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Synthetic biology

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Note by the Secretariat

I. Introduction

1. In its decision 15/31, the Conference of the Parties to the Convention on Biological Diversity established a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology and agreed to start its work for one intersessional period. The process consists of the following steps:

(a) Information gathering;

(b) Compilation, organization and synthesis of information;

(c) Assessment;

(d) Reporting on outcomes.

2. In the same decision, the Conference of the Parties established the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment. In its terms of reference, set out in section B of the annex to the decision, the Group was requested to: (a) make use of existing tools and approaches to enable a participatory process to review and assess the information gathered through the horizon scanning process; (b) identify and prioritize trends and issues regarding developments in synthetic biology; (c) identify capacity-building, technology transfer and knowledge-sharing needs in the light of the outcomes of the process; (d) prepare a report on the outcomes of its assessment to be submitted to the Subsidiary Body on Scientific, Technical and Technological Advice; and (e) make recommendations to the Subsidiary Body on specific issues that might require further consideration by the Conference of the Parties and/or the Conference of the Parties serving as the meetings of the Parties to the Protocols.

3. Also in the same decision, and with a view to supporting the work of the multidisciplinary Ad Hoc Technical Expert Group, the Conference of the Parties requested the Executive Secretary to convene discussions of the Open-ended Online Forum on Synthetic Biology and invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the

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Executive Secretary information relevant to trends in new technological developments in synthetic biology.

4. The multidisciplinary Ad Hoc Technical Expert Group met twice in person: first to determine how horizon scanning, monitoring and assessment would be conducted during the intersessional period; and second to finalize the assessment of the trends and issues in synthetic biology, identify capacity-building, knowledge-sharing and technology transfer needs in the light of the outcomes of the process and make recommendations to the Subsidiary Body.

5. The present document contains information on the horizon scanning and assessment activities undertaken during the intersessional period in relation to the programme of work on synthetic biology. Section II contains an overview of the methodology followed, section III information on the horizon scanning, monitoring and assessment conducted by the multidisciplinary Ad Hoc Technical Expert Group, section IV information on capacity-building, technology transfer and knowledge-sharing, section V information on the review of the process and section VI recommendations for consideration by the Subsidiary Body. Lastly, the annexes contain the outcomes of the report of the Group, namely, the outcomes of the first horizon scanning, monitoring and assessment step (annex I), information on capacity-building, technology transfer and knowledge-sharing (annex II), the review of the process (annex III), the refined methodology for broad and regular horizon scanning, monitoring and assessment (annex IV) and the recommendations of the Group (annex V).

II. Methodology followed for horizon scanning, monitoring and assessment

6. At its first meeting, held from 11 to 14 July 2023, the multidisciplinary Ad Hoc Technical Expert Group determined an expert-driven process for the 2023–2024 intersessional period. The process consisted of two parallel activities, namely, a multidisciplinary expert-driven submission process and a complementary literature review.[1] It fulfilled the four steps of horizon scanning, monitoring and assessment specified in the annex to decision 15/31. The activities were based on a revised list of 54 trends and issues in synthetic biology produced by the Secretariat and guided by the provisions of paragraph 6 of decision 15/31. The revised list was thus drawn on the basis of the report of the Ad Hoc Technical Expert Group on Synthetic Biology on its meeting held in 2019,[2] *Technical Series No. 100: Synthetic Biology*, the submissions of information and the discussions held in the Open-ended Online Forum on Synthetic Biology.

7. The multidisciplinary expert-driven process consisted of the following steps: (a) submissions by the Group members, including three new items identified by the Group; (b) compilation of a shortlist of 37 items by the Secretariat, (c) production by the Group members of a prioritized list of 17 items, including 5 items earmarked for a detailed assessment; (d) further information gathering for assessment through additional submissions of information and discussions in the Open-ended Online Forum; and (e) compilation and synthesis of the information for the Group.

8. In accordance with the process agreed on, the Secretariat conducted in parallel a complementary literature review, which consisted of a quantitative exploration of the publication landscape over the period 2012–2023. At the time of reporting, the literature review was still under peer review (scheduled from 16 January to 1 March 2024), and a revised version will be made available as information document CBD/SBSTTA/26/INF/5.

9. At its second meeting, held from 29 January to 2 February 2024, the multidisciplinary Ad Hoc Technical Expert Group conducted an assessment of the five trends and issues that it had identified for a more detailed assessment (see annex II). Owing to time constraints, no assessment was conducted on the other 12 items on the prioritized list. The information gathered, compiled, organized

[1] See CBD/SYNBIO/AHTEG/2023/1/3, annex I, sect. B, for a detailed description of the process.
[2] CBD/SYNBIO/AHTEG/2019/1/3.

and synthesized during the multidisciplinary expert-driven process for those 12 items will be made available in information document CBD/SBSTTA/26/INF/4.

10. The process is presented in more detail in annex III, in relation to the four steps of horizon scanning, monitoring and assessment laid out in the annex to decision 15/31.

III. Horizon scanning, monitoring and assessment of the trends and issues in synthetic biology

11. In its decision 15/31, the Conference of the Parties specified that the coordinating actors for the assessment step of the broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology were the multidisciplinary Ad Hoc Technical Expert Group and the Subsidiary Body.

12. During their online meeting held in October 2023, the Group members prioritized 17 trends and issues in synthetic biology, of which 5 were earmarked to undergo a more detailed assessment, namely:

(a) Self-spreading vaccines for wildlife;

(b) Self-limiting insect systems;

(c) Development of engineered gene drives to control vector-borne diseases and invasive species;

(d) Integration of artificial intelligence and machine learning;

(e) Inequity in the participation of developing countries in the context of synthetic biology.

13. At the second meeting, the Group members performed an assessment of the aforementioned five trends and issues (see annex I). Owing to time constraints, the list of 12 additional items that made up the prioritized list (see annex I, sect. VI) were not assessed by the members. The full list of trends and issues considered during the present cycle of horizon scanning can be found in section VII of annex I.

IV. Capacity-building, technology transfer and knowledge-sharing

14. In its decision 15/31, the Conference of the Parties requested the Executive Secretary to facilitate international cooperation and promote and support capacity-building, technology transfer and knowledge-sharing regarding synthetic biology, taking into account the needs of Parties and indigenous peoples and local communities. In addition, it requested the multidisciplinary Ad Hoc Technical Expert Group to identify capacity-building, technology transfer and knowledge-sharing needs on the basis of priorities determined by Parties on issues related to synthetic biology and in the light of the outcomes of the horizon scanning process.

15. At its second meeting, the multidisciplinary Ad Hoc Technical Expert Group identified initial inputs for potential options that Parties might wish to consider for capacity-building, technology transfer and knowledge-sharing in the context of synthetic biology (see annex II for detail).

V. Review of the process

16. In its decision 15/31, the Conference of the Parties requested the Executive Secretary to prepare a report on the operation of the horizon scanning process and to submit it for peer review to support a review of the effectiveness of the process by the Subsidiary Body, which would, on that basis, make a recommendation on the need to extend the process.

17. In response to the request, the Secretariat prepared an initial report on the effectiveness of the process and made it available as part of document CBD/SYNBIO/AHTEG/2024/1/2. On the basis of their experience in conducting the horizon scanning process, the Group members provided feedback

during the second meeting. In response, the Secretariat prepared the review of the process (see annex III).

18. It is important to note that the four steps specified in the annex to decision 15/31 were addressed in the current cycle of the horizon scanning process. Monitoring elements, however, may require further development.

19. The following steps could be potentially followed to optimize the methodology for the horizon scanning process in future cycles, should there be any:

(a) Information gathering on all trends and issues in synthetic biology;[3]

(b) Compilation, organization and synthesis of information;[4]

(c) Screening and prioritization of trends and issues in synthetic biology;[5]

(d) Information gathering on prioritized trends and issues to support assessment;[3]

(e) Compilation, organization and synthesis of information;[4]

(f) Assessment of the prioritized trends and issues in synthetic biology;[6]

(g) Reporting on outcomes.[7]

20. Further considerations for the steps above are provided in annex IV.

21. Furthermore, in line with decision 15/31, the Secretariat was conducting at the time of reporting a peer review of the outcomes and operations of the horizon scanning process. The comments received have been compiled and will be provided in information document CBD/SBSTTA/26/INF/6 to support the Subsidiary Body in its review of the effectiveness of the process.

VI. Recommendations

22. The Subsidiary Body may wish to:

(a) Endorse the results of the horizon scanning, monitoring and assessment conducted by the multidisciplinary Ad Hoc Technical Expert Group;

(b) Note the needs for capacity-building, technology transfer and knowledge-sharing related to synthetic biology identified by the multidisciplinary Ad Hoc Technical Expert Group in the light of the outcomes of the horizon scanning, monitoring and assessment provided in annex II;

(c) Finalize the review of the horizon scanning, monitoring and assessment contained in annex I, on the basis of annex III, also taking into account the peer review of the outcomes undertaken for that process;

(d) Adopt the refined methodology for a broad and regular horizon scanning, monitoring and assessment, as contained in annex IV;

[3] Step A (information gathering) of the process established in decision 15/31, with the Secretariat as the coordinating actor.
[4] Step B (compilation, organization and synthesis of information) of the process established in decision 15/31, with the Secretariat as the coordinating actor.
[5] Step C (assessment) of the process established in decision 15/31, with a multidisciplinary ad hoc technical expert group as the coordinating actor.
[6] Step C of the process established in decision 15/31, with a multidisciplinary ad hoc technical expert group, the Subsidiary Body, the Conference of the Parties and, as relevant, the Conference of the Parties serving as the meetings of the Parties to the Protocols as the coordinating actors.
[7] Step D (reporting on outcomes) of the process established in decision 15/31, with a multidisciplinary ad hoc technical expert group, the Subsidiary Body, the Conference of the Parties and, as relevant, the Conference of the Parties serving as the meetings of the Parties to the Protocols as the coordinating actors.

(e) Adopt the recommendations of the multidisciplinary Ad Hoc Technical Expert Group contained in annex V.

Annex I

Results of the process for broad and regular horizon scanning, monitoring and assessment

1. After identifying, through an information-gathering step, several trends and issues in synthetic biology with relevance to the realization of the three objectives of the Convention on Biological Diversity, the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment used a standardized scoring method combining the prioritizations of its individual members to select 17 trends and issues for further consideration (as provided in document CBD/SYNBIO/AHTEG/2024/1/INF/1). Of the 17 trends and issues, 5 were selected through an expert-driven indicative preferencing exercise for a deeper assessment, which is provided in sections I to V below. The list of five priority trends and issues selected for a deeper assessment and the combined list of the 17 trends and issues as they are presented do not reflect any ranking order. The additional 12 trends and issues on the prioritized list, that is, those not subject to an assessment by the Group, are listed in section VI, while the full list of trends and issues submitted during the process for horizon scanning, monitoring and assessment is provided in section VII.

2. Several overarching elements were identified with respect to the trends and issues in synthetic biology, in particular for the five prioritized trends and issues, namely:

(a) New synthetic biology applications are increasing in complexity and scale across all kingdoms of life and may entail multi-species and multi-kingdom applications in domestic and wild populations with relevance to all three objectives of the Convention;

(b) The increasing complexity in the range of tools, the fields of applications and the potential for cumulative, synergistic and scaling effects may all result in unpredictability and uncertainty regarding the potential impacts of synthetic biology applications, the application of the precautionary approach is important;

(c) The development of the applications of synthetic biology is largely concentrated in developed countries, which may bring unique challenges and cause disparities in opportunities for research, development, technology assessment, monitoring, management and participation in developing countries. This geographical imbalance also requires particular consideration in terms of the potential impacts and harms to biodiversity, biosafety and local rights, including in the case of field-testing or application outside the jurisdiction of the developer, in developing countries;

(d) The consideration of transboundary impacts has become crucial, especially when engineered organisms have the capability or are designed to spread in, integrate into or displace a population. This is notably relevant in such scenarios as the development of self-spreading vaccines, modified microorganisms or engineered gene drive organisms. In this regard, it should be noted that it is specified in the Cartagena Protocol on Biosafety that risk assessment should be carried out on a case-by-case basis;

(e) To meet the third objective of the Convention, it is imperative to ensure the fair and equitable sharing of both monetary and non-monetary benefits arising from synthetic biology. Such a commitment reflects a principled approach to promoting responsible and inclusive practices in the utilization of synthetic biology resources and in combating inequity;

(f) The far-reaching, permanent and inheritable genetic modification of wild organisms introduces the idea of redesigning nature. This creates a paradigm shift in how genetic engineering relates to nature’s intrinsic value and the objectives and practices of biodiversity conservation;

(g) There is recognition that the development of new synthetic biology applications and developments in associated fields, in particular artificial intelligence, are advancing at a faster pace than the required progress in related regulatory systems, as well as risk assessment, risk management, monitoring and technology assessment;

(h) Current experience with risk assessment, biosafety and biosecurity measures is important and should be considered for the assessment of the impacts of synthetic biology;

(i) For reasons of equity and precaution, decision-making on synthetic biology applications, including release into the environment, should, wherever possible, be informed by the assessment of potential impacts, including socioeconomic, cultural and ethical impacts, and a multidisciplinary, participatory process for allowing inputs from all affected stakeholders, indigenous peoples and local communities, women, youth and rights holders is important in view of the cross-cutting nature of synthetic biology;

(j) Liability and redress are a key issue in the context of synthetic biology applications and may require further consideration for applications falling outside the scope of the Cartagena Protocol;

(k) It is recognized that nature embodies different concepts to different peoples, including biodiversity, ecosystems, Mother Earth and systems of life;

(l) The consideration of the rights, knowledge, including traditional knowledge associated with biodiversity, innovations, worldviews, values and practices of indigenous peoples and local communities is important when assessing the potential impacts of synthetic biology;

(m) The principles of gender and intergenerational equity should be considered when assessing the use of synthetic biology applications that may have long-term or permanent effects on the environment and the functions that nature maintains, and its relationship with people and society;

(n) Applications of synthetic biology could have positive or negative implications for sustainable development, including addressing or worsening the drivers of biodiversity loss, and could have an impact on the objectives of the Convention and the Kunming-Montreal Global Biodiversity Framework, which highlights the importance of an assessment step.

I. Integration of artificial intelligence and machine learning

A. Description

3. Rapid advances in artificial intelligence and machine learning have led to a significant increase in their use for the development of organisms, components and products of synthetic biology. The artificial intelligence algorithms are developed from the use of large data sets (e.g. chemical information and sequencing data) to train computational models (e.g. neural networks) to provide predictions and inform the engineering or creation of synthetic biology organisms, components and products

4. The use of artificial intelligence and machine learning approaches exists in a large and growing number of tools and applications. There are two main types of artificial intelligence: (a) discriminative artificial intelligence models, which are based on statistical sorting approaches to big data and provide a prediction based on probability; and (b) generative artificial intelligence models, which apply probability-based algorithms trained on large data sets to generate synthetic new data. Both can be used to predict the outcomes of genetic interventions, support experimental design, facilitate genomic annotation and automate searches in large databases.

5. The main types of artificial intelligence used in synthetic biology are:

(a) Text-based large language models (e.g. ChatGPT and BARD),[1] for the development and management of synthetic biology (e.g. for enforcement actions, regulatory texts and risk assessment);

(b) Biodesign tools (e.g. generation of novel promoters, generative machine learning and text-to-protein platforms, for the creation of novel engineered protein sequences (e.g. ProtGPT, Chroma and ProGen));

(c) Automated science, for automating laboratory work, biofoundries, breeding and greenhouses;

(d) Cyberphysical systems incorporating elements of both synthetic biology and artificial intelligence (e.g. plants developed by InnerPlant engineered to emit fluorescence signals in order to guide artificial intelligence-enabled digital agriculture systems).

B. Contextualization

6. Developments in artificial intelligence and machine learning are causing paradigm shifts across many sectors (e.g. science, economics and industry) all over the world, best demonstrated by the recent global uptake of and hype around generative artificial intelligence applications, such as ChatGPT. Those shifts include the integration of artificial intelligence and machine learning into the field of synthetic biology, which is aimed at improving efficiency, speed and novelty in developing synthetic biology applications (e.g. reduced time for development and optimization, the integration of large data set inputs, and automated design and engineering).

7. Furthermore, several companies that are behind the development of generative artificial intelligence applications (e.g. Meta, Google/DeepMind, Microsoft, NVIDIA, Salesforce and Stability AI) have increased their funding or are entering into joint ventures with biotechnology companies (e.g. Gingko Bioworks) or institutes (e.g. the Broad Institute). This change brings new entrants and financing into the field of synthetic biology, which may increase the interest in the field itself, such as in the case of the breakthrough in protein folding (e.g. AlphaFold).

C. Time frame and current level of research activity[2]

8. Discriminative artificial intelligence has already been applied to the field of synthetic biology, while generative artificial intelligence tools for synthetic biology are becoming more widely available and increasing in complexity and number. Significant investments in research and technology are expected in the next few years, which may lead to an increase in the quantity of synthetic biology products and applications in the next five years. However, scaling the production from laboratory settings to commercial use remains a limiting factor, as the transition from algorithm output to functioning synthetic biology application (i.e. “from digital to physical”) is challenging and currently still requires human oversight and expertise.

9. Current research and development are mainly focused on engineering proteins. Start-ups are likely to bring novel engineered proteins to market in the next three to five years. In addition, the use of artificial intelligence is being rapidly taken up for engineering microbes and genetic elements, including the increasing use of generative artificial intelligence models. In contrast, the use of artificial intelligence for plant breeding is currently slower and more incremental. Furthermore, the integration of artificial intelligence into cyberphysical systems is ongoing and nearing market readiness. The implementation of novel uses of artificial intelligence, such as circuits in biological

[1] Bard was renamed Gemini after the present meeting.

[2] The time frame is, in addition, interconnected to the readiness of and research in risk assessment, technology assessment, governance instruments.

hosts, are still at a proof-of-concept stage and far from use, which is not expected before more than 10 years from now.

D. Considerations of impacts on the objectives and principles of the Convention[3]

10. The integration of artificial intelligence and machine learning with synthetic biology could have both potential positive and negative impacts on the objectives of the Convention. The impacts will be related to the specific use of an application, but may include:

(a) *Help to conservation efforts*. The accelerated development of products and organisms intended to aid conservation efforts may allow for the replacement of non-sustainable materials or aid climate change mitigation (e.g. by facilitating the creation of engineered proteins for biosequestration systems, replacement of fossil fuels, degradation of plastics and environmental pollution);

(b) *Reduced biological diversity and ecosystem functions.* There might be disruptions of biotic interactions in the soil microbiome, adverse interactions with other organisms and the unintended persistence of novel proteins in the environment;

(c) *Replacement of natural products*. Protein or metabolic engineering could potentially either reduce pressure on biodiversity or disrupt the sustainable use of biological diversity;

(d) *Changes in land use, ocean use and agrobiodiversity*. There might be a more efficient use of resources (e.g. through an optimized synthetic biology product) or change in land use for agriculture (e.g. cyberphysical systems);

(e) *Energy, water and resource extraction costs caused by artificial intelligence systems*. Such costs are also significant;

(f) *Challenges to the sharing of benefits derived from the utilization of genetic resources*. Such challenges may arise from the facilitated use of digital sequence information of genetic resources (e.g. through the wide availability of sequence information in public databases as underlying data sets).

E. Governance considerations

11. The broad use of artificial intelligence is starting to be regulated at the international and regional levels, but governance frameworks for more specialized or specific uses, such as the integration with synthetic biology, may not be developed yet. Efforts are under way to create artificial intelligence governance frameworks in other domains (e.g. explainable artificial intelligence in the European Union), high-level international events are being held (e.g. those of the High-level Advisory Body on Artificial Intelligence and the Munich Security Conference) and the Governments of some countries are starting to address the biosecurity risks of generative artificial intelligence (e.g. the United Kingdom of Great Britain and Northern Ireland and the United States of America).

12. Potential governance considerations related to biological diversity include:

(a) *Access and benefit-sharing from the utilization of sequences from genetic resources (e.g. in relation to the Nagoya Protocol and digital sequence information)*. There are challenges to tracing back to a specific provider country when, potentially, hundreds, thousands or even millions of sequences were used;

[3] The importance of ethical considerations is highlighted in the Convention, with an emphasis placed on transparency and informed consent processes. Furthermore, the precautionary approach is embraced and incorporated through risk assessment.

(b) *Liability and redress*. The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol covers living modified organisms, but products (e.g. synthetic proteins) are beyond its scope;

(c) *Process-based risk assessment*. There is a lack of transparency and of ability to explain processes behind the decisions made by the computational algorithm;

(d) *Risk assessment*. There is a lack of identification of donor organism, comparators, novelty of application, complexity of the receiving environment, availability of environmental data, understanding of microbial interactions in the environment and microbiome functioning;

(e) *Reliability*. The precision and accuracy of results may not be reliable in the light of artificial intelligence hallucination errors;

(f) *Indigenous peoples and local communities*. The use of traditional knowledge may be facilitated;

(g) *Databases*. Ownership and governance of data and verification of data quality may be required;

(h) *Intellectual property*. Ownership is an issue when thousands of accessions have been used in the design and creation of a novel sequence.

F. Additional considerations

13. Further topics of consideration may include:

(a) Underlying data sets, in relation to data poisoning (i.e. erroneous data fed into the training of the model to produce a false result), biasing (i.e. underlying data reinforcing or influencing a result) and gaps in the availability of negative results for training the models;

(b) Biosecurity, in terms of lowered barrier for amateur or less skilled actors to creating, designing or developing applications of synthetic biology, the entrance of new actors unfamiliar with risk issues, and military use;

(c) Dual use, in relation to the rapid development of therapeutics and the production of novel pathogens or toxins;

(d) Economics, in relation to the concentration of companies providing data, models or analyses.

II. Inequity in the participation of developing countries in the context of synthetic biology

A. Description

14. Developed countries have taken the lead in research and development in the field of synthetic biology. However, the participation of developing countries in capacity-building, research, development, assessment, monitoring and management of synthetic biology is important for achieving the objectives of the Convention and the Kunming-Montreal Global Biodiversity Framework, and developing countries currently face challenges in their ability to research, assess and use the technology, resulting in inequitable participation.

B. Contextualization

15. Since synthetic biology is resource-intensive from a technical and regulatory standpoint, the likelihood of inequity is inherent. The historical patterns of dominance by developed countries in scientific research and development have resulted in developing countries heavily relying on

developed countries for access to technology, especially in the case of synthetic biology. Furthermore, barriers to equitable participation may stem directly from resource limitations, intellectual property restrictions and ethical concerns. Efforts to address those issues are focused on capacity-building, technology transfer, knowledge-sharing and collaboration.

16. In the field of synthetic biology, however, inequity also acts as a significant driver of both biodiversity loss and financial insecurity. Ensuring the equitable participation of developing countries in the field of synthetic biology has the potential to yield improved health outcomes (e.g. through the enhanced nutrition of crops, vaccine development and novel diagnostic tools for health care), food security and local innovation (e.g. by adapting orphan crops to new biotic or abiotic stressors, support for research jobs in developing countries and novel nature-inspired applications). In addition, equitable participation can create sustainable bioeconomies, a shift from petroleum-based economic activities and additional socioeconomic value from resources.

C. Time frame and current level of research activity[4]

17. Inequity in the field of synthetic biology is considered to be a long-standing issue.

D. Considerations of impacts on the objectives and principles of the Convention[5]

18. In view of the inequitable participation of developing countries in the field of synthetic biology, the following potential impacts could occur:

(a) *Continued reliance on resource extraction*. Developing countries remain primarily exporters of raw materials, leading to a reliance on resource extraction and negatively affecting conservation efforts;

(b) *Reduced understanding and benefit-sharing of national genetic resources*. There is an inability to catalogue genetic resources and store information in databases, and limited resources and access to next-generation sequencing technologies;

(c) *Continued pressure on biological diversity*. There is a risk of continued use of chemical pesticides and polluting activities, and a risk associated with waste management;

(d) *Hindered ability to gain access to the potential benefits of synthetic biology applications* (owing to a lack of resources);

(e) *Complications in sustainable land and marine use, including in traditional production systems.*

E. Governance considerations

19. Inequity in the participation of developing countries in the context of synthetic biology could have potential governance implications, including for:

(a) The implementation of Articles 8 (j), 16, 17, 18 and 19 of the Convention and Article 26 of the Cartagena Protocol;

(b) Inclusion, in relation to language, technical gaps and traditional knowledge;

(c) Detection and identification, in relation to the availability of tools and resources, laboratory infrastructure, access to reagents, multiple ports of entry and increased volumes of trade;

[4] The time frame is, in addition, interconnected to the readiness of risk assessment, technology assessment, governance instruments and relevant research that supports them.

[5] The Convention places a high priority on ethical considerations, emphasizing transparency and informed consent processes and furthermore, the precautionary approach is embraced and incorporated through risk assessment.

(d) Technology and risk assessment effectiveness, in relation to a lack of resources and of awareness of applications;

(e) Government prioritization, in terms of enabling policies, the establishment of appropriate regulatory frameworks, improved bureaucracy to prevent research delays (e.g. permits and contracts for genetic resources) and resource mobilization;

(f) Capacity-building and further awareness of the applications of synthetic biology (e.g. experience in assessing applications of synthetic biology relates to the effectiveness of risk assessment and regulation, agency building and autonomy);

(g) Cooperation and collaboration, both regional and international;

(h) Intellectual property patents being obtained without the involvement or recognition of affected Parties.

F. Additional considerations

20. Inequity in the participation of developing countries in the context of synthetic biology could have further potential impacts, such as:

(a) Continued dominance by developed countries for research and development in the field of synthetic biology;

(b) A lack of development of bioeconomies;

(c) Dependence on developed countries for access to technology, knowledge and assessment;

(d) Underused research potential in developing countries;

(e) Ineffective participation in discussions and debates on the applications of synthetic biology.

21. Mutual learning and experience sharing through bidirectional flows of information for improving participation and mutual respect might therefore be needed to address some of those issues.

III. Development of engineered gene drives to control vector-borne diseases and invasive species

A. Description

22. Engineered gene drives are genetic systems that are transmitted to progeny at super-Mendelian (> 50 per cent) frequencies. These can theoretically be employed in all sexually propagating species (e.g. vertebrates and invertebrates) with the aim of reducing population sizes or altering certain properties in a population or species. Those systems are based on various molecular mechanisms[6] to achieve biased inheritance and spread through populations with no possibility for recalling or reversing.

23. Some examples include *Anopheles gambiae* containing an engineered gene drive designed to reduce malaria transmission, living modified *Drosophila suzukii* containing an engineered gene drive for use in fruit orchards and rodents containing engineered gene drives aimed at controlling invasions on islands.

[6] E.g. clustered regularly interspaced short palindromic repeats-associated protein (CRISPR-Cas), homing endonucleases and meiotic or toxin-antidote systems.

B. Contextualization

24. Engineered gene drives are being researched and developed with the objectives of addressing public health concerns (e.g. the burden of such vector-borne diseases as malaria and dengue) and controlling insect populations, or as an intervention to control invasive species or agricultural pests (e.g. in complement to the use of pesticides or poison baits). Engineered gene drive applications are mostly intended for environmental release in the wild and in agricultural or urban environments.

25. That approach, however, does not address the root causes (e.g. social determinants of health and the spread of invasive species) as alternative instruments and practices (e.g. agroecological approaches) might. In terms of efficacy, there is no certainty yet that engineered gene drives will be successful in suppressing mosquito disease vector populations and, more fundamentally, alleviate disease burden, owing to such issues as resistance development, complex ecological factors and current inabilities to engineer target species, including important disease vectors.

C. Time frame and current level of research activity[7]

26. Systems designed to suppress insect vectors of human disease and agricultural pests are the most advanced, but environmental release is not imminent. Living modified rodents containing engineered gene drives to control invasive species on islands are likely to require longer development, as rodents are less amenable to genetic engineering. Other taxa to which engineered gene drives may be applied, albeit much further into the future, include weeds, snails, fish, arachnids and fungi.

27. Overall, current research activity is focused on further technical refinements, which would be likely required before the deployment of those applications in nature and application to new organisms. However, there has been an increase in the quantity of patent filings related to insects containing engineered gene drives for agricultural purposes.

D. Considerations of impacts on the objectives and principles of the Convention[8]

28. The environmental use of living modified organisms containing engineered gene drives may have impacts on the objectives of the Convention, depending on their case and use. The impacts may be similar to those of other modified insect systems, such as self-limiting insects. Some potential impacts include:

(a) Reduced pressures, through reduced populations of the vectors of human and animal disease, the control of invasive alien species, reduced human traffic in fragile island ecosystems, reduced chemical pesticide use and reduced damage from agricultural pests;

(b) Unintended species extinction, through the elimination of non-target organisms or of an endogenous species if an engineered gene drive application spreads to the native range of the host species;

(c) The disruption of ecosystems, through the suppression of a species, disrupted pollination or food chain collapse;

(d) Reduction in genetic diversity, through reduced fitness, potential increased disease susceptibility or reduced capacity to adapt to environmental changes;

(e) Biological invasion, through niche replacement by an alternative animal disease vector, secondary pest invasion or population rebound;

[7] The time frame is, in addition, interconnected to the readiness of risk assessment, technology assessment, governance instruments and relevant research that supports them.

[8] The importance of ethical considerations is highlighted in the Convention, with an emphasis placed on transparency and informed consent processes. Furthermore, the precautionary approach is embraced and incorporated through risk assessment.

(f) The disruption of traditional land use and management.

E. Governance considerations

29. In terms of governance, engineered gene drive applications are to be considered as "living modified organisms" under the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol. The relevant provisions, such as those in Articles 15, 16, 17, 23 and 26 of the Cartagena Protocol, therefore apply. In addition, one main development in the area of governance is the preparation of additional voluntary guidance materials for risk assessments of living modified organisms containing engineered gene drives under the programme of work on risk assessment.

30. Other potential governance considerations include:

(a) Spatial and temporal distribution, such as spread over large geographical areas, long-term persistence in the environment, evolutionary change of the molecular mechanism, regional coordination, lack of proven mitigation measures and irreversibility;

(b) Assessment, such as that of cumulative interactions or scaling effects arising from the use of various engineered gene drive applications or other non-engineered gene drive technologies;

(c) Risk assessment methodology, with regard to the use and reliability of models, appropriate comparators, the treatment of uncertainty and phased testing approaches;

(d) Data reliability and availability, owing to a potential lack of environmental baseline data;

(e) Risk management, owing to a potential lack of developed risk management measures and complexities related to monitoring;

(f) Global governance, in terms of early detection and rapid response mechanisms, lists of species of local concern or field-testing outside the jurisdiction of the developer;

(g) The incorporation of socioeconomic, cultural, ethical and conceptual considerations in decision-making, especially including those related to women and youth;

(h) Indigenous peoples and local communities, to ensure their Free, prior and informed consent and take account of the right to refusal, community dynamics and relationships, and traditional knowledge;

(i) The establishment of processes to identify and approach communities potentially affected by engineered gene drive releases in order to ensure the free, prior and informed consent from all relevant communities, bearing in mind, in particular, the potential spread from transboundary movements;

(j) Intellectual property, in terms of access to technology and ownership;

(k) Food sovereignty and security, in terms of implications for agroecological food systems and rights of farmers and peasants.

F. Additional considerations

31. Further topics of consideration could include:

(a) Public health, through the eradication of vector-borne human diseases, pathogen evolution and response, niche replacement, population dynamics (e.g. rebounding effects and "chaser" dynamics);

(b) Socioeconomics, through a reduced disease burden leading to improved socioeconomic conditions;

(c) Animal welfare, by avoiding the use of poisoning, trapping and culling methods;

(d) Transparency, in relation to a lack of publicly available information from developers and conflict of interest;

(e) Fairness, justice and disparity, as a large spatial distribution may not allow individuals or local communities to "opt-out", or through compatibility with agroecological, organic or traditional farming systems.

IV. Self-limiting insect systems

A. Description

32. Self-limiting insect systems may be considered as additional developments of existing biocontrol systems using genetic engineering techniques. They are implemented using transgenic cassettes (e.g. genetic circuits) to create a genetic modification akin to the sterile insect technique, which has been used for decades. The use of living modified insects involve the release of modified adult males (first generation) or encapsulated larvae or eggs (second generation), which, when they mate, do not produce insects that survive to maturity.

33. Specific examples of self-limiting insects include those developed by Oxitec, such as the living modified yellow fever mosquito (*Aedes aegypti*), which is aimed at controlling dengue, and, for agricultural settings, the living modified diamondback moth (*Plutella xylostella*) and the Friendly™ Fall Armyworm (*Spodoptera frugiperda*).

B. Contextualization

34. Self-limiting insect systems are applications that are developed to reduce the numbers of disease vectors (e.g. malaria, dengue and yellow fever) or agricultural insect pests and aimed at not persisting in the environment. They may be considered as a further development of existing biocontrol systems using genetic engineering, which attempt to address the inherent challenges associated with sterile insect technique, such as fitness, costs and effectiveness, as well as insecticide resistance. These applications could thus be considered as novel tools for integrated pest management in wild, agricultural or urban settings. The aim of the self-limiting systems can be addressed by other means and approaches. The evaluation of alternative approaches on a case-by-case basis should be considered. To date, genetically engineered self-limiting insects have not been successful at addressing their intended objectives of controlling pests or reducing adult mosquito populations and disease burden.

C. Time frame and current level of research activity[9]

35. Since 2010, field trials for self-limiting insects based on genetic circuits have been carried out in Brazil (e.g. mosquitoes and fall armyworm), Burkina Faso (*Anopheles gambiae*), Malaysia (e.g. mosquitoes), Panama (e.g. mosquitoes), the United States (e.g. mosquitoes and diamondback moth) and the Cayman Islands (e.g. mosquitoes). Two mosquito varieties are currently commercially available in Brazil (e.g. the first and second generations of *Aedes aegypti*). Regarding other self-limiting systems, such as those based on the precision-guided sterile insect technique, greenhouse trials of *Drosophila suzukii* have been conducted in the United States (e.g. by Agragene). Open release field trials might be seen as soon as 2024 for *D. suzukii* and within 10 years for others (e.g. for living modified *A. gambiae* in the Gambia).

36. Research is ongoing to develop new systems, such as precision-guided sterile insect technique using CRISPR-Cas, engineered gene drive-type systems and flightless female phenotype, as well as applications for new insect species.

[9] The time frame is, in addition, interconnected to the readiness of risk assessment, technology assessment, governance instruments and relevant research that supports them.

D. Considerations of impacts on the objectives and principles of the Convention[10]

37. The use of self-limiting insect systems may have impacts on the objectives of the Convention and could be experienced at the three levels of biodiversity: genetics, species and ecosystems. The systems may lead to:

(a) Population reductions, through a disruption to food webs, unintended horizontal gene transfer to non-target species resulting in unintended effects, novel toxins or the induction of allergenicity;

(b) Changes in population dynamics, through population rebounds following environmental release;

(c) Reduced damage to biodiversity, through the control of invasive species, reduced chemical pesticide use or reduced disease transmission;

(d) Biological invasions, through niche replacement by alternative disease vectors, secondary invasive species or invasions to unintended environments;

(e) Persistence, through the unexpected survival of lethality cassettes, with negative impacts on genetic diversity;

(f) Changes in genetic diversity, through reductions due to horizontal gene transfer or hybridization with laboratory strains;

(g) Improved sustainable use, through a reduction in pests in food systems;

(h) Challenges to agrobiodiversity and sustainable use, through the extension of monoculture industrial agricultural systems.

E. Governance considerations

38. Self-limiting insects would be considered under the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol, as the insertion of a transgenic cassette makes them living modified organisms.

39. The following points may necessitate further governance considerations:

(a) Assessment, in terms of cultural, ethical, conceptual and cumulative considerations;

(b) The process to identify an approach for communities potentially affected by releases to ensure their free, prior and informed consent;

(c) Risk assessments, in terms of genetic stability, the incomplete phenotypic expression of selective lethality, next-generation effects, large spatiotemporal distribution, the treatment of uncertainty;

(d) Risk management, in terms of sustainability, monitoring and persistence, as well as the appropriate use of liability and redress provisions;

(e) Tools for detection and identification, which are appropriate for field use, based on DNA-based and protein-based techniques, and visual detection using fluorescent markers;

(f) The availability of data, such as baseline environmental data (e.g. population densities, biotic interactions, spatial distribution and movement), data generated for assessments, limitations, impacts on native species, and efficacy;

[10] The importance of ethical considerations is highlighted in the Convention, with an emphasis placed on transparency and informed consent processes. Furthermore, the precautionary approach is embraced and incorporated through risk assessment.

(g) Risk-benefits analysis, in terms of existing alternative interventions (e.g. social determinants of disease, access to treatment, chemical pesticides and cost of inaction);

(h) Indigenous peoples and local communities, in terms of the mainstreaming and integration of relevant guidance under Article 8(j) of the Convention (e.g. Akwé: Kon Voluntary Guidelines, Rutzolijirisaxik Voluntary Guidelines for the Repatriation of Traditional Knowledge, Mo' otz Kuxtal Guidelines), "as well as to ensure their prior and informed consent", "free, prior and informed consent" or "approval and involvement".

F. Additional considerations

40. Further topics of consideration in relation to use of self-limiting insect systems may include:

(a) Health, in relation to a reduction of human disease vectors, the spread of antibiotic resistance through horizontal gene transfer, niche replacement resulting in the introduction of secondary disease vectors, and reduced exposure to chemical pesticides;

(b) Food security and nutrition, in relation to reduced agricultural losses and the rise of secondary pests;

(c) Fairness, justice and disparity, as large spatial distribution may not allow individuals or local communities to "opt-out", as well as in relation to the distribution of impacts across whole communities and incompatibility with agroecological, organic or traditional farming systems;

(d) Economics, in relation to reduced health-care costs, a decreased loss of economic output related to illness and death, increased economic security and a cost comparison of available approaches;

(e) Sustainability, in relation to high cost if efficacy is low, a potential need for multiple releases, and reliance on the use of additional products in conjunction with the self-limiting insect systems;

(f) Transparency, in relation to sources of funding and the use of the Biosafety Clearing-House.

V. Self-spreading vaccines for wildlife

A. Description

41. Self-spreading vaccines for wildlife are designed to limit the spread of wildlife diseases through the use of deliberately transmissible, engineered viral vectors to induce an immune response to a pathogen (e.g. use of a betaherpesvirus as a vector for rabies). They can be subdivided into species-specific (highly targeted to host organisms) or non-specific viral vectors (wide host range, such as mammalian pox viruses). In some cases, non-replicating viral vectors are engineered to reconfer vector replication and spread among hosts. Some specific examples include applications to control Lassa fever in apes and rodents, as well as Ebola virus in monkeys and bats.

42. Despite technical feasibility, ethical, ecological and regulatory concerns surround the self-spreading vaccine approach, as releasing genetically engineered organisms with contagious self-spreading capabilities into the environment introduces substantial challenges in risk assessment, monitoring long-term effects and mitigating harm, especially with evolving dimensions that test the current limits of knowledge. The complexity with the recombinant vector raises concerns, for example, with regard to unknown evolution and virulence risk upon release. Further concerns involve the possibility of the viral vector co-opting the immunogenic insert, thereby expanding its ecological niche or hosts. Issues of concern extend to the biology, ecology and population dynamics of hosts, as well as potential vaccine transmission to other species, including human beings.

B. Contextualization

43. The development of self-spreading vaccines for wildlife is aimed at addressing various challenges in wildlife conservation, animal disease management and preventing zoonotic spillover into human populations. Since emerging infectious diseases have become an increasing concern, owing to globalization and the challenges of managing diseases once endemic, novel solutions are being sought. The self-spreading vaccine approach, however, does not address the root causes of diseases (e.g. human encroachment on wildlife, climate change) and opportunity costs.

44. Furthermore, while there is potential for self-spreading vaccine applications for wildlife to be scaled up or developed rapidly, in view of existing infrastructure related to the production of human vaccines, instruments to take ethical, cultural, conceptual and ecological considerations into account and conduct a technology assessment are not in place.

C. Time frame and current level of research activity[11]

45. The time frame for the release of viral self-spreading vaccines is uncertain, owing to a broad range of challenges and concerns associated with the approach. Most research is still in early development and exploring computational models to assess the evolutionary outcomes of viral evolution. However, crisis conditions (e.g. pandemics or ecological crises) might potentially accelerate that timeline.

46. Self-spreading vaccines in wildlife primarily aimed at addressing and preventing zoonotic diseases are being developed in the United Kingdom and the United States. The research is aimed at developing applications for deployment in South America and West Africa, targeting rabies in bats and Lassa fever in rodents. For example, developers of a Lassa fever viral vaccine are claiming proof-of-principle completion by early 2024.

D. Considerations of impacts on the objectives and principles of the Convention[12]

47. Some potential impacts on the objectives of the Convention include:

(a) Reduced damage to native biodiversity and restoration of ecosystem functioning by controlling invasive species and overcoming pesticide resistance;

(b) Improved disease management and resilience in wildlife populations, in particular for areas difficult to reach;

(c) Unintended effects, such as genotoxic effects from horizontal gene transfer or recombination events, changes in the virulence of the pathogen and expanded host specificity;

(d) Spillover into non-target hosts due to wide host specificity (e.g. poxviruses);

(e) Intellectual property rights issues, in terms of balancing the need for innovation with fair and equitable access to the benefits of the technology, especially for communities contributing to genetic resources.

E. Governance considerations

48. Regarding specific governance considerations, self-spreading vaccines for wildlife would be considered as living modified organisms under the Cartagena Protocol.

[11] The time frame is, in addition, interconnected to the readiness of risk assessment, technology assessment, governance instruments and relevant research that supports them.

[12] The importance of ethical considerations is highlighted in the Convention, with an emphasis placed on transparency and informed consent processes. Furthermore, the precautionary approach is embraced and incorporated through risk assessment.

49. There could be specific elements that may require further consideration in terms of governance, including:

(a) The interaction of self-spreading vaccines with non-target organisms, including human populations;

(b) Large spatiotemporal distribution, in relation to Persistence, efficacy, next-generation effects, consent of potentially affected populations and encroachment on traditional lands and waters;

(c) Uncertainty regarding the availability of suitable risk assessment, technology assessment and monitoring tools;

(d) Risk management, in relation to spread, containment, irreversibility of release and stepwise testing approach;

(e) A lack of knowledge on viral evolution and pathogen response, and superinfection;

(f) The limited availability of guidance materials, as most vaccine guidance is focused on clinical applications for human populations;

(g) Specific governance and regulation aspects, such as ensuring the free, prior and informed consent of indigenous peoples and local communities and others that might be affected by the technology;

(h) The assessment of cultural, ethical, conceptual and cumulative aspects;

(i) The alignment of the sustainable practices and assessment of the socioeconomic implications for local communities, livelihoods and traditional practices;

(j) Transboundary aspects, as regulatory requirements vary across countries, and in terms of regional and international collaboration;

(k) Monitoring of vaccine evolutionary change, spread and reversion to wild type;

(l) Impacts on the achievement of Targets 9, 10 and 17 of the Kunming-Montreal Global Biodiversity Framework.

F. Additional considerations

50. Some key considerations across different domains include:

(a) The prevention of zoonotic spillover into human populations;

(b) Effective public engagement and education, in terms of conflation with human vaccine hesitation and opposition (e.g. misinformation), transparent communication, access to information and the timely publication of regulatory documents and scientific publications;

(c) The sustainability of the intervention, as they are not addressing the root causes of disease (e.g. human encroachment on wildlife areas and climate change), costs;

(d) Dual use.

VI. List of 12 trends and issues in synthetic biology

51. During the intersessional period, the following 12 additional trends and issues in synthetic biology were identified by the Group members:

(a) Engineered bacteria for nitrogen-fixation and fertilizers;

(b) Transient modification of agricultural plants, pests and pathogens using RNA interference or nanomaterials;

(c) Genome-edited plants;

(d) Microbiome engineering for non-medical purposes;

(e) Use of synthetic biology in wild organisms in the context of resilience in threatened species;

(f) Synthetic biology applications for bioremediation, biodegradation or biomining;

(g) Technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature;

(h) Ability to recreate viruses by chemical DNA synthesis;

(i) Interaction of synthetic biology organisms in the environment and potential for cumulative effects;

(j) Dual-use nature and biosecurity implications of synthetic biology;

(k) Transboundary movements and relation to detection and identification of synthetic biology organisms, parts and products;

(l) Increased field-testing of synthetic biology applications, including in areas outside the national jurisdiction of the developer or funder.

52. It should be noted that the Group members did not have sufficient time to assess the 12 trends and issues. However, additional information thereon can be found in information document CBD/SBSTTA/26/INF/4.

VII. Full list of trends and issues in synthetic biology

Number	*Trend or issue*
1	Use of synthetic biology in wild organisms in the context of resilience in threatened species
2	Self-spreading vaccines for wildlife
3	Genome-edited plants
4	Genome-edited animals
5	Metabolic engineering of crops
6	Engineering photosynthesis
7	Increasing carbon capture efficiency in plants
8	Engineered sterility of non-native plant species
9	Transient modification of agricultural plants, pests and pathogens using RNA interference or nanomaterials
10	Virus-induced genome editing and genetic modifications
11	Microbiome engineering for non-medical purposes
12	Engineered bacteria for nitrogen-fixation and fertilizers
13	Synthetic biology applications for bioremediation, biodegradation or biomining
14	Development of engineered gene drives to control vector-borne diseases and invasive species
15	Self-limiting insect systems
16	Paratransgenetic approaches for controlling vector-borne diseases

17	De-extinction of extinct animals
18	Living materials and biofilms
19	Capture and recycling of greenhouse and waste gases using synthetic biology applications
20	Synthetic biology-enabled production of petrochemical precursors and industrial chemicals
21	Synthetic biology-enabled production of cosmetics and fragrances
22	Synthetic biology-enabled production of food, food ingredients and flavours
23	Synthetic biology-enabled production of antibiotics, natural products and medically relevant compounds
24	Plant bioproduction of vaccines and antivenoms
25	Medical and therapeutic synthetic biology applications
26	Biosensors, sensory devices and diagnostics
27	Synthetic biology-enabled production of fabrics, textile dyes and materials
28	Biofabricated wildlife products
29	Non-biological uses of synthetic biology
30	Cell-free systems
31	Increased sophistication of genetic circuits
32	Increased sophistication and expansion of genome editing tools
33	Mitochondrial and plastome engineering
34	Use of genome editors to create null or negative segregants
35	Genetically engineered containment systems
36	Technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature
37	Integration of artificial intelligence and machine learning
38	Automation and use of biofoundries
39	Improved next-generation sequencing and bioinformatics
40	Improvements in DNA synthesis and assembly
41	Ability to recreate viruses by chemical DNA synthesis
42	Improvements to genome and karyotype engineering
43	Development of protocells, minimal cells and artificial living machines for research purposes
44	Advances in xenobiology
45	Advances in protein engineering
46	Adoption of the Kunming-Montreal Global Biodiversity Framework
47	Inequity in the participation of developing countries in the context of synthetic biology
48	Increased field-testing of synthetic biology applications, including in areas outside the national jurisdiction of the developer or funder
49	Transboundary movements and relation to detection and identification of synthetic biology organisms, parts and products

50	Increased scale and use in series of synthetic biology interventions
51	Interaction of synthetic biology organisms in the environment and potential for cumulative effects
52	Dual-use nature and biosecurity implications of synthetic biology
53	Cyberbiosecurity
54	Changes in ethical standards
55	Novel organisms as chassis for synthetic bioproduction (insects, fungi, plants)
56	Aquatic living modified organisms
57	Redesign of existing synthetic promoters

Annex II

Capacity-building, technology transfer and knowledge-sharing

1. In decision 15/31, the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment was tasked with identifying capacity-building, technology transfer and knowledge-sharing needs based on priorities determined by Parties on issues related to synthetic biology and in the light of the outcomes of the horizon scanning process. Starting with related submissions from Parties, the Group provided reflections and considerations in the form of a table of options (see below). The table comprises a collection of diverse insights regarding capacity-building, knowledge-sharing and technology transfer provided throughout the horizon scanning process. It is essential to interpret it as a reservoir of ideas meant for reflection, and it is emphasized that its purpose is to stimulate discussions rather than to serve as a comprehensive implementation plan.

2. While the multidisciplinary Ad Hoc Technical Expert Group was kept informed by the Secretariat of other processes on capacity-building, access and transfer of technology and knowledge-sharing under the Convention on Biological Diversity, the development of the aforementioned options was carried out independently from those other processes.

3. Group members noted that considerations under the topic of synthetic biology should take into account the full "technology cycle", from technical needs assessment to research and development steps, technology and other assessments, technology transfer, technology dissemination and processes of regulation, monitoring and enforcement. It was felt that the broader concept of "technology facilitation" (as used by the Technology Facilitation Mechanism of the United Nations, which is based on multi-stakeholder engagement) was a useful approach in this regard and that the options listed in the table below applied to all stages of the technology facilitation cycle.

4. The use of synthetic biology is interlinked with the multidisciplinary assessment of its impact on the objectives of the Convention.

5. In view of the outcomes of the horizon scanning, monitoring and assessment, it was noted that such a process in itself usefully advanced capacity-building and knowledge-sharing. The multidisciplinary Ad Hoc Technical Expert Group identified 17 key areas for consideration through its horizon scanning process and considered that the options outlined below for capacity-building, technology transfer and knowledge-sharing were relevant to all 17 topics. The Group focused its discussions on five of those topics and identified clear needs for capacity-building and knowledge-sharing across all five. The Group was of the view that the proposed process for broad and regular horizon scanning, monitoring and assessment of synthetic biology might contribute to promoting capacity-building and knowledge-sharing with regard to the current development of synthetic biology applications and their potential impact on the objectives of the Convention.

6. The multidisciplinary Ad Hoc Technical Expert Group also extensively addressed the topic of technology transfer when considering the matter of inequity between developed and developing countries in the context of synthetic biology. The opinion was expressed that technology facilitation in the context of synthetic biology could potentially support developing countries in gaining access to tools and technologies for using synthetic biology with the goal of developing national bioeconomies, which some countries might consider contributive to achieving the objectives of the Convention. However, that opinion must be balanced against the need to assess, manage and regulate adverse socioeconomic and environmental impacts, including on human health, indigenous peoples and local communities, the health of Mother Earth and all biodiversity and ecosystems, in line with the precautionary approach and Article 26 of the Cartagena Protocol on Biosafety.

7. It was noted in the multidisciplinary Ad Hoc Technical Expert Group that it should not just fall on individual countries to carry out capacity-building, technology transfer and knowledge-sharing activities, and that there was also a need for international cooperation and global and regional development assistance inclusive of all actors, in particular indigenous peoples and local communities, women and youth.

8. The effective participation of indigenous peoples and local communities, women and youth in capacity-building, knowledge-sharing and technology transfer activities requires time, attention to process and the building up of a relationship of trust and respect.

Initial inputs for potential options that Parties may wish to consider in the context of capacity-building, knowledge-sharing and technology transfer in the context of synthetic biology

Options for capacity-building	*Options for knowledge-sharing*	*Options for technology transfer*
(a) Building capacity by sharing the results of the broad and regular horizon scanning, monitoring and assessment, especially for indigenous people and local communities, women, youth and holders of other knowledge systems; (b) Ensuring that cultural, social, ethical issues related to synthetic biology are considered in the light of the reality and needs of indigenous people and local communities, their oral ways and a lack of information and knowledge through the use of culturally appropriate tools, including indigenous languages; (c) Providing sustainable funds and technical support for capacity development; (d) Strengthening risk assessment research, especially on the ecological impacts of synthetic biology applications; (e) Providing training on intellectual property rights related to the development of synthetic biology products; (f) Developing tools to complement or generate risk assessment and monitoring methods, for example, regarding the assessment of ethical, cultural and socioeconomic factors, including potential benefits, in addition to environmental and human health factors for policymakers, regulators, civil society, scientists, youth, women, indigenous people and local communities, and other sectors to ensure engagement in policy relevant initiative; (g) Providing access to adequately equipped and staffed laboratories and related infrastructures, reagents, supplies and computational tools for research and development, risk identification and	(a) Making use of the knowledge derived from the broad and regular horizon scanning, monitoring and assessment, respecting and understanding the different systems of knowledge, and including its contextualization in languages other than English; (b) Raising awareness of the implications of synthetic biology techniques, taking into consideration possible synergies and conflict with traditional knowledge systems; (c) Funding specific research projects through strategic collaborations and legal and technological cooperation tools; (d) Increasing public education and awareness regarding synthetic biology applications and techniques, including the implications of their use, taking into consideration possible synergies and conflict with traditional knowledge systems; (e) Ensuring facilitated access to scientific publication databases and other scientific information for developing countries; (f) Developing mechanisms for understanding the potential impacts on the three objectives of the Convention when developing commercial products; (g) Setting up rules and options surrounding the use and limits of frameworks for intellectual property for the protection of community rights and traditional knowledge, including through the application and development of sui generis frameworks in the context of the rapidly evolving field of synthetic biology;	(a) Taking into account the results of the broad and regular horizon scanning, monitoring and assessment in the prioritization of technology transfer; (b) Ensuring continuity from the initial technology transfer to the latest advancements; (c) When carrying out technology facilitation, considering the cultural ways of indigenous peoples by promoting the engagement of the various entities and stakeholders that play a key role in synthetic biology development, dissemination, potential regulation and potential use within each country; (d) Transferring technologies and skills to enable monitoring, detection, enforcement and risk research and assessment; (e) Providing scholarships, fellowships and field visits, including through mentorship opportunities in a cross-jurisdictional and interdisciplinary fashion broadly inclusive of indigenous peoples and local communities, women and youth; (f) Providing training in the use of artificial intelligence in sciences; (g) Mobilizing financial resources from developed countries for the benefit of developing countries for the purpose of risk assessment, technology assessment and monitoring, including by establishing and equipping laboratories, increased availability of reagents and access to appropriate computational resources;

Options for capacity-building	*Options for knowledge-sharing*	*Options for technology transfer*
assessment, technology assessment and monitoring purposes; (h) Providing tools and techniques to detect and monitor the organisms, components and products of synthetic biology, including continuous training opportunities in new techniques and technology assessment for researchers at all levels, university educators, policymakers, indigenous peoples and local communities, youth, women and relevant stakeholders and computational lab equipment technicians, as well as government agencies related to environmental protection; (i) Providing specific training to public sector and small and medium-sized enterprise researchers at the institutional level to ensure an understanding of how to assess the potential impacts of products, data requirements for risk assessment, transparency and the value of inclusion of negative data in the reporting when developing new products for commercialization, bearing in mind the various stages of product development; (j) Increasing North-South fair and equal scientific cooperation to strengthen capacities in techniques and application relevant at the national and regional levels; (k) Institutionalizing capacity-building processes and ensuring capacity-building by establishing training programmes in global and regional institutions (centres of excellence) for all targeted groups in technology assessment, regulation and risk assessment monitoring and other relevant areas, and by allocating resources to carry out those activities.	(h) Sharing international, regional and bilateral agreement benefit-sharing mechanisms for promoting innovation and aggregate value to the genetic resource of megadiverse countries; (i) Sharing an assessment of institutional arrangements and public-private partnership models and their impact on the objectives of the Convention, and of whether or not they actively foster the development of fair and equitable beneficial technologies for countries, including a larger North-South cooperation; (j) Introducing a new category of national records in the Biosafety Clearing-House specifically for synthetic biology activities, including collaborative projects, and making the submission of such records mandatory for Parties; (k) Encouraging parties, countries, and non-governmental organizations to use the Biosafety Clearing-House to disseminate information regarding funding and training opportunities in synthetic biology; (l) Establishing a dedicated synthetic biology portal on the Biosafety Clearing-House to facilitate collaborative knowledge-sharing among Parties, countries, organizations and the private sector; (m) Requiring Parties to report on synthetic biology projects that need to be reviewed under their national regulatory systems and to make them available as part of a mandatory record on the Biosafety Clearing-House.	(h) Creating draft protocols or suggestions for engaging on technology transfer; (i) Supporting the development of in situ genetic sequencing capabilities in developing countries; (j) Conducting voluntary technology transfer on mutually agreed terms; (k) Developing a white paper or non-binding guidelines for synthetic biology technology transfer in the context of the Convention, including with regard to intellectual property rights issues, monitoring and assessment of the technology.

Annex III

Review of the process for broad and regular horizon scanning, monitoring and assessment of the most recent developments in synthetic biology

1. The multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment developed a multidisciplinary expert-driven process for broad and regular horizon scanning, monitoring and assessment and completed the first cycle of that process successfully.

2. The first cycle of the broad and regular horizon scanning, monitoring and assessment was undertaken during the 2023/24 intersessional period. The multidisciplinary Ad Hoc Technical Expert Group was established to support the process in accordance with the terms of reference annexed to decision 15/31. The Group held two in-person meetings and one online meeting. It agreed on a way forward for the process for horizon scanning, as shown in figure II of the report on the first meeting of the Group.[1]

I. General reflections

A. Overview

3. The following general conclusions can be drawn:

(a) The multidisciplinary Ad Hoc Technical Expert Group has been able to address the four steps of the horizon scanning, monitoring and assessment outlined in decision 15/31;

(b) A sound multidisciplinary process under the Convention on Biological Diversity has been developed and has provided a unique experience;

(c) The multidisciplinary nature of the Ad Hoc Technical Expert Group has substantially contributed to the overall process for the horizon scanning, monitoring and assessment by allowing for valuable insights into the potential impacts of synthetic biology on the objectives of the Convention;

(d) The Group members had an opportunity to engage and share diverse experience and knowledge, which further enhanced the multidisciplinary perspective. The mutual learning experience was considered valuable to the experts and further enhanced the multidisciplinary nature of the process;

(e) The multidisciplinary Ad Hoc Technical Expert Group, supported by the Secretariat, successfully completed its task within six months during the 2023/24 intersessional period through efficient planning, collaborative spirit and commitment to excellence;

(f) In order to implement the wider mandate given in decision 15/31, the Secretariat required additional human and technical resources. That wider mandate, which included such elements as designing the process and identifying needs for capacity-building, technology transfer and knowledge-sharing, went beyond the broad and regular horizon scanning, monitoring and assessment.

[1] CBD/SYNBIO/AHTEG/2023/1/3.

B. Overall considerations and recommendations for strengthening the process

4. The following considerations and recommendations are put forward:

(a) Enhancing the multidisciplinary nature of the process can be achieved by ensuring adequate resources for broader participation;

(b) To enrich the horizon scanning, monitoring and assessment, consideration should be given to seeking inputs from a more diverse range of stakeholders, including scientists in fields relevant to the assessment of synthetic biology, indigenous peoples and local communities and other holders of other levels of knowledge. To do so, a greater allocation of time and financial resources would be beneficial;

(c) Addressing challenges related to visas and resources would facilitate the effective participation of stakeholder groups, such as women and youth. Furthermore, time zone differences had an impact on timing and participation in online sessions;

(d) To optimize the process, consideration should be given to the development of a mechanism, such as an observatory on synthetic biology, for monitoring or facilitating the issues included in the prioritized list or the provisional selection list.

II. Elements for improving the process

1. Step A: information gathering

5. The information-gathering step was an iterative process carried out in two phases. The first phase was aimed at obtaining information for scanning the horizon and was based on a variety of sources, including:

(a) The Open-ended Online Forum on Synthetic Biology;

(b) Submissions of information from Parties and stakeholders;

(c) Submissions from the members of the multidisciplinary Ad Hoc Technical Expert Group;

(d) A literature review.

6. The second phase was aimed at supporting the assessment by gathering more targeted information relevant to the particular trends or issues to be assessed. Overall, the two-step process used in the horizon scanning, monitoring and assessment was considered adequate by the Group members.

7. Elements for future consideration include the following:

(a) It may be necessary to call upon additional specific expertise during the information-gathering step to further inform the assessment step;

(b) Information gathering could be strengthened by engaging diverse stakeholders, including in languages other than English, such as indigenous peoples and local communities, scientists and practitioners. In addition, consideration should be given to integrating the research priorities of Parties and other Governments, also recognizing the multidisciplinary nature of information gathering;

(c) A proactive approach to initiating the literature review earlier in the process could enhance support for the assessment step, allowing for a more comprehensive exploration of diverse resources, in line with the multidisciplinary nature of the process. Furthermore, strengthening the requirement for search terms through collaborative input from the multidisciplinary Ad Hoc Technical Expert Group could significantly improve the overall effectiveness of that essential phase;

(d) The Biosafety Clearing-House would be a valuable resource to consider during the information-gathering step;

(e) Future iterations of the process should include a review of the status of the prioritized topics and assess whether they remain a trend or issue. Furthermore, a literature review could be conducted during the first information-gathering step to inform the horizon scanning and prioritization. Mechanisms could be established to share that information with Parties.

2. Step B: compilation, organization and synthesis of information

8. The information produced during the two phases of information gathering were compiled, organized and synthesized by the Secretariat.

9. Further considerations on the present step are provided below:

(a) The peer-review process would be an important element to complete when finalizing the literature review, including by providing relevant search terms;

(b) The timely and effective compilation and synthesis of information are key to carrying out the assessment step;

(c) The criteria for synthesizing information should be aligned with the overall methodology of the process, to ensure that they provide the basis for the discussions during the assessment step.

3. Step C: assessment

10. For the assessment step, the Group members performed both a prioritization step during the online meeting held in October 2023 and an assessment step during the second in-person meeting.

11. The prioritization consisted of an exercise whereby the experts assigned the individual items on the shortlist a score between 1 and 1,000, on the basis of their impacts on the objectives of the Convention, their relevance to Parties to the Convention and urgency. Z-scores[2] were then calculated, and the summed results were distributed. The items that received an overall positive z-score were then selected for the prioritized list. Because this was an expert-driven process, an indicative preference exercise and further sorting resulted in a list of five further-prioritized items. For the assessment step, the experts developed harmonized structures to facilitate the assessment of the items on the prioritized list.

12. Further considerations on the present step are provided below:

(a) The screening step for the assessment step can be undertaken in the following order: exchange among experts; initial z-scoring; discussions and exchange among experts; and final z-scoring. It should be noted that the multidisciplinary Ad Hoc Technical Expert Group should have the flexibility to decide how to use the results of a second z-scoring or whether additional methods are required during prioritization;

(b) The inclusive participation of experts from different disciplines, including representatives from indigenous peoples and local communities, academics and specialized experts, is essential for the assessment step. It ensures a well-rounded consideration of diverse perspectives when evaluating the potential impacts of technological developments and complements the expertise available in the multidisciplinary Ad Hoc Technical Expert Group;

(c) Other knowledge systems, forums and appropriate information-gathering methodologies should be incorporated into the assessment process;

[2] Z-scores are calculated by subtracting the mean (average) from the initial score and then dividing it by the standard deviation. This ensures that scores are comparable (standardized), that is, that they can be meaningfully aggregated across participants with different means and variances in their scoring. Z-scores are commonplace in a range of areas, including in foresight and horizon scanning (in health, ecology and bioengineering) and biology (e.g. to calculate height and weight relative to the broader population distribution).

(d) The assessment step would also benefit from information provided through the monitoring of the trends and issues in synthetic biology.

Annex IV

Refined methodology for broad and regular horizon scanning, monitoring and assessment

1. At its first meeting, the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment decided on an overarching process for its work on the basis of the steps outlined in the annex to decision 15/31. The following methodology could be considered as a template for potential future iterations.

I. Information gathering regarding all trends and issues in synthetic biology

2. Initial information gathering should be conducted by the Secretariat of the Convention on Biological Diversity as the coordinating actor and draw on submissions of information from Parties, other Governments, indigenous peoples and local communities, relevant organizations and members of the multidisciplinary Ad Hoc Technical Expert Group, discussions held in the Open-ended Online Forum on Synthetic biology and a literature review. This stage can be considered as step A (information gathering) of the annex to decision 15/31.

3. The step of information gathering could be strengthened through engagement with and outreach to diverse stakeholders, including indigenous peoples and local communities, scientists and practitioners, in multiple languages. Furthermore, the incorporation of the research priorities of Parties and other Governments, regulatory applications and grant approvals, as well as information available in patent databases and on the Biosafety Clearing-House, could also complement the information gathered.

II. Compilation, organization and synthesis of information

4. The first compilation, organization and synthesis of information would be conducted by the Secretariat as the coordinating actor. This stage can be considered as step B (compilation, organization and synthesis of information) of the annex to decision 15/31.

5. Peer-review processes are important elements to conduct before finalizing literature reviews and patent analyses.

III. Screening and prioritization of trends and issues in synthetic biology

6. The screening and prioritization step is conducted by the members of an expert group. It involves longlisting, shortlisting and, last, prioritization. This stage could be considered as part of step C (assessment) of the annex to decision 15/31.

7. The present step can be undertaken in the following order: exchange among experts of the multidisciplinary Ad Hoc Technical Expert Group; initial z-scoring;[1] discussion of the results among experts; second z-scoring exercise; and deliberations to determine the prioritized list in the light of the outcomes of the z-scoring exercise. The criteria on which the z-scoring is based can vary, but required elements include consideration of the potential impacts on the objectives of the Convention, urgency and likely priority for Parties.

[1] Z-scores are calculated by subtracting the mean (average) from the initial score and then dividing it by the standard deviation. This ensures that scores are comparable (standardized), that is, that they can be meaningfully aggregated across participants with different means and variances in their scoring. Z-scores are commonplace in a range of areas, including in foresight and horizon scanning (in health, ecology and bioengineering) and biology (e.g. to calculate height and weight relative to the broader population distribution).

8. Further methods for prioritization may be required, as necessary.

IV. Information gathering on prioritized trends and issues to support the assessment

9. Following the prioritization step, an additional information-gathering exercise should be completed to gather information for the assessment step. The coordinating actor for the present step is the Secretariat, and the step should include outreach to specialists with expertise in the trend or issue in synthetic biology under consideration.

10. Owing to its iterative nature, this stage can be considered as part of step A (information gathering) of the annex to decision 15/31.

V. Compilation, organization and synthesis of information to support the assessment

11. The Secretariat is, here again, the coordinating actor for the compilation, organization and synthesis of the information collected for the assessment of the prioritized trends and issues in synthetic biology.

12. Owing to its iterative nature, this stage can be considered as part of step B (compilation, organization and synthesis of information) of the annex to decision 15/31.

VI. Assessment of the prioritized trends and issues in synthetic biology

13. The assessment of the prioritized trends and issues in synthetic biology is performed by the Group members and then reviewed by the Subsidiary Body on Scientific, Technical and Technological Advice and the Conference of the Parties. This stage can be considered as step C (assessment) of the annex to decision 15/31.

14. It is essential that the assessment be inclusive and multidisciplinary to ensure a holistic result. It should therefore include representatives from indigenous peoples and local communities, academia and specialized experts, as needed, to complement the expertise of the members of the multidisciplinary Ad Hoc Technical Expert Group.

VII. Reporting on outcomes

15. The report of the assessment should be submitted to the Subsidiary Body for endorsement and further submission to the Conference of the Parties. This stage can be considered as step D (reporting on outcomes) of the annex to decision 15/31.

16. Providing the report in the six official working languages of the United Nations should be an important consideration, as well as finding mechanisms to distribute the outcomes to Parties.

VIII. Further considerations and monitoring

17. Trends and issues in synthetic biology from previous cycles should be reviewed during the initial information gathering step (step A) to assess whether they continue to be of importance and to understand how they evolve overtime.

18. Adjustments to the methodology should be made to take into account the experience gained in conducting horizon scanning, monitoring and assessment.

Annex V

Recommendations of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment to the Subsidiary Body on Scientific, Technical and Technological Advice

The Subsidiary Body on Scientific, Technical and Technological Advice may wish to consider the following recommendations from the multidisciplinary Ad Hoc Technical Expert Group:

General considerations

1. Acknowledge that the first cycle of the horizon scanning, monitoring and assessment of synthetic biology revealed valuable information on current developments and their potential impacts on the objectives of the Convention on Biological Diversity and its Protocols;

2. Recommend that the methodology used for the first cycle take into account the review of the process for broad and regular horizon scanning, monitoring and assessment of the most recent developments in synthetic biology conducted by the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment[1] and serve as a basis for such a process to be conducted in each biennium, while keeping the methodology under review at future meetings of the Group;

3. Note that a multidisciplinary approach is vital for assessing the impacts of synthetic biology on the objectives of the Convention and its Protocols;

4. Recognize the relevance of broad and regular horizon scanning, monitoring and assessment to mitigating inequity in the context of synthetic biology and contributing to the implementation of the objectives of the Convention and the goals and targets of the Kunming-Montreal Global Biodiversity Framework;

5. Take note of the preliminary analysis of the prioritized list of 17 trends and issues in synthetic biology contained in document CBD/SYNBIO/AHTEG/2024/1/INF/1;

6. Note that the broad and regular horizon scanning, monitoring and assessment can be enriched through outreach to indigenous peoples and local communities and by strengthening the development of relevant participatory instruments and tools;

7. Choose to identify one or more trends and issues in synthetic biology that have already undergone initial assessment under the present process for horizon scanning, monitoring and assessment, and requests the multidisciplinary Ad Hoc Technical Expert Group to undertake a process that may include, over the biennium 2025–2026, additional information gathering; compilation, organization and synthesis of information; and additional assessment;

8. Forward synthetic biology products that, according to the outcomes of the horizon scanning, monitoring and assessment, may constitute living modified organisms, to the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity to address the aspects within the scope of the Protocol;

9. Forward synthetic biology products that, according to the outcomes of the horizon scanning, monitoring and assessment, relate to the utilization of genetic resources to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access to Genetic

[1] CBD/SBSTTA/26/4, annex III.

Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity;

10. Consider recommending to Parties to undertake a capacity self-assessment in order to address existing and continuing inequalities in the participation of developing countries in synthetic biology and to develop proposals for strengthening the capacities of developing countries in that field, taking into account areas of particular interest to indigenous peoples and local communities, women and youth, as appropriate;

11. Note the capacity-building, technology transfer and knowledge-sharing needs identified under the horizon scanning, monitoring and assessment, including in the context of the Framework;

12. Consider using and strengthening a multidisciplinary approach to broad and regular horizon scanning, monitoring and assessment of the latest developments in synthetic biology by, inter alia, further evaluating the socioeconomic, cultural, conceptual and ethical impacts of the genetic modification of wild organisms on the objectives of the Convention;

13. Consider measures for enhancing the dissemination of information on scientific and technology assessments, including through the clearing-house mechanisms;

14. Recommend that the Secretariat facilitate continued multidisciplinary reviews by Parties, other Governments, indigenous peoples and local communities, women, youth and relevant organizations of the multidisciplinary Ad Hoc Technical Expert Group process by means of submissions through the Open-ended Online Forum on Synthetic Biology, as part of the mechanism to gather information for assisting the Conference of the Parties in making further decisions regarding future horizon scanning, monitoring and assessment, bearing in mind the rapid pace of technological change in synthetic biology;

15. Note that the development of synthetic biology continues to have relevance for all kingdoms of life and for all objectives of the Convention, as well as for the goals and targets of the Framework;

16. Note that, as synthetic biology applications are now being developed for taxa in all kingdoms of life, the implications of their potential or actual use in wild populations may be subject to further review, and that such applications might have potential positive and negative impacts in various contexts, such as species resilience or threatened species management;

17. Develop a white paper or non-binding guidelines on synthetic biology technology transfer in the context of the Convention, including with regard to intellectual property issues, monitoring and assessment of the technology;

18. Explore options for supporting and establishing appropriate procedures, as well as providing appropriate financial or technical resources, to contribute to the effective monitoring of trends and issues in synthetic biology that need to be considered under any future broad and regular horizon scanning, monitoring and assessment in relation to the three objectives of the Convention;

Artificial intelligence and machine learning

19. Note that the accelerated development of artificial intelligence and machine learning in the field of synthetic biology may have significant adverse impacts on the objectives, principles and provisions of the Convention and that those potential impacts need further evaluation;

20. Note that artificial intelligence and machine learning could, in principle, have potential positive impacts on the objectives of the Convention, including by enhancing the utilization of genetic resources and the fair and equitable sharing of the associated monetary and non-monetary benefits;

21. Initiate a policy formulation process to address in more detail the implications of the integration of artificial intelligence with synthetic biology on the objectives, principles and provisions of the Convention. The process could include:

(a) A request to the multidisciplinary Ad Hoc Technical Expert Group to undertake a further assessment leading to a report addressing, inter alia, potential impacts on biosafety, the sustainable use of biodiversity, equitable access and benefit-sharing, social, economic and cultural aspects, impacts on traditional knowledge and practices, and other relevant matters;

(b) A request to the Secretariat to prepare a technical series publication on the topic of artificial intelligence and synthetic biology;

(c) A request to the Secretariat to convey insights from the process into United Nations system-wide initiatives relevant to the governance of artificial intelligence and biotechnology, including the High-level Advisory Body on Artificial Intelligence of the Secretary-General, the Summit of the Future and other relevant forums;

22. Consider the development of effective and equitable governance arrangements for artificial intelligence data sets, foundation models, algorithmic biodesign tools, automated science tools and the use of synthetic biology organisms, components and products in cyberphysical systems. Parties may also wish to explore the implications of the accelerated development of artificial intelligence and machine learning for the implementation of the three objectives of the Convention, as well as related rules, provisions and targets, including under the Framework;

Self-spreading vaccines in wildlife

23. Recommends, in the absence of reliable data on self-spreading vaccines, without which there is an inadequate basis for assessing their potential risk, and in accordance with the precautionary approach:

(a) To conduct an appropriate assessment of the ecological, socioeconomic, cultural and other impacts of self-spreading vaccines and any potential adverse effects on biological diversity, taking also into account risks to human health, ensuring that the assessment has been carried out in a transparent manner, in line with the precautionary approach, and that the conditions for the safe use of those vaccines have been met;

(b) To develop mechanisms to ensure the free, prior and informed consent of all potentially affected communities, including indigenous peoples and local communities;

(c) To examine whether there is an appropriate evidence base on which to justify potential field tests or commercial use has been conducted;

Development of engineered gene drives to control vector-borne diseases and invasive species

24. Consider the need for a wider assessment of the socioeconomic, cultural, and ethical impacts of engineered gene drives, in particular on indigenous peoples and local communities, to facilitate decision-making in line with the precautionary principle, decision 14/19 and other relevant decisions of the Conference of the Parties and the processes under the Cartagena Protocol;

Inequitable participation of developing countries in the development of synthetic biology

25. Review, for reducing the inequity gap between developed and developing countries, the list of options for capacity-building, technology transfer and knowledge-sharing needs related to synthetic biology and to submit it for consideration to the Subsidiary Body on Implementation, as appropriate;

Self-limiting insect systems

26. Decide to consider self-limiting insects as a potential topic for the further development of guidance on risk assessment in line with annex I to decision CP-9/13.