



POSITION PAPER EU LEADERSHIP ON INNOVATION AND GENE DRIVE RESEARCH

The European Union has the ambition to lead global efforts towards equitable and sustainable growth and development. Achieving these goals requires dramatic progress to address public health and environmental challenges, not only in Europe but across the world. Support to increase access and use of existing tools and knowledge is an essential part of the role the EU can play, but a transformative change is needed in some areas to truly achieve the EU's goals.

The EU's global leadership is needed to build a supportive environment for research and development of new tools, including gene drive approaches, and ensure financial, human, and other resources for these activities. To show effective leadership, the EU and the Member States should:



- Continue to support European researchers and ensure that financial, human, and other resources are directed towards gene drive research in the future.
- Fully implement the [European Consensus on Development](#) and the attached commitment to promote research and investment in new health technologies, make better use of science, technology, and innovation to combat malaria and other infectious diseases and promote environmental sustainability.
- Reaffirm the need to combat malaria and call for additional efforts to support research and innovation for new health technologies among the key actions of the new comprehensive EU-Africa

strategic partnership.

- Strengthen the implementation of the new EU Biodiversity Strategy for 2030 supporting research on innovative tools for conservation to achieve the fundamental target to halve the number of Red List species threatened by invasive alien species before 2030.
- Lead the way to an ambitious Post-2020 Biodiversity Framework that explicitly recognizes the essential role that innovation plays in the development of novel tools and approaches for conservation.
- Share the EU's robust expertise and wealth of knowledge on biosafety and risk assessment with other countries within the context of establishing regional regulatory harmonization.
- Renew its commitment to a cautious approach to gene drive research at the next Conference of the Parties of the CBD, in line with its previous positions, the recommendation of EFSA and the principle of case-by-case risk assessment.

PUBLIC HEALTH AND CONSERVATION NEED INNOVATION

Public health and conservation researchers, experts and practitioners are investigating the possible strategies and tools available to achieve progress in these areas. New tools are particularly urgent for some public health and environmental challenges, such as the prevention of infectious diseases transmitted

by vectors and the negative impact of invasive alien species on biodiversity.

- As highlighted by the Covid-19 pandemic, preparedness for dangerous pathogen outbreaks is decisive. Climate change and globalization are creating favorable conditions for the spread of various invasive species of mosquitoes, such as *Aedes aegypti* and *Aedes albopictus*, with increased risk of epidemics of viruses such as dengue, chikungunya and Zika in several European countries. Lyme disease, a condition transmitted by ticks, already affects between 650,000 and 850,000 Europeans every year but remains almost overlooked. The global threat posed by vector-borne diseases, which together account for more than 17% of all infectious diseases, should not be underestimated. These diseases cause 700 000 deaths per year and create significant additional health care costs for states and people, along with loss of productivity, school days, investment and tourism. In Latin America alone, the average annual cost of dengue is calculated at US\$ 3 billion, while the impact of malaria in Africa is estimated to reach US\$ 12 billion. Currently, the burden of vector-borne diseases is mainly borne by developing countries. Eliminating infectious diseases such as malaria and dengue is a fundamental step towards the achievement of Sustainable

Development Goals (SDGs), such as poverty reduction, food security, quality education, and gender equality.

- Invasive alien species are one of the main drivers of biodiversity loss and one of the focus of the new EU biodiversity strategy for 2030. Of the 1,872 species now considered threatened in Europe, 354 are under threat from invasive alien species, which has cost €12 billion/year to the EU in the last 20 years. As noted by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), 1 million plants and animal species are at risk of extinction, especially on islands where 75% of reptile, bird, amphibian, and mammal extinctions have taken place. Biodiversity loss is not only an environmental issue but also a developmental, economic, security, social, and moral issue as well. Current negative trends in biodiversity and ecosystems are estimated to undermine progress towards 80% of the assessed targets of the SDGs, related to poverty, hunger, health, water, cities, climate, oceans, and land.

While current methods to address both vector-borne diseases and invasive alien species have allowed some measure of success, alone they are not sufficient to achieve the objectives of effective protection of people's health and ecosystems.



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Current strategies have financial and environmental limitations, and their replicability and scalability are insufficient. Long-term, sustainable, and cost-effective approaches are needed to complement existing tools and enable success in controlling vector-borne diseases and invasive alien species. The development of new tools is fully supportive of the commitments taken by the EU in the European Consensus on Development, which calls for the promotion of research and investment in new health technologies and best use of science and technology to support environmental sustainability. New tools are necessary to the EU to step up the implementation of the existing regulation on invasive alien species to achieve the EU target to halve the number of Red List species threatened by invasive alien species before 2030. Gene drive research has been identified as an important area for research on new tools for conservation and public health by key institutions, such as the [African Union](#), the UK [Royal Society](#), the [Lancet Commission on Malaria Eradication](#) and [WHO](#).

IS THE EU READY FOR GENE DRIVE RESEARCH?

- **The EU already leads research investments on gene drive:** The EU is a global leader in the field of gene drive research. **Several projects researching gene drives for public health have been supported by the EU through both the 7th Programme for Research and Horizon 2020, with an overall budget of EUR 25,748,224.** Research groups in some EU Member States, such as Italy, have built world-class research facilities to enable cutting-edge research on gene drive for malaria control in Africa. Although the majority of the European projects focus on possible uses of gene drive approaches outside the EU, gene drive research could be relevant for preventing potential epidemics of mosquito-borne diseases in Europe.
- **The EU is ready to regulate gene drive research:** Gene drive research is subject to strict oversight and regulation by the government of the countries in which it takes place. The EU has put in place a thorough precautionary regulatory framework on Genetically Modified Organisms (GMOs) that is equally applicable to gene drive organisms. This Framework incorporates the elements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which is the basis for national legislation on GMOs worldwide. In the EU, any gene drive laboratory research is subject to government and research institutions' permissions, and any field release is also subject to the Member States' approval. **By default, there cannot be any release, for research or use, of a gene drive organism without government permission in the EU.**
- **The EU's case-by-case approach to risk assessment is fit for purpose:** To be authorized in the EU, any release of gene drive organisms has to undergo an in-depth assessment of all identified risks, following

the European Food Safety Authority (EFSA) guidance. **EFSA has recently published a [draft opinion](#) on the risk assessment of gene drive organisms. One of the main suggestions of the opinion is that any risk assessment of gene drive applications should be conducted on a case-by-case basis, as a blanket approach to the evaluation of gene drive organisms is not possible.** This recommendation is consistent with the best practice for risk assessment for other organisms, including all other GMOs. A case-by-case evaluation would enable the risks of different potential gene drive applications to be assessed accurately, as they will vary according to the type of modification made, the species involved, and the ecosystem and geography of introduction. EFSA's suggestions are in line with the recommendations of other European authorities and bodies such as [EASAC](#), [the Netherlands Commission on Genetic Modification \(COGEM\)](#), the [French Haut Conseil des Biotechnologies](#) and those of other governments and international institutions such as the [World Health Organisation](#), and [US National Academy of Sciences, Medicine and Engineering \(NASEM\)](#).

- **CBD has endorsed a step-by-step approach to gene drive research, in line with the EU's position in 2016 and 2018:** At its last meeting in 2018, the UN Convention on Biological Diversity (CBD) concluded that,

following case-by-case risk assessment and with the engagement of relevant stakeholders, gene drive research can responsibly proceed, without creating new specific requirements or limitations that would not apply to other GMOs. In the coming months, new decisions from CBD are expected to consolidate further the existing set of principles and best practices. The EU's position in 2016 and 2018 was to support an open but cautious approach. Research on gene drive has been underway for over 15 years, with researchers in the field showing their commitment to best practices and responsible research, which the EU should continue to support.

- **EU efforts on gene drive research are consistent with WHO work on malaria and vectors control and CBD work on invasive alien species:** The EU regulatory and scientific efforts on gene drive research are consistent with the work carried out by the WHO, that [recommended](#) a phased testing pathway for genetically modified mosquitoes which is relevant to gene drive technologies and [showed clear interest for the development](#) of gene drive research. Besides, the EU engagement in the development of the new tools for the management of invasive alien species would support the work of CBD on this topic, which is a long-standing agenda item of CBD discussion.

What is gene drive and potential applications

Gene drive research is one of a promising areas of scientific research for the development of new tools that could, along existing ones, offer complementary, sustainable, and cost-effective strategies to reverse current biodiversity loss and tackle public health threats, such as malaria.

Gene drive is a genetic phenomenon that occurs in nature and causes a selected trait to spread through a species via sexual reproduction over several generations. Gene drive works by increasing the likelihood that a modified gene will be inherited by its offspring. Typically, genes have a 50% chance of being inherited, but gene drive systems could increase that chance to upwards of 99%. This means that over the course of several generations, a selected trait could become increasingly common within a specific species.

Public health and ecosystem conservation are two of the main areas where research on gene drive has focused, although other uses are also possible.

- Public health:** Several proposals have been made which would use gene drive to reduce the burden of vector-borne diseases, particularly those spread by insect vectors, such as malaria, which affect several hundred million people a year. This could be done by inserting a trait that makes the vector organism unable to host the pathogen or one which affects the local population dynamics of the host organism to reduce that population.
- Conservation:** Potential applications of gene drive in this field could enable the elimination of introduced invasive species that threaten native ecosystems or that carry infectious diseases that put the survival of other species at risk. This is, for example, being considered to manage rat populations on islands, where as an invasive species, they undermine the survival of many local animals and birds and are the primary cause of extinctions.

Figure 1: Gene Drive Inheritance

