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Conservation through synthetic biology

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Key points

- Synthetic biology is creating new options and hope for the recovery and conservation of endangered and threatened species.
- Existing mechanisms can be used to ensure the safe and equitable deployment of synthetic biology.
- Quad countries can play a leading role by: raising awareness of synthetic biology's conservation potential; and demonstrating the utility of existing governance mechanisms.

Policy recommendations

Quad countries should:

- Publicise synthetic biology's conservation potential through a select group of demonstration projects in agreed upon critical areas of need.
- Adopt a unified user-friendly presentation of the results of their diverse regulatory processes, ideally using the format based on the Cartagena Protocol on Biosafety.
- Standardise the presentation of the results of their risk assessment of living modified organisms, produced in accordance with the Cartagena Protocol.

The conservation crisis is increasingly dire. With species disappearing at an unprecedented rate, new solutions for the recovery and conservation of endangered and threatened species are desperately needed. Synthetic biology is creating new options and hope for nature, but seeking new ways of regulating synthetic biology would slow progress. Building on the Quad's agreement to cooperate on synthetic biology policies, it should raise awareness of both the potential for synthetic biology to support conservation, and the utility of existing mechanisms for ensuring its safe and equitable deployment.

Unprecedented biodiversity loss

Adopted in December 2022, the Kunming-Montreal Global Biodiversity Framework (GBF) is an action plan to transform society's relationship with biodiversity by 2030.[1] The GBF notes that 'biodiversity is deteriorating worldwide at rates unprecedented in human history'.[2] One million species already may face extinction, including many within decades.[3]

GBF Target 4 calls for "urgent management actions to halt human-induced extinction of known threatened species and for the recovery and conservation of species, in particular threatened species, to significantly reduce extinction risk, as well as to maintain and restore the genetic diversity within and between populations …"[4] The GBF underlines the importance of science, technology, and innovation to deliver solutions.

Quad leadership and synthetic biology

Quad countries can support the GBF's realisation through synthetic biology — a field of science that involves redesigning organisms for useful purposes by engineering them to have new abilities. In 2021, the Quad agreed to monitor trends in critical and emerging technologies, including synthetic biology, and to look for policy-related opportunities to cooperate.[5] Acting together, Quad countries have unparalleled means to responsibly advance the timely deployment of synthetic biology to address critical environmental challenges, including species conservation.

Synthetic biology has great potential, with advances in modern genetic engineering providing methods of disease eradication, resiliency development, and enhancing reproductive success. There are several examples of synthetic biology applications for conservation, such as the cloning of the black-footed ferret[6] and Przewalski's Horse,[7] as well as the development of novel Elephant Endotheliotropic Herpesvirus (EEHV) assays and vaccines to protect elephants[8]. These advances are driven by rapidly developing technology and a growing understanding of the nuances of comparative genomics across species.[9]

New regulation is not the answer

Some have recommended that Quad countries focus on harmonising the regulation of biotechnology, including international standards and a new common regulatory framework on gene editing technologies.[10] While there is merit in doing so, agreeing on standards and "aligning" national legislation will be difficult and slow. Further, there is a risk that process-based regulation of specific technologies could result in unnecessary bureaucracy that prevents realisation of the positive potential of synthetic biology. Given the urgency of the threat, a more proactive approach is necessary to halt and reverse extinction risks, starting with publicising the potential benefits of synthetic biology for conservation through international policy dialogues.

Make existing mechanisms work

Leveraging existing mechanisms can be used to ensure the safe and equitable deployment of synthetic biology. Yet some governments and stakeholders are seeking to address this technology as a "new and emerging issue" under the Convention on Biological Diversity (CBD). They are formulating a horizon-scanning process to identify near-term applications, timelines for research or commercialisation, and potential positive or negative impacts on the conservation and sustainable use of biodiversity. Those pressing for more regulation frequently raise fears about potential adverse environmental impacts, including through unintended effects, and inequitable access to advanced technologies and their benefits.

In contrast, the United States and others are calling for states to use, insofar as possible, existing governance and legal frameworks to address this issue. They argue for a balanced, case-by-case approach that avoids stigmatising new technologies and protects health and safety while enabling innovation, investment, and access.[11]

The Cartagena Protocol on Biosafety to the CBC provides a framework for a harmonised approach to environmental risk assessment and management for organisms produced with synthetic biology techniques. The protocol came into force in 2003 and in 2020 government and other experts confirmed "that most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives" fell under its purview.[12]

The protocol focuses on environmental protection in connection with living modified organisms (LMOs) resulting from modern biotechnology: it requires governmental consent before a new

LMO is imported for environmental release.[13] To facilitate this, parties to the protocol must publish summaries of their national risk assessments and decisions on the import or release of LMOs through the publicly available Biosafety Clearing House (BCH).[14] Although Australia and the US are not parties to the protocol, all Quad countries publish risk assessments and decisions to the BCH.

Quad countries should standardise the presentation of the results of their risk assessment of LMOs, whether or not they are produced using synthetic biology. The 2,500-plus records published in the BCH to date are as diverse as the number of countries involved. Differences in presentation, level of detail and terminology render it difficult to find and compare information. The QTN might consider adopting South Africa's approach, which uses Annex III of the protocol as a template.

This simple step could have a significant impact. It would help demonstrate how existing mechanisms can be used to address biosafety in connection with viable products of synthetic biology. It would counter calls for new regulations for "emerging" technologies and thereby help avoid duplicative work and minimise unwarranted regulation, while creating a standardised method of discussing the ethical and societal implications of synthetic biology in the context of biodiversity. A dedicated Quad task force could build on this step to raise more awareness of the positive potential of synthetic biology for addressing priority species-related challenges.

Conclusion

Urgent action is needed to address biodiversity loss. Quad countries should collectively raise awareness of the potential for synthetic biology to contribute to species conservation and the utility of existing mechanisms — specifically, the Cartagena Protocol — for evaluating synthetic biology applications involving living organisms from an environmental perspective. Quad countries should agree on a unified presentation of results of their diverse regulatory processes. Using a common format based on the Cartagena Protocol would result in user-friendly information that could be shared widely to help build capacity and confidence in other countries. This would help demonstrate that complex new regulations for synthetic biology are unnecessary and thereby enable the use of synthetic biology for species conservation.

Notes

[1] "Kunming-Montreal Global Biodiversity Framework (GBF)", Annex at para 3, accessed 4 December 2023, https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-04-en.pdf
[2] GBF, Annex at para 2.
[3] IPBES (2019): Global Assessment Report on Biodiversity and Ecosystem Services. E. S. Brondizio, J. Settele, S. Díaz, and H. T. Ngo (editors). IPBES secretariat, Bonn. 1,148 pages, accessed 4 December 2023, https://doi.org/10.5281/zenodo.3831673. Summary for Policy Makers, key message A.
[4] GBF, Target 4.
[5] "Quad Summit Fact Sheet," 24 September 2021, accessed 4 December 2023, https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/24/fact-sheet-quad-leaders-summit/
[6] Rachel Fritts, "Cloning goes wild", *Science*, 13 January 2022, accessed, 4 December 2023, https://www.science.org/content/article/conservation-first-cloned-ferret-could-help-save-her-species
[7] Emily Mullin, "A new cloned horse offers hope for endangered species", *WIRED*, 4 May 2023, accessed 4 December 2023, https://www.wired.com/story/cloning-endangered-species-przewalskis-horse/
[8] Iyer ML, Molter CM, Flanagan JP, Bauer KL, Bernardy R, Hoffman D, Parkinson L, Brainard BM, Evans TS, Pursell T, Ling PD. NOVEL DIAGNOSTIC AND THERAPEUTIC APPROACHES TO

ELEPHANT ENDOTHELIOTROPIC HERPESVIRUS 1A HEMORRHAGIC DISEASE IN A CAPTIVE JUVENILE ASIAN ELEPHANT (*ELEPHAS MAXIMUS*). J Zoo Wildl Med. 2022 Mar;53(1):232-240. doi: 10.1638/2021-0096. PMID: 35339171, accessed 4 December 2023, https://pubmed.ncbi.nlm.nih.gov/35339171/

[9] Sacha Vignieri, "Zoonomia", *Science*, Vol 380, Issue 6643, 27 April 2023, accessed 4 December 2023, https://www.science.org/doi/10.1126/science.adi1599

[10] See e.g., Dirk van der Kley, "Shaping the Quad's DNA: How can Quad countries manage biotech opportunities and risks?", Quad Tech Network, QTN Series (November 2021); Takshashila Institution, "The Case for Quad Cooperation in Biotechnology" Takshashila Technical Series 2022-02 (January 2022).

[11] Mr. Adam Cornish, United States of America (#2737), accessed 4 December 2023, https://www.cbd.int/synbio/current_activities/open-ended_online_forum/?threadid=2556

[12] SBSTTA/24/4/Rev.1, at para. 19, accessed 4 December 2023.

[13] Cartagena Protocol on Biosafety, Art. 7(1), 9(2)(c) and 9(3), accessed 4 December 2023.

[14] While the United States is not a party to the protocol, it participates as an observer in its meetings and routinely publishes risk assessments and decisions pursuant to its regulatory processes on the Biosafety Clearing House.

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About the Quad Tech Network

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