

**Convention on
Biological Diversity**Distr.: General
19 April 2024

English only

**Subsidiary Body for Scientific,
Technical and Technological Advice**
Twenty-sixth meeting
Nairobi, 13–18 May 2024
Item 5 of the provisional agenda*
Synthetic biology

**Synthesis of peer review comments on the outcomes and methodology
of the horizon scanning process******Note by the Secretariat****I. Introduction**

1. In 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. In the same decision, the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology was established to support this process.
2. The Conference of the Parties also requested the Executive Secretary to prepare reports on the outcomes and operation of the horizon scanning process and to submit those reports for peer review to support the review of the effectiveness of the process by the Subsidiary Body on Scientific, Technical and Technological Advice at its meeting prior to the sixteenth meeting of the Conference of the Parties.
3. The multidisciplinary Expert Group met in July 2023, October 2023 and January 2024 to develop a methodology and conduct one cycle of broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology. At their meeting in October 2023, the multidisciplinary Expert Group prioritized 17 items, including 5 items for a detailed assessment. At their meeting in January 2024, the Group conducted an assessment of the 5 trends and issues that it had identified for a more detailed assessment. The outcomes are contained in annex I to document CBD/SBSTTA/26/4. Owing to time constraints, no assessment was conducted on the other 12 items on the prioritized list. The information gathered, compiled, organized and synthesized during the multidisciplinary expert-driven process for those 12 items was made available in information document CBD/SBSTTA/26/INF/4.
4. In addition to the outcomes of the horizon scanning and assessment process, a refined methodology was drafted based on the steps provided in decision 15/31 and the experience gained during the first cycle of horizon scanning. The refined methodology, presented in annex IV to document CBD/SBSTTA/26/4, has the following steps:

* CBD/SBSTTA/26/1.

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

- (a) Information gathering regarding all trends and issues in synthetic biology;
- (b) Compilation, organization and synthesis of information;
- (c) Screening and prioritization of trends and issues in synthetic biology;
- (d) Information gathering on prioritized trends and issues to support the assessment;
- (e) Compilation, organization and synthesis of information to support the assessment;
- (f) Assessment of the prioritized trends and issues in synthetic biology; and
- (g) Reporting on outcomes.

5. In response to the request in decision 15/31, the Secretariat issued notification No. 2024-027,¹ inviting Parties, other Governments and relevant organizations to submit general comments on the outcomes and the refined methodology.

6. This document aims to summarize the peer review comments received regarding the outcomes and operation of this process in line with the request in decision 15/31 and support deliberations at the twenty-sixth meeting of the Subsidiary Body.

II. Information received related to the outcomes and methodology of the horizon scanning process

7. A total of sixteen submissions were received from:

- (a) Six Parties (Australia, Brazil, Burkina Faso, Burundi, Mexico and United Kingdom of Great Britain and Northern Ireland);
- (b) One other Government (United States of America);
- (c) Nine organizations (ETC Group, Gene Ethics, German Association for Synthetic Biology, Global Industry Coalition, Japan Citizens' Network for Sustainable Food and Agriculture, Pro Natura, Public Research & Regulation Initiative, SynBio Africa and Pollinis).

8. General comments received through the peer review process are synthesized below. Comments related to the text of annexes I and IV to document CBD/SBSTTA/26/4 can be found in the original submissions, which have been made available on the Biosafety Clearing-House.²

A. Outcomes of the horizon scanning process

9. Overall, three Parties and five Organizations welcomed the outcomes of the horizon scanning and assessment process, noting that the outcomes represented a comprehensive overview of some of the emerging trends and issues in synthetic biology. It was noted that these outcomes represented an important first step in the horizon scanning process and highlighted the need for an extensive understanding of the benefits, risks and challenges posed by developments in synthetic biology. These were considered in some submissions as being crucial for adequately addressing the potential impacts of synthetic biology applications in a thorough manner. Further, the emphasis on the precautionary principle, the need to address inequity in the field of synthetic biology and the transboundary potential of synthetic biology applications were noted as key elements in the outcomes.

10. However, in their submission, one Party did not agree with the outcomes or conclusions reached by the multidisciplinary Expert Group. There was a view that the trends and issues could have been refined to provide better focus to the horizon scanning process, noting that some of the trends and issues were substantially similar. Additionally, there was a view that the assessment may not be sufficiently robust since there was a lack of the technical expertise required to assess the

¹ Available at: www.cbd.int/notifications/2024-027

² Available at: <https://bch.cbd.int/en/submissions-to-notifications?schema=submission¤tPage=1¬ification=2024-027>.

prioritized trends and issues in synthetic biology. It was noted that this could be observed through the use of generalizations throughout the text (e.g., the potential unintended effects lacked the context or case-specificity, further clarification is needed regarding the challenges posed by synthetic biology to the fair and equitable sharing of benefits arising out of the utilization of genetic resources in the overarching elements).

11. One point raised in several submissions was that the outcomes were not presented in a balanced manner. In general, it was noted that the text broadly focuses on the potential negative impacts of the synthetic biology, while limited consideration was given to the potential positive impacts of synthetic biology on the objectives of the Convention on Biological Diversity. Further, it was raised that existing or alternative strategies could have been further nuanced as they could have adverse impacts, which have not been fully taken into account. Thus, it was suggested that a balanced perspective that recognizes both the opportunities and challenges would have been crucial for policymakers to make informed decisions and develop appropriate strategies.

12. Regarding the consideration of safety and regulatory challenges, it was noted that although diverse approaches exist for the various applications of synthetic biology, these were not mentioned in depth in the text. For example, although synthetic proteins are not covered under the Cartagena Protocol on Biosafety, they could be covered under other mechanisms. Further, it was noted in one submission that there are presently no applications that are ready to enter the market or have been commercialized that have outpaced the development of appropriate risk assessment, technology assessment or risk management strategies, nor the required development of relevant regulation.

13. In addition to the above, one Party also noted that the report does not acknowledge that most synthetic biology activities are conducted under containment and that a step-by-step approach of increasing scale of environmental exposure is often taken to ensure a sufficient amount of safety data has been gathered. Similarly, there were also views that the existing experience with synthetic biology applications and living modified organisms could also have been better acknowledged. Thus, it was suggested that these points could have been made clearer to emphasize those issues that are most relevant to the potential positive and negative impacts on biological diversity.

14. Regarding further improvements, several suggestions were offered. To strengthen the outcomes presented, there was a view that supporting evidence (e.g., citations) could have been provided. It was also noted that the information presented in the literature review could have been incorporated into the outcomes to avoid some misalignment between the two documents. Further, there were suggestions that considerations could have been extended to a larger variety of ecosystems (e.g., aquatic ecosystems), ecosystem functions and inter-systemic interactions, as well as detail socio-economic, cultural, ethical and human rights considerations more thoroughly.

15. In some of the submissions, it was suggested that it would have been important to highlight the provisions in the Convention on Biological Diversity more thoroughly. For example, since the outcomes refer to impacts on intellectual property, it would be important to note Article 16, paragraph 5 of the Convention on Biological Diversity. As another example, the relevance of participatory governance and measures for technical and scientific cooperation and technology transfer could have been emphasized in accordance with Articles 16, 17 and 18 of the Convention on Biological Diversity, as well as decision [15/8](#). In one submission, it was also noted that the topic of digital sequence information has been addressed separately from synthetic biology since the thirteenth meeting of the Conference of the Parties.

1. Integration of artificial intelligence and machine learning

16. Due to the novelty of the integration of artificial intelligence and machine learning in synthetic biology, there was a view that additional information related to biosafety, cultural considerations, ownership, responsible data use, data governance, intellectual property and liability may have been important to include. Further, it was mentioned in one submission that the validity, source and governance used in training datasets would also be key considerations in this regard. In another submission, cost-benefits analyses could have been further considered to provide further context.

17. However, since artificial intelligence should be seen as an enabling tool for genetic engineering, there was also a view that the products produced through the application of artificial intelligence would be the most relevant to the objectives of the Convention on Biological Diversity and environmental risk assessment. Thus, it was noted in some submissions that the assessment failed to establish a link between the use of artificial intelligence for the design of synthetic biology applications and the potential impacts on the objective of the Convention on Biological Diversity (e.g., “reduced biological diversity and ecosystem function”). Further, it was also highlighted the integration of artificial intelligence in synthetic biology will not compensate for the supervision of trained experts and will not replace the principles of rational design and predictive engineering approaches.

18. In their submission, one Party highlighted that there are other ongoing multilateral discussions, such as at the United Nations General Assembly, which aim to advance discussions on the topic of artificial intelligence in general. Thus, there was a view that it would be important to understand the outcomes of those processes.

19. Regarding the inclusion of information related to digital sequence information in this section, it was noted by one Party that discussions on digital sequencing information occur separately from synthetic biology. However, in another submission, one Party suggested that the use of artificial intelligence in synthetic biology will further complicate the governance of digital sequence information and thus there was a need for effective mechanisms to ensure fair and equitable benefits sharing resulting from the use of digital sequence information and traditional knowledge.

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

20. Overall, there was a view that there should have been the recognition that not all of the developments would be equally accessible or beneficial to all countries due to a lack of resources to invest in research and development related to synthetic biology and/or their effective regulation. Thus, further information related to how facilitating equitable participation could positively impact on the objectives of the Convention on Biological Diversity would have been an important inclusion to demonstrate the importance of this topic. At the same time, the importance of ensuring a balanced perspective that does not imply that developing countries are more prone to impacts and harm to biodiversity was also raised.

21. Similarly, it was noted the need to substantially increase technical and scientific cooperation, capacity building and technology transfer, as well as to enhance access to innovation for developing countries could be further enhanced. Further, it was noted that inequity may be detrimental for the uptake of more sustainable practices and thus there is a requirement for North-South, South-South and triangular cooperation, which could have been further emphasized. Similarly, it was also highlighted the importance of bi- and multidirectional flows of information, shared experiences and mutual learning between both developing and developed Parties as being important for further expansion in this section. The lack of information sharing and capacity for monitoring and assessment could have also been highlighted as needing further improvement.

22. In their submission, one Party concluded that the outcomes suggested that there was a need to update and democratize the governance frameworks in order to address growing inequity between countries regarding their participation in the field of synthetic biology. In addition, one Organization noted in their submission that in addition to the content presented under this topic, developing countries also faced challenges that may hinder their ability to meaningfully participate in discussions and decision-making processes.

23. Some submissions supported the potential opportunities derived from bio-economies being highlighted, while others noted that there could be potential adverse effects. There were however differing views on the role of bio-economies in developing countries.

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

24. The work related to the development of additional voluntary guidance materials to support case-by-case risk assessment of living modified organisms containing engineered gene drives under the programme of work on risk assessment under the Cartagena Protocol on Biosafety was highlighted. The need for a non-duplicative and coordinated approach between the programmes of work under the Convention and its Protocols was therefore stressed, noting the previous decisions taken by the Conference of the Parties and the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.

25. Regarding the content, it was noted that the section did not balance the potential positives compared to the potential negatives. Some submissions additionally suggested that some of the potential impacts may be too hypothetical and that efficacy of engineered gene drive systems is outside of the scope of the Convention on Biological Diversity. Further, in another submission, it was noted that recent scientific evidence indicating that mosquito populations may not be completely controlled or eradicated through the use of engineered gene drives. Thus, there was a suggestion that this could have been further taken into account.

26. In some submissions, considerations on socio-economics, ethical aspects and liability and redress related to the release of living modified organisms containing engineered gene drives could have been further developed due to their importance. In their submissions, some Organizations suggested that impact assessments and risk management measures are key elements related to this topic in synthetic biology.

4. Self-limiting insect systems

27. In one submission, it was noted that the potential impacts of self-limiting insect systems may be similar to non-transgenic sterile insects and thus further nuance might be required. In addition, it was noted that self-limiting insect systems could be considered to be “living modified organisms” pursuant to the Cartagena Protocol on Biosafety and thus, it was suggested that this topic could be potentially duplicative to work under the Cartagena Protocol on Biosafety.

28. Further, in some submissions, it was noted that this topic may not be novel, rather than an expansion of a technology from mosquitoes to agricultural pests. National experiences with self-limiting insect systems and over a decade of research on living modified insects were mentioned as being available to support discussions. However, there was also a view that the uncertainties regarding these applications have not been yet fully described.

5. Self-spreading vaccines for wildlife

29. In their submission, one Party suggested that expertise from the World Health Organization and the World Organization for Animal Health would have greatly contributed to the assessment. Further, there was a question whether animal health would be within the scope and mandate of the Convention on Biological Diversity. In another submission, it was suggested that this section could have clarified that these applications are being designed to not address the primary drivers of zoonotic spillover, but they aim to prevent zoonotic spillover as part of a various types of prevention measures that could be potentially employed.

30. Regarding the risk of these types of viral vectors spreading to other species than the intended target wildlife host(s) or becomes pathogenic within its targeted species population, it was suggested that this risk was lower than presented in the section. It was noted that often these viral vectors encode only a structural protein of a pathogenic virus or organism recognized by the immune system of the host. Thus, over time, it is anticipated that the pathogenic coding sequences would evolve to be phased out of the genome of the viral vector, eliminating its vaccine properties rather than evolving novel virulence. In contrast, there were also views that due to potential spread and viral evolution, a high degree of risk exists for these applications, which could be complicated by a lack of available literature and potential for rapid development.

6. Additional trends and issues in synthetic biology

31. Regarding the additional trends and issues in synthetic biology, there were views by both Parties and Organizations that further analysis could have been conducted on the additional 12 topics on the prioritized list. However, one Party stated in their submission that they did not agree with the prioritized list of 17 trends and issues in synthetic biology. Further, some submissions also noted that the use of synthetic biology for improving the resilience of threatened species might be incompatible with conservation practices and that currently there are no successful examples of the use of synthetic biology to conserve nature.

32. In one submission, it was suggested that genome-edited plants and animals would have been trends and issues to consider, particularly how they relate to transboundary movements, liability and redress and detection and identification. Further, it was noted that the use of CRISPR-Cas³ to introduce genetic changes does not have a history of safe use. The submitting Organization additionally suggested that these two trends and issues could have relevance for the work under the Cartagena Protocol on Biosafety. Further, it was suggested that topics on “Synthetic biology enabled production of cosmetics and fragrances” and “Synthetic biology-enabled production of food, food ingredients and flavours” should have also been addressed as labelling and standards (e.g., FAO/WHO Codex Alimentarius) are lacking at both national and international levels.

33. In accordance with the findings of the literature review for the period 2012–2023, there was also a view that it would have been beneficial to have an assessment of the trends “Transient modification of agricultural plants, pests and pathogens using RNA interference or nanomaterials”, “Synthetic biology applications for bioremediation, biodegradation or biomining”, “genome-edited plants” and “microbiome engineered for non-medical purposes” due to their potential positive impacts on food security, the ability to remediate or restore of the environment and agricultural lands, enable sustainable production of high-value compounds, improve resource use efficiency, contribute to the conservation and sustainable use of biological efficiency and their potential positive contributions to the United Nations Sustainable Development Goals.

B. Refined methodology

34. In their submission, one Party noted their support for the refined methodology provided that the activities would be carried out within the scope of the Convention on Biological Diversity and resource limitations. It was further suggested that that activities related to horizon scanning should be linked to conservation and sustainable use of biological diversity, as well as contribute to the implementation of the Kunming-Montreal Global Biodiversity Framework. In some submissions, it was suggested that this refined methodology should be applied for the remaining trends and issues on the prioritized list. However, there was also a view that there was no need to continue the process.

35. Regarding the time required for the process, it was noted in some submissions that the time period for the cycle conducted during the period 2023–2024 was insufficient. It was suggested that this may have limited the scope of the process and had a negative impact on the quality of the outcomes. However, a 2-year cycle was also raised as being important in some of the submissions.

36. Regarding the multidisciplinary nature of the process, a multidisciplinary and participatory approach to the evaluation of synthetic biology was highlighted as being necessary, given the complexity and interconnection of social, cultural, economic and environmental factors. Similarly, the need to increase involvement of the scientific community was also stressed in some submissions. Thus, it is critical to ensure the effective participation and collaboration of all stakeholders, including indigenous peoples and local communities, farmers, youth and women, to ensure the process is comprehensive and inclusive. Importantly, it was also noted that meaningful engagement and participation from all experts involved in the process, particularly from the members of the multidisciplinary Expert Group, would be critical. In one submission, inconsistent participation

³ Clustered regularly interspaced short palindromic repeats (CRISPR); CRISPR-associated protein (Cas)

during the process conducted during the period 2023–2024 could have potentially impacted the outcomes.

37. Regarding the composition of the multidisciplinary Expert Group, the composition of the Group should attempt to better reflect a multidisciplinary nature rather than an expanded list of experts. For example, the expertise within the Group during the period 2023–2024 may also have not been sufficient to gather inputs of the necessary depth to produce a forward-looking horizon scan. In addition, there was a view that it would be important to use independent experts during the process, noting the importance of managing conflicts of interest. However, it was also noted that many scientists, who have an in-depth understanding of the technical aspects of synthetic biology, may also have potential conflicts of interest. Thus, a balance might be necessary and required to achieve a sufficient level of expertise.

38. In some submissions, it was mentioned that transparency in the process could be improved or enhanced, particularly for the collection and analysis of information. It was suggested that this is crucial for ensuring the credibility and legitimacy of the results. It was further suggested that improved transparency could potentially address concerns and perspectives from both Parties and marginalized groups.

39. Regarding the information gathering steps, there were views that the process could be improved by sourcing information from a multidisciplinary pool of experts. It was also suggested that engagement with industry and relevant stakeholders would also be key in this regard. Further, the importance of integrating of different knowledge systems was raised as being necessary for the process and would support the work of the multidisciplinary Expert Group.

40. Further, there was a recognition that the literature review should be conducted early in the information gathering process to ensure that discussions are focused. It was also suggested in some submissions that a multidisciplinary approach should also be taken regarding the methodology and search term development to ensure relevant publications from indigenous peoples and local communities, women, youth and civil society are duly captured in the literature review. However, there was a view that a literature review, although an important tool, should not replace the multidisciplinary Expert Group.

41. For the compilation, organization and synthesis of information, the need to present the information in a manner that acknowledges both the potential positive and negative impacts of synthetic biology applications was noted in some submissions.

42. In terms of screening, prioritization and assessment, there was a suggestion that the multidisciplinary Expert group should consider ecological, economic, societal and biosafety considerations when performing these steps. It was also mentioned in one submission that perspectives should be weighed equally during the deliberations of the Group. Further, there was also a view that the process used to select and prioritized topics for the cycle conducted in the period 2023–2024 could be considered to be a limitation. It was noted in the submission that the process involved debates rather than objective or standardized scoring methods for filtering the trends and topics in synthetic biology.