



## Convention on Biological Diversity

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### Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment First meeting

Montreal, Canada, 11–14 July 2023

Item 3 of the provisional agenda\*

#### Implementation of the mandate

### Summary of discussions of the Open-ended Online Forum on Synthetic Biology

*Note by the Secretariat*

#### I. Introduction

1. At its fifteenth meeting, by its [decision 15/31](#), the Conference of the Parties to the Convention on Biological Diversity 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 the same decision, the Conference of the Parties requested the Executive Secretary to convene online discussions of the Open-ended Online Forum on Synthetic Biology to support the work of the multidisciplinary Expert Group.

2. Pursuant to the decision, the Open-ended Online Forum on Synthetic Biology was convened from 20 to 31 March 2023. A total of 211 participants registered, of whom 87 actively participated. A total of 194 interventions were made, of which 97 were made by Parties, 5 by non-Parties, 88 by organizations and 4 by representatives of indigenous peoples and local communities.

3. To support the deliberations of the multidisciplinary Expert Group, two topics and five guiding questions were identified:

(a) Topic 1: Trends within the field of synthetic biology

Question 1a: What are some examples of near-future applications? And what is the time frame for release of the applications, either for research or commercialization (0–5 years; 5–10 years; 10+ years)?

Question 1b: What could be the potential positive and potential negative impacts vis-à-vis the three objectives of the Convention arising from such applications?

Question 2: Are there any trends that were not identified by the Ad Hoc Technical Expert Group on Synthetic Biology that should also be considered?

(b) Topic 2: Points to consider for carrying out the process of broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology

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\* CBD/SYNBIO/AHTEG/2023/1/1.

Question 1: What particular points should be considered when carrying out each of the steps specified by the Conference of the Parties for the process for broad and regular horizon scanning, monitoring and assessment?

Question 2: Share information on methodologies and approaches that have been used for other horizon scanning processes that you believe could be useful for the horizon scanning on synthetic biology under the Convention on Biological Diversity and provide examples if possible.

4. The following table provides a breakdown of the interventions by question posed:

<i>Question</i>	<i>Number of interventions</i>	<i>Number of participants</i>
Topic 1, question 1a	57	45
Topic 1, question 1b	41	35
Topic 1, question 2	26	24
Topic 2, question 1	30	27
Topic 2, question 2	40	30

5. The forum was moderated by Martin Cannell of the United Kingdom of Great Britain and Northern Ireland.

6. The present document provides a summary of the views shared through the Open-ended Online Forum. For a complete account of all interventions, it is recommended to refer to the original online interventions.<sup>1</sup> In addition, the bibliographical references shared during the Forum can be found in the annex to the present document.

## II. Summary of the interventions

### A. Topic 1: trends within the field of synthetic biology

7. In the [report](#) on its meeting held in 2019,<sup>2</sup> the Ad Hoc Technical Expert Group on Synthetic Biology identified a non-exhaustive list of trends that could inform the process for broad and regular horizon scanning, monitoring and assessment. In addition, the Secretariat of the Convention published the [CBD Technical Series 100: Synthetic Biology](#), which further complements the report of the Expert Group by providing the state of development of some of the applications of synthetic biology and also identifying emerging trends in the field of synthetic biology. Thus, to inform the work of the multidisciplinary Expert Group, the participants were asked to share information on the trends identified by the Ad Hoc Technical Expert Group on Synthetic Biology in 2019 and potential trends for examination by the multidisciplinary Expert Group.

*Question 1a: What are some examples of near-future applications? And what is the time frame for release of the applications, either for research or commercialization (0–5 years; 5–10 years; 10+ years)?*

8. Under this question, participants were requested to share information on examples of near-future applications of synthetic biology and, if possible, estimate the time frame for the release of these applications. In doing so, there was divergence on whether sprays that elicit an RNA interference response could be producing a living modified organisms or genetically modified organism or would be considered a pesticide. Similarly, there was also divergence about whether organisms produced through genome editing should be considered as applications of synthetic biology.

<sup>1</sup> [www.cbd.int/synbio/current\\_activities/open-ended\\_online\\_forum/](http://www.cbd.int/synbio/current_activities/open-ended_online_forum/).

<sup>2</sup> CBD/SYNBIO/AHTEG/2019/1/3.

9. As such, the participants shared the following information on the near-future applications of synthetic biology:

(a) 0-to-5-year time frame:

- Engineered microbes (bacteria and algae) for remediation or waste-recycling
- Genome edited agricultural crops, for example, using clustered regularly interspaced short palindromic repeats (CRISPR), transcription activator-like effector nucleases
- The use of synthetic biology for producing petrochemical precursors and industrial chemicals
- Field trial of self-spreading viral vaccines, such as modified raccoon poxvirus vaccine against *Pseudogymnoascus destructans*
- Self-spreading vaccines to control Lassa fever in rats, rabies in bats and ebola in primates<sup>3</sup>
- *Bacillus subtilis* ZB183™, a modified bacteria for breakdown of acetaldehyde following alcohol consumption
- BioElixOne – *Escherichia coli* expressing Cas9 and guide RNAs to target genes in *Salmonella* sp. to prevent its growth in the intestine
- EVO2106A – double-stranded RNA spray pesticide for use in agricultural settings
- Squalene production by fermentation (e.g. by Amyris)
- *Escherichia coli* strain Nissle 1917 engineered as a therapeutic for infectious diseases, metabolic disorders, inflammatory bowel diseases and cancer
- Biosensors and synthetic biology-based diagnostics, for example, for use in medicine and environmental water monitoring
- Synthesis of modified viruses
- Cell-free biology
- Genome editing using codon-optimized or rewritten DNA inserts

(b) 5-to-10-year time frame:

- Engineered plants and animals for remediation or waste-recycling
- Sugarcane-based fermentation to produce bio-identical molecules, such as plastics
- Soybeans with modified oil qualities for use as biofuels
- Environmental use of double-stranded RNA sprays as herbicides and insecticides,
- Use of double stranded RNA sprays for delayed senescing
- Use of genome editors to create null segregants
- Use of genome editors for use in veterinary medicine and rodent control
- Projects resulting from the International Genetically Engineered Machine competition
- Genome editing gene therapy based on lentivirus or adeno-associated virus vectors to treat genetic disorders
- Retrobiosynthesis<sup>4</sup> using designed and optimized gene circuits for product synthesis

(c) Over-10-year time frame

- Engineered chytridiomycosis resistance in Australian frogs, such as corroboree frogs
- Use of synthetic biology applications as sensors for disease-associated biomarkers or to modify intestinal microbiota composition
- New functional organisms as a result of artificial genome synthesis

10. In sharing examples, several participants also noted the following new developments, but did not specify a time frame for their release:

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<sup>3</sup> A Cytomegalovirus-based vector vaccine is being developed for primate immunization against Ebola.

<sup>4</sup> The synthesis of organic chemicals from inexpensive precursors and evolved enzymes.

- *Escherichia coli* with a re-programmed codon usage (replacing two of six serine for leucine codons) to prevent viral infection and gene transfer
- Genome editing of sorghum (striga resistance), teff (reduced lodging and grain shatter) and *Brassica carinata* (improved oil quality)
- Increased sophistication of genome editing, such as a CRISPR RNA-guided protease
- Machine learning-informed and synthetic biology enabled semi-continuous algal cultivation
- Genome editing and engineering of organelles and plastids, such as mitochondria
- Replacing mitochondrial haplotype with one from a closely related species, could be used for conservation or resilience to climate, abiotic stress or pathogen resistance
- Gene drive therapy for HIV in high-risk population groups
- Horizontal Environmental Genetic Alteration Agents
- Organism and locus-specific genome editing of microbial communities
- Modified plasmodium parasites for malaria control
- Novel viral delivery methods for genome editing plants and bacteria
- CRISPR-mediated transactivation in mosquitoes
- Bio-inspired and “living” materials, such as the FUNGATERIA project, which use bacterial strain as a chassis for sensor-containing genetic circuits to interact with fungal mycelium to direct activity, influence growth or morphology of the fungus
- Bacteria modified to degrade nitrobenzene
- Bacteria engineered for modified behaviour through the expression of the plasmid-encoded neutral network
- Mammalian cells containing logic gates controlled by unnatural amino acids
- New biodegradable materials, such as bio-plastics and marine degradable plastics
- Engineering ribulose-1,5-bisphosphate carboxylase-oxygenase to increase catalytic efficiency and thus carbon capture (possible on a research scale, but not large scale)
- Novel carbon fixation pathways that could be leveraged within minimal/synthetic cells and/or in the development of artificial photosynthesis
- Microorganisms engineered to capture carbon and convert industrial carbon dioxide emissions
- CRISPR-based nucleic acid detection and quantification of environmental DNA for identifying invasive species or providing insights in distribution of threatened species
- Low-cost DNA and RNA circuits designed by machine learning
- Organisms for industrial and pharmaceutical use
- Use of open-air proteins for modifying genetic materials
- Increased field testing
- Microbial production of plant metabolites, for example, stevia-derived sugar rebaudioside M
- Microbial production of chitoooligosaccharides, using microbial cell factories expressing highly specific and selective enzymes to produce defined chitoooligosaccharides, also improved yield
- New sterility systems to control invasive species or allow for exotic/non-native forestation for lumber and pulp production

11. When considering the time frames for release, it was noted that it could be difficult to predict the time frame for release. One factor mentioned was that there is a difference between an application being near term or ready for release and the ability to do so if it is regulated. It was also noted that a patent might be available for a new application, it might not be a reliable indicator of the application nearing development. Furthermore, it was suggested that when an application is in later development, it may not perform as expected outside controlled environments or there could be problems scaling up the production of the application. However, it was also suggested that synthetic biology applications have “signals of advancements” from fundamental research to translational research,

applied research and decisions to support application or not, all of which could be used to place developments within time horizons.

12. Regarding engineered gene drives, there were diverging views about the specific time frame for their release. Some participants believed that engineered gene drives for insects and mice would be released within the next five years, others thought that these would not be released until later. It was also mentioned that limited field-testing of the components of the engineered gene drive systems (rather than the whole system) would occur within the next five years. Furthermore, it was noted that there are currently 32 proposals for six insect orders, with the mosquito projects being the most advanced, and 42 non-insect project proposals. Furthermore, it was noted that new developments have made the engineered gene drive system in *Aedes aegypti* more efficient.

13. For the use of synthetic biology (e.g. metabolic engineering) to synthesize natural product compounds, flavours and fragrances, it was suggested that some products are already on the market and others are in the late stages of development (e.g. vanillin). However, some participants thought some of these compounds could be made available in the 5-to-10-year time frame, if not later.

14. Examples of national initiatives were also shared. For example, the National Key Research and Development Programme of China “Synthetic Biology” was launched in 2018, with the main research tasks of artificial genome synthesis, artificial components and gene circuits, artificial cell anabolism and function-specific synthetic biological systems. The programme focuses on solving the basic scientific problems of synthetic biological design, improving the ability to construct artificial biological systems and innovating key technologies of synthetic biology. In another example, it was mentioned that the Government of the Republic of Korea was expanding their state-led bio-foundries and bio-manufacturing capacities.

*Question 1b: What could be potential positive and the potential negative impacts vis-à-vis the three objectives of the Convention arising from such applications?*

15. Under this question, participants were asked to share potential positive and potential negative impacts of synthetic biology applications vis-à-vis the three objectives of the Convention.

16. Many participants highlighted that the impacts, both the potential positive and the potential negative, would need to be assessed on a case-by-case basis. It was noted that the fact that one application may be beneficial or detrimental in a certain social, political, economic, and ecological context does not mean that the same technology would have the same impacts in another context. Furthermore, some also pointed out that using synthetic biology may not make an application inherently risky. However, in contrast, others mentioned that there could be a potential to overestimate the potential of an application and thus emphasized the precautionary principle.

17. In line with the International Union for Conservation of Nature publication [Genetic Frontiers for Conservation](#), it was suggested that the potential impacts could be categorized into ecological effects, human effects, application issues and ethical issues. It was also mentioned that the potential impacts could be guided by the precautionary principle; the relevance of both the living and the non-living components of the process, the history of use and the products of the synthetic biology; potential impacts of organisms, components and products on the three objectives of the Convention; and consideration of direct and indirect effects also taking account of socioeconomic and full life-cycle analysis.

18. Several potential positive impacts were shared:

- Prevention of extinctions
- Addressing of intractable conservation issues
- Reversing the sense of conservation loss
- Enabling the production of products from renewable sources without high energy inputs and chemicals
- Enabling production of economically infeasible compounds (e.g. for pharmaceutical use)

- New tools to combat vector-borne diseases, such as malaria
- Decrease pesticide use
- Decrease land use
- Reduce chemical and plastic pollution
- Expand biodegradable alternatives to plastics
- Reduce pressure from harvesting from nature and wildlife (e.g. alternatives to horseshoe crab blood for testing biomedical applications)
- Environmental remediation
- Control invasive species
- Reducing soil erosion in agricultural applications
- Decrease fuel use
- Increasing on-farm insect biodiversity
- Improving or restoring crop quality and productivity (e.g. microorganisms for nitrogen-fixation and engineering abiotic stress tolerance)
- Improved food security and human health
- New antibiotics
- New wastewater treatment
- Biofuel production
- Carbon capture
- Increase biodiversity (e.g. through trait shuffling and facilitating cross-domain genetic transfer)
- Creation of new collaborations and new jobs

19. Several potential negative impacts were shared:

- Invasive
- Impact on rural livelihoods
- Dual-use (e.g. military or private misuse)
- Fitness advantages
- New class of pollutants
- Limits of detection for microbes
- Rapid evolutionary change
- Extinction/removal of population from environment
- Gene flow
- Emergence of unpredictable properties (e.g. unexpected virulence of Mousepox, resistance in engineered gene drive experiments)
- Horizontal or vertical gene transfer into wild or domesticated populations could lead to genetic and biological diversity loss
- Uncertainty of estimating gene dynamics in wild

20. One participant also cautioned that the impacts of synthetic biology might be unlikely owing to the lack of funding for scaling up the application and field-testing. Furthermore, it was noted that synthetic biology organisms released into the environment may not be able to compete in the same environments with highly evolved natural organisms for resources and would be ultimately subjected to the same evolutionary pressures all organisms face. The participant noted that extant organism lineages have evolved over the course of three billion years and these natural organisms exceed what humans are able to design with biological materials.

21. Some participants also mentioned that synthetic biology applications could challenge the benefits sharing of genetic resources owing to data governance and intellectual property rights. They suggested that some applications of synthetic biology could be considered to be out of the scope of access to genetic resources.

22. Regarding modified microorganisms, the following points might be important to consider: lack of knowledge of intended and unintended releases; potential for controllability and irreversibility of release; potential of global spread; dynamics of viruses designed to spread and modify, including gain-of-function mutations; antibiotic resistance genes (e.g. contamination of food with contained use organisms); and lack of knowledge of interaction between microorganisms, hosts and other microbes in the environment.

23. For applications based on modified algae, it was suggested that these applications may also carry a high level of uncertainty with respect to their high spread potential, replacement of wild relatives, ecological niche, influence on other organism, monitoring in aquatic areas beyond national jurisdiction and lack of available risk management strategies.

24. In reference to living modified organisms containing engineered gene drives, the following points were raised: complexity of the receiving environment, lack of control measures, irreversibility of release, outcrossing with related species, unpredictability of errors produced through CRISPR/Cas9, resistance to engineered gene drive and impacts on the ecosystem if a species is removed. More specifically for living modified mosquitoes containing engineered gene drives, it was also mentioned that there could be changes to pathogenicity or vector competence, inability to restore the population to the wild type, lack of efficacy, genetic instability and development of resistance and socioeconomic impacts (e.g. cost-effectiveness and alternatives). For example, it was suggested that in cases where the local populations would not be eliminated and result in mixed populations, complex dynamics may arise where local elimination would result in gaps in populations and wild-type rebounds to fill the localized empty niches. It was further suggested that for living modified organisms containing engineered gene drives, modelling studies have not assessed or predicted the potential effects on biodiversity and whole ecosystems. Furthermore, it was mentioned that validation of these models could be a challenge.

25. To manage some of the risks and minimize the potential negative impacts, specific measures could be implemented, such as designing less competitive organisms by modifying metabolic pathways, replacing metabolic pathways to build in a dependency on external biochemicals, silencing or removing traits, designing evolutionary robust biological circuits, using biological systems based on alternative biochemicals and biochemical structures, the incorporation of genetic safeguards and firewalls, and designing protocells that lack key features of living entities (e.g. growth and replication).

26. Cyberbiosecurity was also highlighted insofar as synthetic biology research and development are reliant on computerization and automation. Thus, there could be risks arising from the integration of information and communication-based technologies. For example, the computers involved in the development process could have weakness that could be exploited in malicious ways, made to work in unintended manners or deliberately be tasked to lead to something adverse. Knowledge gaps could also unintentionally lead to potential negative outcomes or with high likelihood potentially cause negative effects in a susceptible context. Taken together, these could be blamed on technology or nature. In this context, it was also mentioned that it would be important to recognize that automation and machine learning are also highly susceptible to various forms of bias. For example, mis- or disinformation could be used to train artificial intelligence models, which could then potentially lead to computer generated mis-classifications and could negatively impair genuine research. It could also enable further spreading of misinformation and illegitimate access to sensitive processes, biomaterial and equipment. Thus, it was suggested there could be other areas where computerized technology, networked systems and automation could lead to biosafety and biosecurity risks that are not well understood or recognized at this time owing to information and communication-based technology weak spots and dual-use potential of synthetic biology.

27. Ethical considerations were also raised, in particular surrounding the idea of “naturalness”. It was noted that certain applications of synthetic biology could be produced with changes similar to those found in nature and thus might be considered to be equivalent to a natural state. However, it

was mentioned that applications in this case may not be similar and thus may not have the same intrinsic safety profile. Building from the idea of “naturalness”, it was highlighted that the term has diverging views and may have different meanings depending on the culture. One participant mentioned that an integrity framework encompassing “integrity” and “agency” may improve upon and offer more flexibility compared to the lens of “naturalness”.

28. Regarding the sophistication of genetic modification techniques, it was suggested that there was an increased scale of intervention in the environment, which could result in the establishment of mutations and facilitate their spread in the environment. It was also noted that predicting the outcomes of such interventions in natural systems may not be reliable. However, other participants disagreed. Some noted that a higher complexity of genetic modification may not lead to a decrease in predictability and that technological developments are aimed at improved efficiency and predictability of outcomes without necessarily creating novel issues.

29. It was mentioned that tools and kits (e.g. CRISPR kits) are becoming more readily available to the public, potentially allowing for more people (with or without biosafety training) to modify organisms, which may result in unintended use of an application. In these cases, the unintended use may not be held to a risk evaluation or ethical and socioeconomic, cultural, considerations. However, others noted that tools, such as CRISPR, may not lead to unintended modifications in non-target organisms owing to the lack the regulatory genetic sequences for replication and modification of non-target organisms and specificity of the system. It was also noted that new tools in synthetic biology could increase accessibility and lower the barrier to use the technologies, which could be seen as improving the fair and equitable benefit sharing of these technologies and enable Parties to build capacities for research and development within synthetic biology.

30. It was also mentioned that the process for broad and regular horizon scanning, monitoring and assessment could support Target 17 of the Kunming-Montreal Global Biodiversity Framework by supporting countries in their participation in research and development, which could give countries access to benefits and minimize potential risks.

*Question 2: Are there any trends that were not identified by the Expert Group that should also be considered?*

31. Under this topic, participants were asked to share information on trends that were not identified by the Expert Group at their meeting held in 2019 and that should be considered by the multidisciplinary Expert Group.

32. The following topics were suggested for consideration by the Expert Group:

- Technological convergence of synthetic biology with other fields, such as nanotechnology and artificial intelligence
- Dual-use and biosecurity of synthetic biology (e.g. microorganisms, horizontal environmental genetic alteration agents, engineered gene drives and “Do-It-Yourself” biology)
- Exponential growth of the synthetic biology market without significant participation of developing countries
- Establishment of the Kunming-Montreal Global Biodiversity Framework to support the implementation of Articles 16, 17, 18 and 19 of the Convention
- Interaction of synthetic biology organisms in the environment, cumulative effects
- Synthetic biology techniques that increase human intervention in nature
- Field-testing applications outside national jurisdiction of the developers or funders
- Changes in ethical standards, such as “*norm-erosion*”
- Regulatory documents and final projects are not being made public in a timely manner

- The transboundary movements into and use of applications developed in non-Party territories on other territories, especially for countries without the ability to detect and identify the applications and their impacts on the environment
- Public engagement, awareness and communication
- Use of big data
- Biofoundries
- Modified microorganisms, such as viruses, synthetically synthesized viruses (e.g. horsepox virus) and self-spreading vaccines
- Genetic modification to create sterility to enable the widespread use of non-native plants, for example, non-native fast-growing trees for plantation use that would otherwise become invasive
- Complex applications of genome editing, such as de novo domestication and ribonucleoprotein complexes
- Transgenic and foliar applications based on RNA interference
- Transient expression
- Engineering photosynthetic pathways
- Artificial chromosomes
- Hachimoji DNA (expanded DNA and RNA bases)
- Paratransgenesis
- Living materials
- Xenobots
- Novel protein engineering
- RNA circuits
- Viral and nanoparticle delivery systems
- Bioelectronics, such a DNA digital storage and bioactive cells
- Null or negative segregants
- Plastid engineering and organelle modification (e.g. through genome editing)
- Biosensors for environmental applications
- Modified algae applications under semi-contained or open-release conditions
- Engineered gene drives, including anti-CRISPR/Cas and anti-drives

33. However, others agreed with the trends identified in the report of the Ad Hoc Technical Expert Group on Synthetic Biology on its meeting held in 2019, noting that no new trends had been identified. It was suggested that rather there were further refinements in established technologies, suggesting that development may not have been as rapid as some participants suggested.

34. There was disagreement about some of the trends suggested. For example, some participants did not agree with including genome editing and null segregants as part of the trends for consideration. Similarly, there was also disagreement about the inclusion of transient expression using *Agrobacterium* as a trend. One participant also disagreed with the inclusion of the synthetic synthesis of horsepox virus and another disagreed about the use of big data in synthetic biology.

35. Furthermore, it was mentioned that although a specific development may suggest an approach, it does not necessarily mean that there was a new trend (e.g. types of engineered gene drives). Similarly, it was further mentioned that some applications are considered to be part of new evolving developments or reaching a level of development maturity of the instead of a new trend (e.g. self-spreading vaccines). Thus, the participant cautioned against identifying all new technological developments as new trends.

**B. Topic 2: Points to consider for carrying out the process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology**

36. The second topic was considered based on two questions that were aimed at further elucidating the key points to be considered for carrying out the process for broad and regular horizon scanning,

monitoring and assessment of the most recent technological developments in synthetic biology. The first question entailed the provision of specific elements to inform each step of the horizon scanning process outlined by the Conference of the Parties and the second guiding question was aimed to more specifically elucidate methodological aspects of the process while providing examples as appropriate for the process under the Convention.

37. When establishing the process, the Conference of the Parties specified that the process for broad and regular horizon scanning, monitoring and assessment should consist of the following steps: (a) information gathering; (b) compilation, organization and synthesis of information; (c) assessment; and (d) reporting on outcomes. Thus, participants were invited to share their views on the methodologies that could be used for the overall process, as well as any experience they may have in performing similar processes.

*Question 1: What particular points should be considered when carrying out each of the steps specified by the Conference of the Parties for the process for broad and regular horizon scanning, monitoring and assessment?*

38. Under this question, participants shared information on the particular points that should be considered for carrying out the process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology.

39. It was noted that in the report of the Expert Group on its meeting held in 2019, several considerations for performing the process of broad and regular horizon scanning, monitoring and assessment were included.

40. There was a perspective that there is a need for prioritization in the steps defined by the Conference of the Parties to manage the breadth of the field of synthetic biology. In particular, it was raised that without this prioritization, the steps of monitoring and review may not be able to be given the attention required in this process. One determinant of this priority could be the expected time horizon to trials or development of the application beyond containment.

41. Regarding the overall process, it was mentioned that it should be inclusive of the perspectives of a diversity of groups in society, enabling intercultural dialogue and transdisciplinary approaches to learning. Furthermore, the process could be deliberative, open to a broad diversity of groups in society, in particular indigenous peoples and local communities, each of which bring different kinds of knowledge and perspectives. Furthermore, it was suggested that such a multi- and trans-disciplinary approach would assist with fostering technical robustness and social acceptability in policymaking on these applications.

## **1. Information gathering**

42. There was general agreement that the process for information gathering is a critical first step that will need to be robust and inclusive. In this regard, several inputs considered the issue of scope of the applications to be considered as an important element. However, several participants highlighted that the lack of an agreed definition of “synthetic biology” may result in a wide range of potential applications, which might complicate the identification of applications, specific uses and/or industries that are most relevant for the process.

43. There was also a perspective that the scope for horizon scanning could be limited to academic research and development and commercial development and innovation. The former can be relatively easily assessed through the normal academic outputs, such as publications and conference presentations. Public and philanthropic funding foundations were expected to maintain extensive records of relevant projects that they are funding. Patent searches were also suggested as potential information sources while bearing in mind the confidential business information concerning innovation can be an important component of the commercialisation strategy.

44. Data sources were identified as key to the information gathering phase. In this respect, the sources broadly identified for information gathering were scientific literature, such as original

research articles and review articles; applications received by countries for approval of use, including contained use; countries' decisions on received applications; risk assessments based on regulatory or non-regulatory processes; calls for submission of information by the Secretariat; the Open-Ended Online Forum on Synthetic Biology; as well as already established databases, including those established by non-governmental organizations and civil society. In addition, it was suggested that the Clearing-House Mechanism under the Convention and the Biosafety Clearing-House could potentially act as mechanisms to collect such information.

45. The source of such information could be from Governments, academia, private institutions, industry associations, experts, committees, media, patent registries, meetings, conferences and grey literature databases, among others. However, it was noted that certain types of information may not be readily available, such as those from academic institutions, which may take years to publish, commercial activities and negative results.

46. There was also a suggestion that broader representation from industry and the private sector could assist with the sharing of information, including on time frames for the development of the synthetic biology applications, experience with the technology and its development process, regulatory requirement and policy developments, among others. Furthermore, it was mentioned that engagement with other established organizations in the field of synthetic biology, such as the Engineering Biology Research Consortium, and independent scientists could be useful to collect pertinent information. Furthermore, the involvement of civil society organizations could also contribute through their research and action in the field.

47. There were some considerations that an expanded scope of horizon scanning could include more than potential positive and potential negative impact, and thus new and updated tools for ethical assessments and for building ethical reflexivity may be considered.

48. Some participants considered that the early inclusion of context, framing and different knowledge systems in the scope and information gathering as critical. Context evaluations were identified by some participants as important for ensuring inclusivity from the very early stage of information gathering.

49. The perspective that the step of gathering information in horizon scanning could seek input from all sources and from a diverse range of actors, including indigenous peoples and local communities and civil society, was shared. When possible, it was suggested that it should be inclusive of the perspectives of a diversity of groups in society, enabling intercultural dialogue and transdisciplinary approaches. Furthermore, it also should build on the work of national, regional and international relevant horizon scanning or technology assessment processes.

50. There was a suggestion that an additional step be incorporated in the beginning, where the questions that need to be addressed are defined and the relevant criteria for inclusion are outlined. This process would ensure clarity on what leads to follow and how to register, collect and enter the information and data. A scoping trial before starting a full horizon scanning process could be useful in this regard.

## **2. Compilation, organization and synthesis of information**

51. The importance of the compilation, organization and synthesis of information step was highlighted by several participants. In this regard, the key step of systematic review of the synthetic biology/engineering biology scientific literature was stressed, in particular in the context of the large volume of literature, other publications and various other inputs of information on the topic.

52. It was noted that a key step would "filtration" of the extensive information submitted and gathered in the first step. This would require an inclusive prioritization process that would entail ensuring a simplified process that would allow added information to be easily analysed and filtered. The information compiled and synthesized should be made available through the Clearing-House Mechanism.

53. Criteria for filtering the information could be based on a specified time frame for the anticipated trials or applications beyond containment, impact on the objectives of the Convention, urgency of a potential risk or threat, potential benefits to be realized, policy priority or strategic relevance among others.

54. The need to adapt the process to the available resources was noted for consideration, as well as the need for consultants to assist with the volume of information.

55. There were some suggestions that the compilation and assessment be completed by a smaller sub-group of experts serving as rapporteurs for the multidisciplinary Expert Group or the Secretariat.

56. A further suggestion was made to prioritise application scenarios for in-depth case studies.

57. The Secretariat publication *CBD Technical Series No. 100: Synthetic Biology* was highlighted as an example of providing a useful categorization of the developments in synthetic biology.

58. There was also a perspective that the collected information could be divided in various categories (e.g. socioeconomics, cultural considerations) that would be represented in different sections. It was suggested that this organization could improve distinguishing scientific and empirical information from value- and opinion-based information, which could facilitate the next assessment step.

### 3. Assessment

59. There was general agreement that the assessment step was of critical importance and recognition of the need to ensure that the process included approaches that were multi- and trans-disciplinary, as well as participatory. In this regard, several references were made to the report of the Expert Group on its meeting held in 2019, which also highlighted the importance of expertise in a broad range of disciplines, as well as interdisciplinary and intercultural expertise. The reference in paragraph 41 (h) of the report to the importance of employing tools and approaches to enable a participatory assessment process was reiterated by several participants. The need to ensure knowledge and participation of indigenous peoples and local communities, was also stressed. Thus, these broad considerations from multiple perspectives would be required as part of the horizon scanning process for new developments in synthetic biology in order to ensure the three objectives of the Convention.

60. There was a view that the assessment of information should not be restricted to potential positive and negative impacts only but also highlight the gaps in knowledge, the areas requiring further investigation, the availability of tools to monitor, detect and identify, the availability of risk assessment, monitoring and emergency measures. The Assessment step also needs to reflect the multidisciplinary nature of the Expert Group to include not just scientific issues but also socioeconomic, legal, ethical and cultural aspects.

61. The need for case-by-case determination was outlined in several interventions, as well as the role that legal, economic and cultural context has a large effect on which biotechnologies are brought closer to market. However, an intervention also suggested that there could be a potential to conflate potential risks and potential benefits of an application of synthetic biology with actual and potential risks and benefits of other management and technological applications already used or being considered for the same goal or outcome.

62. Several assessment criteria were also mentioned, including impact, innovation, expected use, time frame, anticipated risk level, socioeconomics, legal considerations, ethical issues, barriers to market and public perception.

63. The inclusion of a specific technology assessment step was highlighted by several participants. The comprehensive technology assessment analysis could be an important element to be considered in future deliberations, including the Open-Ended Online Forum on Synthetic Biology. The discussions could potentially be enriched by the extensive technology assessment research literature and expertise that already exists. In contrast, it was mentioned by others that a technology assessment

step may require more time than a typical technical expert group meeting would be allotted. Thus, an additional filtering step was suggested to focus the efforts during the assessment process.

64. An important additional element that was highlighted for the assessment process included the effectiveness of the process of horizon scanning and how it can be improved for future cycles. This was noted to be important and in line with the request by the Conference of the Parties for the Subsidiary Body on Scientific, Technical and Technological Advice to incorporate a review of the effectiveness of the process undertaken.

65. The assessment step will also need to address knowledge gaps and make appropriate assumptions in order to facilitate the overall assessment process.

66. There was recognition of the need for more capacity around knowledge-sharing, as well as guidelines to develop policy and regulations. An emerging concern was the ability of the various stakeholders to participate in the process, as well as the need to ensure complementary capacity-building to ensure sufficient information and support to equally engage and contribute to the process.

67. A precautionary approach, which also respects, inter alia, knowledge gaps and uncertainty of data, can contribute to the long-term resilience of the horizon scanning process. Horizon scanning, monitoring and assessment, if designed in an appropriate manner, can contribute to increasing of robust knowledge and filling data gaps.

#### **4. Reporting on outcomes**

68. Participants noted that the collected information, including knowledge gaps, new techniques, trends and products will need to be incorporated into a succinct report. The goal of the report would be to identify the subset of high-priority technological developments, both positive and negative, to bring to the attention of the Parties. Similarly, there was a further suggestion that the outcomes should be compiled in a manner that would allow for the identification of applications that pose a relevant risk to biodiversity, also taking into account human health and the environment.

69. Some participants were of the view that the report will need to make it clear that the goal of horizon scanning, is not to try to accurately predict the future, but rather to identify, compile and analyse the various signals of change. In this regard, the report would entail the selection of the top 15 to 20 key issues or technologies, prioritized from a much longer list and incorporate paragraph length descriptions of each summarizing key controversies and unknowns.

70. There was a view expressed that the outputs of these horizon scans could be presented to prioritize key issues or technologies for attention. This prioritized report could include key messages for decision makers and outline societal, ethical and legal issues. The additional analyses and written outputs that are far more extensive could be shared separately. These additional reports that approach the level of detail of technology assessments, including chapter-length discussions of the opportunities and challenges presented by the technologies. However, the resource requirements far exceed those devoted to previous processes under the Convention that rely on expert groups as sources of advice and are no doubt out of reach for this purpose.

71. The need for public awareness and reporting on the relevance of the specific findings was also suggested as being important for society more broadly. Some participants recommended that it could be helpful to find graphical ways to report on the outcomes, if possible. This would facilitate communication and broader engagement with society at large.

72. There was a perspective that the report of the outcomes will need to detail the process of horizon scanning and how it can be improved for the upcoming cycles aiming for a “broad and regular” process as agreed in decision [15/31](#). Furthermore, for the effectiveness of the horizon scanning, it is necessary to closely review the results of horizon scanning on synthetic biology that has already been performed or will be performed in each country and to re-contextualize vis-a-vis the three objectives of the Convention. In the long term, it would be useful to establish a horizon

scanning process customized to the needs of the Convention that could also facilitate similar practices in each Party.

73. Lastly, when considering the potential need for updating the horizon scanning data, it was mentioned that the following should be considered: (a) constant review of developments and sources based on usefulness, relevance and evolution; (b) periodicity; (c) reassessment when sufficient new data are available or a step change in technology has occurred; and (d) validation of results by experts.

*Question 2: Share information on methodologies and approaches that have been used for other horizon scanning processes that you believe could be useful for the horizon scanning on synthetic biology under the Convention on Biological Diversity and provide examples if possible.*

74. Under this question, participants were requested to share information on methodologies and approaches from other horizon scanning processes that could be useful to consider for the process that will be undertaken under the Convention. Some participants indicated the importance of clarifying the difference between horizon scanning and foresight. Horizon scanning was regarded as a foresight tool used to systematically scan or review various sources to detect early signs of potentially important developments. Foresight can be regarded as a discipline of exploring and anticipating the future in a structured and systemic way. Its purpose is to help build and use collective intelligence to anticipate developments and shape the future we want.

75. There were a number of general comments that considered the importance of monitoring developments in synthetic biology. Several examples of national level database and project registration activities in Ethiopia, Nigeria, the Philippines and South Africa were presented.

76. Examples of methodologies and approaches that have been used for horizon scanning in other fields and were identified and arguments were presented for their usefulness for the horizon scanning on synthetic biology under the Convention. A range of tools and methodologies were suggested by participants. A number of participants provided examples that highlighted an iterative Delphi process, traditional guided expert panel discussions, scenarios, environmental scanning, multi-criteria decision analysis and the use of the investigate, discuss, estimate and aggregate (IDEA) protocol.

(a) **Delphi method.** This method is a consensus-based approach that involves iterative rounds of surveys and feedback from experts in the field. It can be used to identify emerging technologies, assess their potential impacts and prioritize them for further analysis. Delphi studies are widely used to pool knowledge and build consensus around emerging issues. They often involve two or more rounds involved. In the first round, participants identify relevant issues, which are then pooled and ranked; in the second round, the issues are discussed and re-ranked. This process is iterated until a consensus is reached. Several Delphi variations have been described, from more conventional workshop formats to online tools, such as NVivo (quantitative analysis of text) or Wordle.net (a word cloud tool). The design of a Delphi study should consider the sample size and confounding factors, such as the level of conformity in the group. An example of the Delphi method being used for horizon scanning is the Foresight programme of the Government of the United Kingdom, which used the method to identify emerging technologies in various sectors, including biotechnology;

(b) **Investigate, discuss, estimate and aggregate (IDEA) protocol.**<sup>5</sup> The protocol has recruited a diverse group of experts to answer questions with probabilistic or quantitative responses. These experts investigate the questions and clarify the meanings before providing their expert estimations and credibility intervals. Following this, the experts are provided with the answers to the questions anonymously with a visual summary of the responses if possible. Following a discussion, the experts are then requested to provide another, private estimation. The answers are aggregated,

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<sup>5</sup> World Health Organization (2022) <https://www.who.int/publications-detail-redirect/9789240044173>; Hemming et al. (2017) <https://doi.org/10.1111/2041-210X.12857>.

and a mean value is calculated as the final output. Further discussion and clarifications may be also provided following the aggregation of the responses. The IDEA protocol aims to improve expert judgments and reduce linguistic ambiguity. An example of a horizon scan performed using the IDEA protocol is the 2022 publication of the World Health Organization on emerging trends and technologies for public health;

(c) **Scenarios and scenario planning.** Scenarios are plausible extrapolations about the future that explore various possible outcomes on the basis of various drivers of change. Scenarios can be used to identify key uncertainties, explore alternative futures and inform strategic planning. It was suggested that scenarios that explored the intersection of technological developments and social contexts be developed. Examples of scenarios used for horizon scanning are the scenarios for synthetic biology of the Global Business Network, which explored four possible futures based on different levels of public acceptance and regulatory oversight, and the Synthetic Biology Road Map of the United Kingdom;

(d) **Game playing.** This method has been used in the field of cybersecurity, but it was mentioned that it could be extended to the field of synthetic biology as a method to play through scenarios. In the field of cybersecurity, there are two types of entities: players and intruders. The players communicate or operated with each other while the intruder attempts to steal their information or intercept their secrets. The simulation continues as the players and intruders are changed. With respect to synthetic biology, it was suggested that the “players” could be physical (e.g. cells, biochemical pathways, entire organisms or the environment) or social (e.g. religious beliefs). An example of game playing could be taken from the European Union Agency for Cybersecurity projects on understanding the overlaps between cybersecurity and biotechnology;

(e) **Environmental scanning.** Environmental scanning involves systematically gathering and analysing information from a wide range of sources to identify trends, emerging issues, and potential threats and opportunities. It can be used to identify emerging technologies, assess their potential impacts and inform policymaking and decision-making. An example of environmental scanning being used for horizon scanning is the State of the environment report for 2020 published by the European Environment Agency, in which emerging environmental risks and opportunities in Europe were identified;

(f) **Expert panels.** Expert panels are groups of experts in a particular field that are convened to provide insights and recommendations on emerging trends and issues. Expert panels can be used to identify emerging technologies, assess their potential impacts and prioritize them for further analysis. A key consideration for such panels would be management of conflict of interest. It was also suggested that expert panels should consider the following multidisciplinary expertise; regional representation; various career levels; gender balance; employment sector; and displaced populations, among others and if applicable. An example of expert panels being used for horizon scanning is the Emerging Frontiers in Research and Innovation programme of the National Science Foundation, which convenes expert panels to identify and fund high-risk, high-reward research in emerging areas of science and engineering; the National Committee on Biosafety of the Philippines, which is currently conducting a horizon scan on genome editing and synthetic biology; and the horizon scan for synthetic biology conducted by the Australian Council of Learned Academies;

(g) **Literature review and synthesis.** This method consists of a comprehensive review and synthesis of scientific literature for identifying and assessing the potential impacts of synthetic biology on biodiversity. This approach can be used to identify gaps in knowledge and areas for further research, as well as to assess the potential risks and benefits of various synthetic biology applications. For example, a recent review of the literature on synthetic biology and biodiversity identified potential impacts on ecosystem functioning, species interactions and genetic diversity;

(h) **Multi-criteria decision analysis.** This method is used for evaluating and ranking various options or scenarios on the basis of multiple criteria that can be useful for identifying and evaluating potential policy or management options for synthetic biology and biodiversity. For

example, such an analysis has been used to evaluate the environmental and social impacts of different renewable energy technologies;

(i) **Participatory action research.** These are a set of approaches originally developed by people who were in, or worked in close collaboration with, communities experiencing oppression. People who had previously been marginalized are able to designate the focus of the participatory and dialogue processes themselves. Its premise, to be agreed by everyone involved, is that no one group knows everything. Participatory action research approaches have been adopted by Red de Evaluación Social de Tecnologías en América Latina, which performs regular horizon scanning, monitoring and assessment of technologies; Espace citoyen d'interpellation démocratique in Mali, which used a citizen deliberation on the role of genetically modified organisms in agriculture in Mali; and Prajateerpu, which was a scenario workshop and citizen's jury on potential future use of biotechnology in agriculture and the conservation of biodiversity in India.

77. Other examples of horizon scans were also shared by the participants. The European Food Safety Authority performed two horizon scans for synthetic biology plants and synthetic biology microorganisms that may reach the market within a ten-year time frame. The goal of these horizon scans was to assess the adequacy and suitability of existing guidelines.

78. In another example, a horizon scan by the organization TestBioTech was mentioned. It adopted an approach that combined systemic horizon scan of relevant research and the selection of the most relevant publications by using such criteria as the protection of biodiversity or new technological developments. The findings of the horizon scan were also filed for peer reviewed publications.

79. Recently, the organization EcoNexus performed a horizon scan that roughly followed the same steps as the ones designated by the Conference of the Parties. However, there was an additional step prior to information gathering, in which the questions to be answered, the relevant criteria, the sources of information, methodology for collecting and registering the data were developed and defined. A scoping trial before the full horizon scanning process was also done. It was further noted that having developed the screening methodology, the criteria and the creation of a sharable database was expected to facilitate the continuation and monitoring of developments and trends.

80. The Eionet Horizon Scanning Guide by the European Environment Agency was also highlighted. It consists of the following steps: signal spotting, signal scanning, sensemaking and communicating the output. To implement the various steps, tools, such as modelling, as well as the development and assessment of scenarios, assisted with the horizon scanning process.

81. When considering the methodologies shared during the online discussions, there was a view that combining elements from various methodologies might be more appropriate for the needs of the Secretariat given the steps specified by the Conference of the Parties in decision 15/31. For example, if the multidisciplinary Expert Group were to perform the information gathering step, the process could be constrained and thus a Delphi method may not be appropriate. However, a modified Delphi method could be deployed to prioritize 15 to 20 topics from a longer list and have paragraph-length summaries, including the key impacts and gaps. Thus, for the information gathering step, a method, such as the expert panels used by the Australian Council of Learned Academies, could work for the needs of the Convention. For the assessment step, structured group techniques, such as those employed by the Delphi method and IDEA protocol, were suggested as they could be designed to incorporate the multidisciplinary expertise required.

82. There was also a perspective that technology assessments could complement horizon scanning processes. A project using an additional technology assessment to a horizon scan is the "Intercultural Assessment of Synthetic Biology Applications – Developing a new set of guidelines for the intercultural assessment synthetic biology applications that could have an impact on biodiversity" commissioned by the German Federal Agency for Nature Conservation. The project aims to draft guidelines for the exchange of knowledge and evaluation across cultures, based on participatory action research approaches, in order to promote transparency and legitimacy with regard to the way the issues are framed, the choice of topics, as well as procedures of organisation, facilitation and

communication of the assessment process. Such guidelines were suggested to assist the assessment step.

83. In terms of the reporting of the horizon scanning, monitoring and assessment, the Intergovernmental Panel on Climate Change report was highlighted as an example of how outcomes could be potentially organized and communicated. In particular, the manner in which the report treats uncertainty could be used to ensure the consistent and calibrate language for communicating key findings to decision makers.

84. The horizon scans performed by the German Federal Agency for Nature Conservation were subject to a peer review, which was also suggested for strengthening the results coming from the Convention broad and regular horizon scanning, monitoring and assessment.

## Annex

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