



POSITION STATEMENT ON SYNTHETIC BIOLOGY

Synthetic biology is a promising and fast-growing scientific discipline. Although much of the research in this field is still at an early stage, there are already a number of tangible positive applications emerging from uses of synthetic biology techniques – from novel materials to reducing pollution to breakthrough treatments to fight deadly diseases. Gene drive technologies are one of the possible uses of synthetic biology approaches being explored to contribute to addressing conservation and public health challenges that have not been solved by current methods.

Gene drive approaches were first discussed under the Convention on Biological Diversity (CBD) in 2016, when this field of research was at an early stage. Since then, gene drive research has significantly progressed, increasing knowledge and understanding of its potential applications, risks, and benefits. The research has also highlighted that many years of work remain before any gene drive organisms could be considered for field evaluation, let alone use. This is an excellent opportunity for national authorities and international bodies, from CBD to WHO, to support knowledge sharing, capacity building and preparedness for countries to be in a position to evaluate a request to carry out field evaluation of a gene drive organism.

To stop research is to delay solutions

- The [Outreach Network for Gene Drive Research](#) recognizes that there are still many questions to be answered before any gene drive technology is deemed fit and safe to use. However, current uncertainties should not prematurely block the development of novel tools that could save millions of human lives, and entire animal and plant species. A sound and cautious research pathway can help ensure gene drive research is carried out responsibly and provide answers to the questions asked by policy-makers and other stakeholders.

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POSITION PAPER ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES

There is no one-size-fits-all approach

The impacts of gene drive, both positive and negative, like of many other synthetic biology applications, cannot be predicted in a generalized manner. The risks and benefits associated with each gene drive technology will primarily depend on the type of modification made, the target species, and the ecosystem and geography where the organism with the drive system will be released, rather than only on the gene drive approach itself. Gene drive should be assessed on a case-by-case basis and consider environmental and socio-economic impacts, following the recommendations of the AHTEG on Synthetic Biology ([CBD/SYNBIO/AHTEG/2019/1/3](#)).

- Closing the door on research by creating arbitrary barriers and open-ended delays limit scientists' capacity to provide answers. It also affects the ability of policymakers, regulators, and stakeholders to make informed decisions. Building and maintaining a supportive environment for innovation and research in this field is vital to ensure new tools are safely developed.

Current guidance on risk assessment is appropriate

- Existing guidance for LMOs under CBD, and in national legislations, clearly states that LMOs should be subject to risk assessment prior to release. Gene drive organisms are LMOs and so subject to this guidance, which is long standing. Decision [CBD/COP/DEC/14/19](#) reaffirms this principle, which is well accepted.
- While gene drive organisms may, on a case-by-case basis, raise novel questions or require the examination of new data, current guidance on risk assessment is broadly adequate. Focus should be placed on building capacity and sharing knowledge among countries and research teams.

Stakeholder engagement is embedded in current research guidance

- Engagement with, and support of,

local communities is a cornerstone of responsible research. This includes indigenous and local communities but is not limited to those communities. All communities where research takes place should be engaged early on, meaningfully and continuously throughout the research process, including, but not only, when their agreement is required.

- Other stakeholder groups should be identified by research teams and appropriately informed or engaged, with the recognition that depending on the characteristics of the gene drive organism being researched, the communities directly affected and those who are not can vary and can evolve over time.
- Decision [CBD/COP/DEC/14/19](#) reiterates the importance of stakeholder engagement, a principle endorsed by gene drive researchers and outlined in key guidance documents, such as NASEM's "[Gene Drive on the Horizon](#)", WHO's "[Guidance on Genetically Modified Mosquitoes](#)" and James et al.'s (2018) "[Pathway to Deployment of Gene Drive Mosquitoes](#)".

Implementation will take place mainly at national level, but cooperation is key

- Circumstances, values, and priorities vary from country to country. International

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bodies, such as the CBD, need to put in place enabling frameworks with sufficient flexibility to allow countries to adapt key principles to their national circumstances, laws and priorities. It is important to recognise that national governments may add or specify requirements for research conduct that will guide research activities, research protocols and stakeholder engagement for different gene drive products. This applies to the application of the provisions for “prior and informed consent” or “free, prior and informed consent”, as noted in decision [CBD/COP/DEC/14/19](#).

- Regional cooperation has a key role to play in the implementation of gene drive technologies, because of the possibility of transboundary movement, and also because it will help national authorities benefit from each other’s technical resources and expertise. Sharing experience, knowledge and information will enhance regional capacity to take informed decisions, develop new technologies, address biosafety issues.

Increasing cooperation and information sharing is essential

- Cooperation among scientists, regulators, governments and other relevant stakeholders is crucial for research to progress and for sound risk assessments. The Outreach Network for Gene Drive Research welcomes the importance placed on “coordinated, complementary and non-duplicative” approaches to issues related to synthetic biology, including gene drive.
- The timely and continuous dissemination of knowledge and experiences, especially through the Biosafety Clearing-House (BCH) is an essential component of ensuring knowledge is shared among countries and experts. Increased collaboration between UN agencies involved in gene drive, notably WHO and CBD, is also essential to ensure consistency and coherence in discussions on this topic and in the guidance provided to countries and researchers.



For more information visit:
www.genedrivenetwork.org

Gene drive research delivers benefits beyond product development

Independently of research outcomes, individuals, countries and the research community are already benefiting from knowledge-sharing and capacity-building initiatives. Some examples are:

- Increasing researcher’s exchanges, enabling co-development of technologies;
- New centres of knowledge and excellence for genetic research built in several countries, including India and several in Africa;
- Several postgraduate programmes for Indian and African scientists and others;
- New investments in research facilities, trainings and skills development in remote areas where gene drive research is taking place; and
- Research and development support of new methods to control malaria in several countries affected by the disease.