeframe

10. The timeframe varies for these applications. Some applications are near-term, such as the blight-resistant American chestnut (under regulatory review for release) and other are far-future and still in experimental stages, such as chytridiomycosis-resistant frogs (over 10 years away from release).

2. Potential impacts on the objectives of the Convention of Biological Diversity

11. The use of synthetic biology in wild organisms in the context of resilience in threatened species could have both positive and negative impacts particularly on the first objective of the Convention on Biological Diversity.

12. Some potential positive impacts on the conversation of biological diversity include:

- Tolerance to abiotic stress (e.g., thermal stress, climate change);
- Resistance to biotic stress (e.g., pathogens, pests);
- Increased or maintenance of current genetic diversity;
- Restoration of lost genetic diversity;
- Reduction in insect vector disease transmission; and
- Reverse decline of and increase the number of critically endangered species.

13. Some potential negative impacts on the conversation of biological diversity include:

- Unintended impacts on native flora, fauna and microbes;
- Changes to ecosystem dynamics, such as the biotic-biotic and biotic-abiotic interactions, leading to biodiversity loss;
- Increased competitiveness (e.g., outcompete native species);
- Increased invasiveness;
- Unintended impacts of genetic modification and off-target genome editing (e.g., increased susceptibility to other diseases, invasiveness, loss of genetic diversity, development of toxins, changed cellular regulation); and
- Gene flow (e.g., transfer of antibiotic or herbicide resistance gene cassettes into wild relatives).

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

14. When considering the use of synthetic biology in wild organisms in the context of resilience in threatened species, the Cartagena Protocol on Biosafety is an important instrument support the process of risk assessment of these applications. However, potential challenges to risk assessment, risk management and regulation may still exist. These could include:

- Use of synthetic biology in unmanaged or wild environments;
- Accounting for complexity of ecosystems (e.g., from molecular to ecosystem level);
- Co-existence of modified and non-modified organisms;
- Lack of risk management measures (e.g., irreversibility of release, large spatio-temporal distribution);
- Limited availability of data on whole ecosystems (e.g., species relationships);
- Extrapolation of laboratory or contained use data (e.g., predicting environmental impacts); and
- Transboundary movements.

4. Limits of knowledge

15. In terms of potential limitations to current knowledge about the use of synthetic biology in wild organisms in the context of resilience in threatened species, some considerations may include:

- Behaviour of organisms in the environment;

- Complex biotic relationships in ecosystems (e.g., forest microbiomes, mycorrhizal interactions and mutualistic communities); and
- Invasion biology.

5. Additional relevant considerations

16. Beyond the potential impacts to the objectives of the Convention on Biological Diversity, and potential challenges to risk assessment, risk management and regulation, the use of synthetic biology in wild organisms in the context of resilience in threatened species could also raise additional relevant considerations. Some potential points may include:

- Facilitation of responsible innovation and sustainable development;
- Access to technology in developing countries;
- Liability and redress;
- Ethics (e.g., concept of nature and natural, value of nature, human intervention in nature);
- Free prior and informed consent of indigenous peoples and local communities;
- Attitudes of the public and indigenous peoples and local communities towards engineered species for conservation could be dynamic and change;
- Importance of stakeholder engagement;
- Loss of benefits to provider countries (e.g., when endemic species are found or engineered elsewhere); and
- Diversion from other conservation measures and approaches.

B. Synthetic biology applications for bioremediation, biodegradation or biomining

17. Synthetic biology applications for bioremediation, biodegradation or biomining aim to assist with waste management of environmental pollution, recycling of resources or recovery of valuable metals from the environment. These applications are engineered to degrade, sequester or transform environmental pollutants, as well as precipitate or extract valuable metals using metabolic and/or protein engineering. Specific examples include:

- Engineered applications to detect and sequester pollutants, such as arsenic (e.g., biosensing engineered bacteria to signal presence of specific pollutants);
- Biosensors for detecting aromatic hydrocarbons (e.g., transcription factor coupled to fluorescent protein expression system based on gene circuits)
- Hexachlorobenzene degrading bacteria using a cytochrome P-450cam variant;
- Modifying microbes for plastic recycling (e.g., nylon, polyurethane and polyethylene terephthalate);
- Biosynthesis of a granular material that attracts and sticks to micropollutants such as pesticides, pharmaceuticals and certain chemicals in wastewater;
- Multicellular structured “synthetic jellyfish” to degrade contaminants after an oil spill;
- Novel approaches to detecting, removing and recycling perfluoroalkyl and polyfluoroalkyl substances from water (e.g., engineering proteins to precisely bind per- and polyfluoroalkyl substances);
- Microbial products that sequester radioactive elements through biosorption and biomineralization processes and/or through direct and indirect redox transformation; and

- Designing microbes for sustainable and more efficient extraction of energy transition metals (e.g., copper and lithium).

18. Synthetic biology application for bioremediation, biodegradation or biomining could be relevant for Kunming-Montreal Global Biodiversity Targets 9 (Manage Wild Species Sustainably To Benefit People), 10 (Enhance Biodiversity and Sustainability in Agriculture, Aquaculture, Fisheries, and Forestry) and 17 (Strengthen Biosafety and Distribute the Benefits of Biotechnology). Further, these applications may also be relevant for several United Nations Sustainable Development Goals, such as 2 (Zero Hunger), 6 (Clean Water and Sanitation), 7 (Affordable and Clean Energy), 9 (Industry, Innovation and Infrastructure), 11 (Sustainable Cities and Communities), 12 (Responsible Consumption and Production), 13 (Climate Action), 14 (Life Below Water) and 15 (Life on Land).

1. Timeframe

19. Many applications are in various stages of research, development and release with many being near or medium term. For example, introduction of modified bacteria and enzymes into bioreactors, oceans and landfills is expected in the next 3 to 5 years, pending regulatory review while application for the remediation of per-and polyfluoroalkyl substances could be in 5 to 10 years. Further, several research groups are tackling the challenge of accelerating microbial digestion of multiple plastic-based pollutants.

2. Potential impacts on the objectives of the Convention of Biological Diversity

20. Synthetic biology applications for bioremediation, biodegradation or biomining could have both positive and negative impacts on the objectives of the Convention on Biological Diversity, particularly for the conservation and sustainable use of biological diversity.

21. Some potential positive impacts may include:

- Conservation of natural resources and biodiversity;
- Reduction and removal environmental pollution (e.g., heavy metals, pesticides, pharmaceuticals);
- Remediation of contaminated environments (e.g., from oil spills); and
- Reduced use of toxic compounds.

22. Some potential negative impacts may include:

- Outcompeting native soil microorganisms (e.g., extinctions, loss of diversity);
- Adverse effects on soil function and soil ecosystems (e.g., disrupting or disturbing biotic interactions);
- Gene transfer (e.g., unintended prolonged effects or novel phenotypes in the environment);
- Land use changes (e.g., extraction activities on ecologically significant areas); and
- Unintended adverse effects.

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

23. When considering the synthetic biology applications for bioremediation, biodegradation or biomining, the Cartagena Protocol on Biosafety is an important instrument support the process of risk assessment of these applications. Despite this, potential challenges to risk assessment, risk management and regulation may exist, including sufficiency of available data (e.g., environmental interactions) and treatment of the precautionary principle (e.g., cut-off criteria). However, risk could also be mitigated through the use of microbes with high environmental specificity and further data could be gathered using controlled experiments.

4. Limits of knowledge

24. No information was shared regarding potential limits of knowledge related to this topic.

5. Additional relevant considerations

25. Beyond the potential impacts to the objectives of the Convention on Biological Diversity, the development of synthetic biology applications for bioremediation, biodegradation or biomining should include a careful consideration of the social, ethical, and biosafety dimensions of the research, alongside the intellectual merit, potential profitability or broader positive impacts.

26. Further potential considerations may also include:

- Enhanced quality of life for communities affected by environmental pollution (e.g., improved health outcomes);
- Alternatives to environmental emergency response (e.g., locally adapted solutions for oil spills);
- Shift in focus away from preventing the initial environmental pollution; and
- Increase extraction activities on culturally significant areas.

C. Microbiome engineering for non-medical purposes

27. Microbiome engineering for non-medical purposes focuses on the modification of microbiomes associated with plants, fungi, animals, soils, water, among other organisms and environments. These approaches may also relate to the assembly of synthetic microbial communities with optimized genotypes and phenotypes to address environmental or agricultural concerns. The modification process may involve transgenic and/or genome editing techniques.

28. Some specific examples of applications that could be considered as part of this item include:

- Engineered symbiotic nitrogen-fixing microbes that associate with the roots of crop plants (e.g., maize, wheat, rice);
- Engineered microbiome to protect crops from frost damage;
- Engineered microbes that assist plants to resist pests and diseases;
- Modified soil microbiomes for carbon sequestration (e.g., Audacious project);
- Engineering insect microbiomes for paratransgenetic applications;
- Antibody treatments for modulating livestock microbiome for reduced methane emissions;
- Engineered microbes that reduce methane production from ruminant livestock;
- Varroa mite-resistant honeybees by modifying gut microbiome;
- Increased thermal tolerance in corals;
- Increased chytridiomycosis resistance in frogs;
- Modification of animal microbiomes through selective targeting of bacterial species (e.g., phage-mediated delivery of CRIPSR to kill specific species and bacterial genome editing (Guided Biotics by Folium Science)); and
- Microbial consortia for bioproduction (e.g., petrochemical equivalents, industrial chemicals, materials).

29. The microbiome engineering could have impacts on Targets 10 (Enhance Biodiversity and Sustainability in Agriculture, Aquaculture, Fisheries, and Forestry) and Target 17 (Strengthen Biosafety and Distribute the Benefits of Biotechnology) of the Kunming-Montreal Global

Biodiversity Framework. In addition, these applications may also contribute directly to the Sustainable Development Goals 7 (Affordable and Clean Energy), 9 (Industry, Innovation and Infrastructure), 12 (Responsible Consumption and Production), 13 (Climate Action) and 15 (Life on Land).

1. Timeframe

30. Applications are under various stages of research, development and commercialization. The majority of research is currently focused on the modification of one or two species in a microbiome. Near-term examples include microbial treatments to replace nitrogen fertilizers (commercialized), Guided Biotics (under regulatory approval) and anti-Varroa mite microbes (field trials).

2. Potential impacts on the objectives of the Convention of Biological Diversity

31. Microbiome engineering for non-medical purposes could have both positive and negative impacts on the objectives of the Convention on Biological Diversity, particularly for conservation and sustainable use of biological diversity.

32. Some potential positive impacts could include:

- Pest and disease resistance;
- Tolerance to abiotic stress (e.g., thermal stress, climate change);
- Reduced use of antibiotic (e.g., lowered risk of antibiotic resistance);
- Reduced dependence on chemical fertilizers;
- Reduced methane emissions from ruminants; and
- Carbon-negative chemical manufacturing (e.g., reduction of greenhouse gases).

33. Some potential negative impacts could include:

- Disruption of natural or agroecological microbiome function;
- Perturbation of ecosystem functions (e.g., disruption of symbiotic relationships);
- Horizontal gene transfer resulting in the spread of antibiotic resistance genes or genetic cassettes (e.g., unintended phenotypes, phenotypic persistence);
- Risk for the development of pathogenicity; and
- Unintended, off-target and unforeseen impacts.

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

34. When considering microbiome engineering for non-medical purposes, the Cartagena Protocol on Biosafety is an important instrument support the process of risk assessment of these applications. Despite this, potential challenges to risk assessment, risk management and regulation may still exist. These could potentially include:

- Modification of organisms in their native environments (e.g., modification outside biosafety regulations);
- Containment challenges (e.g., interconnectedness of microbiomes, accidental escape);
- Potential for spread and transboundary movements; and
- Regulatory status if genome-edited (e.g., mixed regulation for genome edited products).

4. Limits of knowledge

35. Despite a recent and growing body of literature on microbiomes for medical purposes, a high degree of uncertainty may be related to non-medical microbiome engineering due to a lack of knowledge to non-human microbiomes. Thus, some potential points for further consideration may include:

- Limited knowledge on microbiomes in general;
- Complexity of partnership networks;
- Microbial and pathogen evolution;
- Indirect effects of microbiomes on soil and plant health; and
- Cumulative effects.

5. Additional relevant considerations

36. Beyond the potential impacts to the objectives of the Convention on Biological Diversity, and potential challenges to risk assessment, risk management and regulation, microbiome engineering for non-medical purposes could also raise additional relevant considerations. Some potential points may include:

- Human health (e.g., reduced antibiotic resistance in food-borne pathogens, reduced exposure to agricultural chemicals, accidental consumption);
- Human microbiomes (e.g., horizontal gene transfer, accidental consumption);
- Organic farming (e.g., spread of modified microorganisms onto organic farms);
- Creation of new low-carbon or circular economies in the case of biomanufacturing applications;
- Intellectual property (e.g., patenting of microbes could impact farmers and stakeholders involved in agri-food system);
- Free, prior and informed consent of indigenous peoples and local communities (e.g., spread onto traditional lands and waters); and
- Public engagement.

D. Engineered bacteria for nitrogen-fixation and fertilizers

37. Applications of engineered bacteria for nitrogen-fixation and fertilizers aim to use microbial engineering to replace chemical inputs into agricultural systems, such as fertilizers. In the case of nitrogen, these applications aspire to the replace ammonia fertilizers, produced through the Haber-Bosch process. One specific example could be engineered bacteria developed by PivotBio, which colonizes maize roots and fixes nitrogen for the plants.

38. Engineered bacteria for nitrogen-fixation and fertilizers may have considerations for Target 17 (Strengthen Biosafety and Distribute the Benefits of Biotechnology) of the Kunming-Montreal Global Biodiversity Framework, the Soil Conservation Strategy by the Food and Agriculture Organization of the United Nations and the Secretariat of the Convention on Biological Diversity and United Nations Sustainable Development Goal 2 (Zero Hunger).

1. Timeframe

39. The engineered bacteria developed by PivotBio are commercially available in North America. Other engineered (single) microbes with greater capacity to fix nitrogen for maize, barley and wheat systems could be commercialized in the near-term, while consortia might only be available in 10 years or longer.

2. Potential impacts on the objectives of the Convention of Biological Diversity

40. The use of engineered bacteria for nitrogen-fixation and fertilizers could have both positive and negative impacts on the objectives of the Convention on Biological Diversity, particularly for sustainable use of biological diversity.

41. Some potential positive impacts may include:

- Energy efficiency for the production of ammonia fertilizers (e.g., reduced emissions depending on energy infrastructure);
- Reduction of environmental pollution from agricultural run-off that leads to declines in fish and other aquatic organisms (e.g., through eutrophication);
- Reduced chemical inputs into agricultural systems (e.g., reduced environmental impact due to agriculture, efficient resource use); and
- Reduction in greenhouse gases (e.g., assist with emissions reductions).

42. Some potential negative impacts may include:

- Increased invasiveness;
- Increased fitness (e.g., displacement of beneficially microorganisms);
- Unintended impacts on due to altered metabolic functions; and
- Negative impacts on animal microbiomes due to exposure.

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

43. When considering risk assessment and risk management of engineered bacteria for nitrogen-fixation and fertilizers, natural (non-modified) biological fixation is likely to provide an appropriate comparator to inform the process of risk assessment. However, following may complicate or pose challenges to the risk assessment of such organisms:

- Containment (e.g., lack of ability to retrieve organisms once released);
- Potential for transboundary movements; and
- Persistence (e.g., phenotypic persistence due to horizontal gene transfer to other species; colonization).

4. Limits of knowledge

44. No information was shared regarding potential limits of knowledge related to this topic.

5. Additional relevant considerations

45. Beyond the potential impacts to the objectives of the Convention on Biological Diversity, and potential challenges to risk assessment, risk management and regulation, engineered bacteria for nitrogen-fixation and fertilizers could also raise additional relevant considerations, such as:

- Cost savings for producer (e.g., reduced procurement of fertilizers);
- Increased soil fertility and productivity;
- Intellectual property (e.g., relationship between patents and food systems); and
- Access to information and lack of transparency.

E. Genome-edited plants

46. When referring to genome edited plants, applications are based on the precise genetic modification of a plant species to induce a variety of different traits, such as herbicide tolerance, pest resistance or improved composition, among many others. Tools, such as CRISPR,[1] induce genetic modifications that range from having single nucleotide variations (e.g., additions, deletions, conversions) to precise additions of genetic sequences (e.g., integration of a gene cassette into a define location on a chromosome, genetic sequence replacements) to complex rearrangements of genetic material. Other applications may also have a series of genomic edits in one plant variety, such as de novo domestication of wild crop relatives.

47. In general, research and development are largely focused on agricultural crop species, but genome editing may also be applied to ornamental flowers and trees. Some specific examples of genome-edited plants include:

- Soybean with high-oleic acid levels;
- Disease resistant banana, cassava, maize, potato and rice;
- Cyanide-free cassava;
- Low-arsenic rice;
- Mustard greens with reduced bitterness; and
- Reduced methane emitting rice.

48. Genome edited plants may have contributions to Target 17 (Strengthen Biosafety and Distribute the Benefits of Biotechnology) of the Kunming-Montreal Global Biodiversity Framework through research on detection and identification and risk assessment to strengthen biosafety capacity. Other targets that could be impacted may include Targets 2 (Restore 30% of All Degraded Ecosystems), 7 (Reduce Pollution to Levels That Are Not Harmful to Biodiversity), Target 9 (Manage Wild Species Sustainably To Benefit People), 10 (Enhance Biodiversity and Sustainability in Agriculture, Aquaculture, Fisheries, and Forestry), 14 (Integrate Biodiversity in Decision-Making at Every Level) and 15 (Businesses Assess, Disclose and Reduce Biodiversity-Related Risks and Negative Impacts). However, it is important to recognize that genome edited plants may have the potential to both assist and hinder the achievement of these targets, depending on the specific traits and manner in which they are used.

49. Further, these applications may also support several United Nations Sustainable Development Goals, such as 1 (No Poverty), 2 (Zero Hunger), 3 (Good Health and Well-Being), 9 (Industry, Innovation and Infrastructure), 12 (Responsible Consumption and Production), 13 (Climate Action) and 15 (Life on Land).

1. Timeframe

50. Genome-edited plants containing small mutations, such as single nucleotide variations or knockouts, have already been authorized, including a high-amylopectin waxy corn and *Camelina sativa* with enhanced omega-3 oil in the United States, as well as a tomato with increased γ-aminobutyric acid levels in Japan and a high oleic soybean in China. Further increases can be expected in the near-term. For plants containing complex genetic rearrangements, commercialization may take over 10 years as further research is required.

51. In addition, it would be important to note that for commercial use, genome-edited varieties would still require several years of breeding and selection before integration into commercial

[1] Other tools, such as meganucleases, zinc finger nucleases and oligonucleotide-directed mutagenesis can also be used to produce single or few base pair changes in plant systems.

varieties despite the potential speed in development in comparison to other genetic engineering technologies, such as those based on transgenesis.

2. Potential impacts on the objectives of the Convention of Biological Diversity

52. Genome-edited plants may have both positive and negative impacts on the objectives of the Convention on Biological Diversity, but these will depend on the specific characteristics of the plant.

53. Some potential positive impacts include:

- Tolerance to abiotic stress (e.g., drought, climatic adaptation);
- Resistance to pests and pathogens (e.g., reduced use of plant protection products);
- Enhanced carbon storage in root systems;
- Improved nutritional content;
- Improved photosynthesis;
- Increased yield;
- Improved soil quality (e.g., protecting soil biodiversity, reduced soil erosion);
- Improved resource and land use efficiency; and
- Enable sustainable use of biological diversity (e.g., enabling product of natural plant metabolites in non-endangered species).

54. Some potential negative impacts may include:

- Increased use of pesticides or herbicides (e.g., traits that enable chemical product use);
- Changes to structure or nutritional content (e.g., unsuitable for consumption by wild animals);
- Hybridization with native plant species (e.g., reduced genetic diversity);
- Changes to toxicity and allergenicity of the plant;
- Unintended on-target and off-target effects (e.g., mutations, complex rearrangements, translocations, insertions and deletions, foreign DNA incorporation);
- Altered cellular regulation (e.g., production of aberrant peptides, changes in metabolite levels);
- Intensification of agricultural management practices; and
- Increased use of genetic resources without benefits-sharing.

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

55. Regulation of genome-edited plants currently varies by jurisdiction. Some countries consider genome-edited plants to fall under the definition of "*living modified organism*" pursuant to the Cartagena Protocol on Biosafety regardless of the outcome of the genome editing process (e.g., single nucleotide variant or transgene), while other consider genome-edited plant to be equivalent to conventional varieties produced through traditional breeding (e.g., for those that do not result in the presence of transgenes). A mixed regulatory landscape may bring challenges to regulatory harmonization internationally, trade and thorough evaluation of the applications if risk assessment is not required. Further, regulatory considerations may need to be in place regarding the unintended incorporation of foreign DNA into the genome edited organism.

56. One of the main challenges for the regulation of genome-edited plants is related to detection and identification. Detection methods may not have the ability to distinguish between mutations caused from targeted mutagenesis and those resulting from natural mutation. Despite the

developments with digital polymerase chain reaction and next-generation sequencing, detecting point mutations or the small addition or deletion of a few bases remains to be a technical challenge. Thus, analytical detection may need to be complemented by other enforcement measures, such as a voluntary registry for collection and dissemination of information.

57. However, other challenges related to genome edited plants may not be fundamentally different than those varieties produced through convention breeding techniques, depending on the trait introduced or enabled. Thus, regulation may need to be considered in proportion to the risks presented by the genome-edited plants, have different approaches depending on the plant species edited or be adaptable to further developments in science.

4. Limits of knowledge

58. No information was shared regarding potential limits of knowledge related to this topic.

5. Additional relevant considerations

59. Beyond the potential impacts to the objectives of the Convention on Biological Diversity, regulation, genome-edited plants could also raise additional relevant considerations. Some potential points may include:

- Improved nutrition and flavour of crops;
- Presence of unwanted secondary metabolites or toxic substances;
- Improved food security;
- Improved storage or increased shelf life;
- Improved development pipeline (e.g., increased breeding efficiency, increased availability of crop varieties, “orphan” and non-staple crops, expedited development pipeline);
- Responsible innovation (e.g., removal of varieties during development that do not meet performance or safety standards, lack of stable phenotypes);
- Due diligence by developer (e.g., ensuring no foreign DNA incorporation);
- Increased seed diversity;
- Increased economic benefits for farmers (e.g., higher yield and quality, increased productivity, cost savings);
- Public acceptance and perceptions;
- Intellectual property (e.g., ensuring access by breeders and farmers at affordable prices, preserving investment incentives, patenting of sequence from centres of origin);
- Access to technology for developing countries;
- Access to information and transparency (e.g., the need for a voluntary registry to improve traceability and information availability);
- Organic and “GMO-free” agriculture;
- Consumer choice and awareness; and
- Public engagement, including indigenous peoples and local communities.

F. Transient modification of agricultural plants, pests and pathogens using RNA interference or nanomaterials

60. Transient modification applications are generally based on the use of RNA interference to cause temporary gene silencing. The technology is based on the sequence homology between the double stranded RNA, hairpin RNA or small interfering RNA and a target messenger RNA. The double stranded RNA structure triggers a cellular response resulting in gene silencing through degradation of messenger RNA, blocking translation or inducing epigenetic changes (e.g., heterochromatin formation).

61. These applications can be formulated as topical sprays, which can be applied to crop plants, to feed or to food products to control pests and pathogens (biopesticides). However, the molecules can also be produced by living modified organisms containing a specific gene cassette, such as crop plants or cell factories, to confer pest resistance (e.g., by feeding) or enhance bioproduction (e.g., endogenous gene silencing). Thus, some applications aim to replace chemical pesticides.

62. Some specific examples of applications that could be considered as part of this item include:

- Topical applications targeting pest insects;
- Foliar sprays of double stranded RNA targeting pathogens on crops (e.g. Tobacco mosaic virus, fungi, viruses);
- Living modified maize expressing RNA interference cassette targeting corn rootworm;
- Living modified cassava expressing RNA interference cassette cassava brown streak disease; and
- Applications to control varroa mite in bee hives (e.g., double stranded RNA sugar solutions fed to bees to confer protection to worker bees).

63. Further, nanomaterials, such as clay nanosheets and biodegradable complexes, are investigated for improving double stranded RNA stability in the environment. These carriers may provide protection from environmental nucleases and ultraviolet light. This is an active and complementary research area to the use of RNA interference-based biopesticides.

64. Transient modification of agricultural plants, pests and pathogens using RNA interference or nanomaterials may contribute to Targets 7 (Reduce Pollution to Levels That Are Not Harmful to Biodiversity) 10 (Enhance Biodiversity and Sustainability in Agriculture, Aquaculture, Fisheries, and Forestry) and 17 (Strengthen Biosafety and Distribute the Benefits of Biotechnology) of the Kunming-Montreal Global Biodiversity Framework. However, RNA interference-based sprays could be considered to be pesticides, which may need further consideration in relation to Target 7, and biosafety safety measures may need strengthening to account for gaps in risk assessment and management to promote Target 17.

65. In addition, RNA interference-based application may also contribute to the United Nations Sustainable Development Goals 1(No Poverty), 2 (Zero Hunger), 3 (Good Health and Well-Being), 13 (Climate Action) and 15 (Life on Land). Furthermore, these applications may also support the Soil Conservation Strategy by the Food and Agriculture Organization of the United Nations and the Secretariat of the Convention on Biological Diversity.

1. Timeframe

66. RNA interference-based applications are immediate to near-term. Several LMOs containing RNA interference genetic cassettes have already been commercialized and approved in several jurisdictions (e.g., BPS-25271-9, DP-Ø23211-2, DP-3Ø5423-1, DPS-Ø4Ø46–8, MON-87411-9, MON-87429-9, MON-877Ø5-6 and MON-948Ø4-4).

67. Spray formulations containing double stranded RNA molecules are undergoing commercialization (e.g., Ledprona from GreenLight Biosciences, Evolutta Agro Biotecnologia and

Sempre Agtech) in the United States of America and Brazil. Ledprona is expected to be the first dsRNA spray application for commercial use in plants. In other jurisdictions, such as China, field trials have been conducted. For example, Shanghai Zhi Sheng You Gu Biotechnology Co., Ltd. Performed tests of products against cotton aphids (*Aphis gossypii*), peach aphids (*Myzus persicae*) and striped flea beetles (*Phyllotreta striolata*). Further, Silray Technology (Shanghai) Co. have begin field testing their RNA interference biopesticides targeting nucleic acid interference factors against Tobacco mosaic virus. Other applications, such as those designed to alter the gender of prawns could also be in the process of commercialization, but it is not clear.

2. Potential impacts on the objectives of the Convention of Biological Diversity

68. The transient modification of agricultural plants, pests and pathogens using RNA interference or nanomaterials could have both positive and negative impacts on the objectives of the Convention on Biological Diversity.

69. Some potential positive impacts could include:

- Reduction of chemical, board-spectrum pesticides (e.g., reduced toxic exposure);
- Low toxicity;
- Specific targeting of pests and pathogens; and
- High environmental degradability.

70. Some potential negative impacts could include:

- Unintended impacts in off-target organisms when used in the environment;
- Unintended gene silencing within target organism;
- Changes in gene expression due to saturation of RNA interference machinery;
- Adverse immunological reactions;
- Persistence in environment (e.g., using novel formulations); and
- Novel forms of resistance development.

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

71. When considering the use of transient modification applications, current regulatory frameworks, such the Cartagena Protocol on Biosafety, are likely sufficient support the process of risk assessment of LMO plants containing RNA interference cassettes. In contrast, since topical applications of double stranded RNA are not living organisms, they would not be considered to be subject to the provisions of the Cartagena Protocol on Biosafety. However, RNA interference-based biopesticides have also been assessed as chemical pesticide products by a few bodies, such as the Organization for Economic Cooperation and Development Working Party on Pesticides Ad Hoc Expert Group on RNA interference pesticides.

72. Despite this, potential challenges to risk assessment, risk management and regulation may still exist for transient modification applications. These may include:

- Stability of double stranded RNA molecules, particularly for novel formulations;
- Next-generation effects (e.g., intergenerational hereditary effects);
- Challenges to definition of "living modified organism" pursuant to the Cartagena Protocol on Biosafety if an organism is transiently modified;
- Treatment of topical applications as chemical pesticides (e.g., differing mode of action from conventional chemical pesticides);

- Exposure pathways of non-target organisms;
- Availability of suitable ecotoxicological testing;
- Limitations in the use of bioinformatic analyses for predicting off-targeting; and
- Lack of rapid and sensitive detection methods for measuring double stranded RNA molecules in the environment.

73. However, it can also be noted that due to the mechanism of RNA interference, there is no modification (i.e., sequence change) at the genome level for these products, even in a transient manner. Rather, gene silencing occurs at the level of transcription and translation.

4. Limits of knowledge

74. The use of transient modification applications in the environment may raise questions regarding current levels of knowledge in relation to the mode of action of these applications and could have implications on the risk evaluations of these application. Some potential considerations may include:

- Fate, kinetics and concentration of double stranded RNA molecules in the environment;
- RNA interference mechanism and specificity (e.g., organismal variation, homology considerations and size requirements of small interfering RNA to trigger an RNA interference response, response and epigenetic effects);
- Impact of polymorphisms and mutations on efficacy and impact of the application;
- Availability of genomic or transcriptomic sequences for all organisms in environment (e.g., prediction of possible off-target effects); and
- Unintended prolonged effects (e.g., epigenetic inheritance mechanisms).

5. Additional relevant considerations

75. In addition to the potential impact and challenges to risk assessment, transient modification of agricultural plants, pests and pathogens using RNA interference or nanomaterials could also raise additional relevant considerations. Some potential points may include:

- Alternative options to conventional pesticides (e.g., targeted pest control);
- Improved farm productivity (e.g., climate change mitigation);
- Human health (e.g., immunological reactions, sequencing homology to product, negligible impact due to physiology);
- Drift of dsRNA sprays to non-target fields or indigenous territories (e.g., co-existence with other production systems, liability, free, prior and informed consent);
- Ensuring access to the technology, particularly for developing countries (e.g., sharing benefits);
- Lack of knowledge sharing between the fields of health and agriculture regarding the use and exposure routes (e.g., oral intake);
- Intellectual property (e.g., extension to exposed organism and off-spring, claims on natural or agricultural systems); and
- Public and stakeholder participation (e.g., need for iterative communication processes).

G. Technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature

76. Advancements in synthetic biology can facilitate the modification of organisms in the field or in nature. These applications include novel mechanisms to deliver molecular machinery, vectors or double stranded RNA molecules to various target organisms without the need for tissue culturing or conventional transformation protocol. Specific example of advancements include.

77. Some specific examples of advancements include:

- Engineered gene drives;
- RNA interference topical applications;
- Horizontal Environmental Genetic Alteration Agents (e.g., insect delivery of viral sectors);
- Pollen-mediated delivery of genome editing machinery;
- Use of modified viruses (e.g., modified viruses to deliver genome editing machinery or induce RNA interference); and
- Use of nanoparticles and other novel chemistries (e.g., DNA nanotubules, engineered proteins).

1. Timeframe

78. Research and development of novel chemistries and new delivery systems was ongoing and nascent for certain applications. However, the modified phages targeting *Salmonella sp*. developed by Folium Science are undergoing commercialization in Brazil, Thailand and the United States (see section II, sub-section C above). In addition, double stranded RNA applications may also be in the near-future (see Section II, subsection F above), while engineered gene drives might be 5 to 10 years away for field testing (see Section I, sub-section C above).

2. Potential impacts on the objectives of the Convention of Biological Diversity

79. The technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature could have both positive and negative impacts particularly on the first objective of the Convention on Biological Diversity.

80. Some potential positive impacts on the conversation of biological diversity include:

- Reduced human damage on fragile ecosystems (e.g., use of engineered gene drives); and
- Reduced use of chemical pesticides (e.g., reduced toxic effects on biological diversity).

81. Some potential negative impacts on the conversation of biological diversity include:

- Disruption of evolutionary processes;
- Impaired biotic-biotic relationships;
- Off-target effects (such as in the case of genome editing, which could potentially cause genetic insertions, deletions, inversions, translocations and rearrangements);
- Horizontal gene transfer (e.g., spread of antibiotic resistance genes); and
- Unintended affects.

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

82. When considering the technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature, potential challenges to risk assessment, risk management and regulation may exist. These could include:

- Lack of published risk assessments;
- Treatment of uncertainty;
- Lack of risk management measures (e.g., potential for irreversibility);
- Regulatory gaps (e.g., biosafety vs chemical regulatory mechanisms, potential for 'grey' area); and
- Labelling and traceability.

4. Limits of knowledge

83. Current knowledge surrounding the technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature could raise questions when used in the environment. Some considerations may include:

- Characterized microbial species in the environment (e.g., poor cultivation in laboratories for vast majority);
- Microbial interactions in the environment (e.g., microbial communities, host relationship); and
- Impact of cumulative effects.

5. Additional relevant considerations

84. Beyond the potential impacts to the objectives of the Convention on Biological Diversity, and potential challenges to risk assessment, risk management and regulation, the technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature could also raise additional relevant considerations. Some potential points may include:

- Health (e.g., plasmid-mediated spread of antibiotic resistance genes to human-health relevant bacterial pathogens);
- Market concentration;
- Liability and redress (e.g., spread of application onto organic farm and subsequent legal status, damage to staple crops);
- Consumer choice (e.g., labelling);
- Dual-use; and
- Military funding (i.e., in the case of Horizontal Environmental Genetic Alteration Agents).

H. Ability to re-create viruses by chemical DNA synthesis[2]

85. Advancements in chemical DNA synthesis and assembly of oligonucleotides can allow for the de novo synthesis of viruses. To achieve infectious viral particles, oligonucleotides are first synthesized and then assembled into longer oligonucleotides based on overlapping homologous regions through the use of assembly strategies, such as polymerase chain reaction techniques, Gibson assembly, among other assembly or extension tools. These long oligonucleotides are then transfected into the appropriate host cell for replication and assembly of viral particles. Technological improvements have allowed for the use of fewer larger oligonucleotides (10 to 30 kilobases in size) for assembly, relied on synthetic genomics in yeast cells to assemble copy DNA and generate infectious RNA (for RNA viruses) and/or utilized helper viruses.

86. Some specific examples of viruses that have been re-created from synthetic oligonucleotide assembly include:

[2] Limited information was shared during the submissions process. Text under this section is based on Technical Series No. 100 and a limited number of references.

- Poliovirus;
- Bacteriophage φX174;
- Horsepox;
- Influenza (e.g., 1918 and H7N9 strains);
- Hepatitis C virus; and
- Coronaviruses (e.g., bat SARS-like coronavirus, SARS-CoV-2).

1. Timeframe

87. Proof of concept studies have occurred since the early 2000s. In 2000, researchers constructed a DNA copy of Hepatitis C virus and in 2002, researchers generated infectious polioviruses from DNA copies. Other significant examples include the synthesis of previously extinct influenza (1918 Spanish pandemic strain) in 2005 and horsepox virus in 2018.

88. Availability of viral sequence information (e.g., Virus Pathogen Database and Analysis Resource) and software tools to guide genome assembly processes may increase the speed of skilled researchers to assemble synthetic viral genomes. Increased capability of commercial nucleotide synthesis could also facilitate the assembly of synthetic RNA genomes (~30 kilobases) in a two to three-week period by skilled researchers.

2. Potential impacts on the objectives of the Convention of Biological Diversity

89. Due to the development of these synthetic viruses in contained settings and for medical purposes, limited information regarding the potential impacts on the objectives of the Convention is available in published literature. However, there could be potential impacts on access and benefit sharing of genetic resources, such in the case of collecting genetic material from one nation to develop therapeutics without appropriate benefits sharing to the country of origin.

90. Regarding other potential impacts on the other objectives of the Convention, there is the potential for negative impacts if the technology is misused. However, if these applications are applied for other uses, there could also be potential positive impacts, such as the development of therapeutics for wildlife or animals.

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

91. When considering the synthesis of viruses, potential gaps may relate to access and benefits sharing regulation, such as in the case of the Convention on Biological Diversity and the Nagoya Protocol. The availability of sequence information online and reduced costs of procuring synthetic oligonucleotides from a commercial provider could potentially allow for researchers to circumvent regulation. Other considerations may also include questions regarding containment and accidental release events, as well as the relationship between other international instruments, such as the Biological Weapons Convention for these applications.

4. Limits of knowledge

92. Limited information is available regarding the development of these applications in relation to the Convention on Biological Diversity.

5. Additional relevant considerations

93. Beyond the potential impacts to the objectives of the Convention on Biological Diversity, and potential challenges to risk assessment, risk management and regulation, the use of synthetic biology in wild organisms in the context of resilience in threatened species could also raise additional relevant considerations. Some potential points may include:

- Novel vaccine and gene therapy platforms;

- Rapid vaccine development;
- Creation of bioweapons; and
- New pathogenic viruses (e.g., human pathogens).

94. However, it is important to note that viral genome assembly requires significant expertise to implement the required workflow and DNA synthesis companies have implemented a Harmonized Screening Protocol to voluntarily screen all orders in alignment with guidance from the US Department of Health and Human Services. While there is not a single DNA screening algorithm used by all IGSC members, DNA-screening software typically aligns a query sequence and 200 bp sub-sequences to a reference database of biological toxins and select agent genomes, genes, or proteins as a means of addressing biosecurity concerns associated with the potential misuse of their products to bypass existing regulatory controls.

I. Interaction of synthetic biology organisms in the environment and potential for cumulative effects

95. An increasing number of synthetic biology applications are enabled by new tools and techniques (e.g., new genome editing technologies), while also being produced due to convergences between various technological developments and fields. As such, individual impacts from each intervention could be combined together, leading to potential scale effects due to the numerous synthetic biology interventions, increased interactions and cumulative effects.

1. Timeframe

96. Cumulative and scale effects might already be occurring. However, these are expected to increase as new applications are rapidly developed and approved for release.

2. Potential impacts on the objectives of the Convention of Biological Diversity

97. The interaction of synthetic biology organisms in the environment and potential for cumulative effects is likely to impact the conservation and sustainable use of biological diversity objectives of the Convention on Biological Diversity.

98. The potential risks and impacts could be synergistic and/or non-linear, such as in the examples of the effect of large numbers observed in research on invasion ecology and the observations of cumulative effects from pesticide interventions. More specifically, synthetic biology organisms may compete with native species in the environment and the behaviour of the organisms out of containment could be unpredictable. Further, hybridization or mutation may further introduce adverse effects or reduce genetic diversity.

99. A better understanding of the interaction of synthetic biology organisms on the environment may facilitate a better understanding of interactions between species, providing insights in how to better manage and protect ecosystems. Further, there could also be novel conservation efforts, such as artificial ecosystems and gene banks, created to address damage caused by human activity.

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

100. When considering the interaction of synthetic biology organisms in the environment and potential for cumulative effects, the challenges to risk assessment are likely related to the unpredictability of these interactions together (e.g., within the organism, between multiple organisms, hybridization), evolutionary factors and the behaviour of synthetic biology organisms in the environment, including interactions between multiple synthetic biology applications in the same environment. Biocontainment measures, such as “kill switches”, may assist in limiting impacts on biological diversity, but would likely require further research and development.

101. Given this, it would be important to foster interdisciplinary research and collaboration, including biology, environmental science, sociology, law and ethics, for informing risk assessment

and regulation of synthetic biology applications. Additionally, there also could be a need for monitoring, particularly for unintended consequences (e.g., due to hybridization and evolution).

4. Limits of knowledge

102. No information was shared regarding potential limits of knowledge related to this topic.

5. Additional relevant considerations

103. Similar to the experience with pesticides, cumulative effects may make the public cautious of synthetic biology-based interventions.

J. Transboundary movements and relation to detection and identification of synthetic biology organisms, parts and products

104. Ensuring the safe movement and detection and identification of the applications of synthetic biology could be important to prevent both unintended and illegal transboundary movements of the applications of synthetic biology. Thus, due to this importance, further work in the field of detection and identification of synthetic biology organisms and increased capacity-building is crucial.

105. Specific examples of applications that have a higher risk for unintentional transboundary movements, include those designed to spread (e.g., engineered gene drives).

1. Timeframe

106. No information was provided regarding the potential timeframe for this topic.

2. Potential impacts on the objectives of the Convention of Biological Diversity

107. Limited information was provided regarding the potential impacts on the objectives of the Convention.

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

108. In terms of regulation of synthetic biology applications that are considered to be LMOs, provisions exist in the Cartagena Protocol on Biosafety to manage transboundary movements. Further certain regional approaches, such as the Integrated Vector Management Platform in West Africa, support decision-making in a regional context by supporting the development of joint-guidelines for evaluating requests and capacity-building initiatives for vector control in the region.

109. Regarding the availability of tools for detection identification and monitoring of the applications of synthetic biology, establishing validated methods for detection and identification that can be used in very different organisms, appropriate identifiers, sampling strategies and detection limits are areas that may require further research and development. Establishing expert centres, improving access to information and investing in laboratory infrastructure may be able to address some of the needs with respect to detection and identification.

4. Limits of knowledge

110. No information was shared regarding potential limits of knowledge related to this topic.

5. Additional relevant considerations

111. Ensuring the safe movement and detection and identification of the applications of synthetic biology could be important to promote a positive public perception of synthetic biology.

K. Increased field testing of synthetic biology applications, including in areas outside the national jurisdiction of the developer or funder

112. Field testing of synthetic biology applications is a precondition for wider release of these applications in the environment and following an extensive development phase in contained laboratory facilities. These trials are used to collect additional data and evaluating efficacy of the

application outside contained conditions. Due to the transformative nature of synthetic biology, some applications aimed at addressing pressing issues in developing countries, field testing may occur outside the jurisdiction of the developer. However, field trials should be conducted in accordance with national legislation of a particular country and not related to the nationality of the developer.

1. Timeframe

113. Field trials for applications of synthetic biology were ongoing and likely to increase in number within the next 5 years.

2. Potential impacts on the objectives of the Convention of Biological Diversity

114. Field testing contributes to the conservation and sustainable use objectives of the Convention on Biological Diversity by generating information on potential impacts and ensuring biosafety risks can be appropriately managed. When field trials are conducted in areas where there is insufficient regulation or rule of law, biosafety risks may not be properly managed. Thus, in these cases, there could be a potential for negative impacts on biological diversity.

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

115. The major challenges to risk assessment and regulation would come from situations where field trials are conducted in areas where there is insufficient regulation or rule of law. In these cases, there is a greater potential for transboundary movements of synthetic biology applications. However, in situations where there are regulations, field testing would be conducted in accordance with national legislation.

4. Limits of knowledge

116. No information was shared regarding potential limits of knowledge related to this topic.

5. Additional relevant considerations

117. No information was shared regarding potential additional relevant considerations related to this topic.

L. Dual-use nature and biosecurity implications of synthetic biology

118. As the relevant technology becomes cheaper and more accessible, the potential for misuse or abuse of the technology could increase and warrant greater attention than before, especially when regulation might be missing, such as in the case for in many countries.

119. Applications based on microorganisms, such as synthetic biology bacteria and viruses, have a higher dual-use risk than those higher-level organisms, such as plants, animals. A bioterrorist would likely be more interested in creating novel pathogens for the organisms of interest. Thus, for certain applications deployed in animals and plants, such as engineered gene drives, short reproductive cycle would be required to have rapid effects.

120. The mis-use or dual-use of applications could have impacts on Targets 13 (Increase the Sharing of Benefits From Genetic Resources, Digital Sequence Information and Traditional Knowledge) and 17 (Strengthen Biosafety and Distribute the Benefits of Biotechnology) of the Kunming-Montreal Global Biodiversity Framework.

1. Timeframe

121. The timeframe for these impacts can vary widely, from immediate to years or decades, depending on specific applications, regulations and scientific advancements. Efforts are ongoing to address biosecurity concerns, requiring ongoing monitoring and policy adaptation. However, potential impacts may be realized within 5 to 10 year time period.

2. Potential impacts on the objectives of the Convention of Biological Diversity

122. The applications of synthetic biology could have both positive and negative impacts on the objectives of the Convention on Biological Diversity.

123. Some potential positive impacts on the conversation of biological diversity include:

- Tools to enhance our understanding of biodiversity and aid conservation efforts;
- Techniques to preserve and analyze genetic diversity of endangered species;
- Ecosystem restoration (e.g., de-extinction initiatives);
- Reduced resource use and support for sustainable agriculture (e.g., engineered crops);
- Reduced reliance on fossil fuels through the use of biofuels; and
- Facilitation of bioprospecting and benefit-sharing agreements.

124. Some potential negative impacts on the conversation of biological diversity include:

- Accidental release of engineered organisms that cause adverse ecological impacts;
- Exploitation of genetic resources without benefit-sharing; and
- Unintended consequences (e.g., development of novel pathogens).

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

125. There could be a need to further consider the relationship between the dual-use of synthetic biology applications and existing international agreements, such as the Biological and Toxin Weapons Convention. Further, risk assessment models may not be fit to assess the risk resulting from mis-use of synthetic biology technologies. In addition, there could be challenges for some countries to monitor for such developments or uses.

4. Limits of knowledge

126. No information was shared regarding potential limits of knowledge related to this topic.

5. Additional relevant considerations

127. The main consideration related to the dual-use nature of synthetic biology relates to misuse and bioterrorism due to a greater access enabling tools and technologies. However, other additional relevant considerations may also include:

- Expedited development of medicines and vaccines;
- Disputes over ownership and control over genetic resources if genetic information is synthesized or manipulated;
- Commercialization of genetic resources;
- Ethics (e.g., human intervention in nature);
- Public perception of synthetic biology; and
- Displacement of traditional industries and small-scale farmers.

Annex

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