

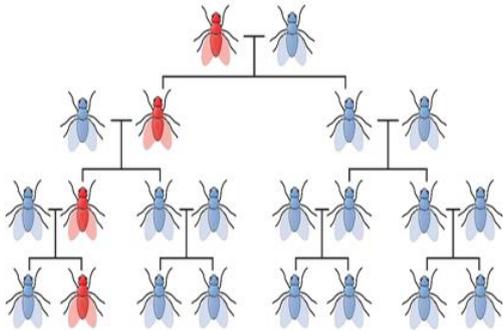
Irreversible ecosystem engineering with Gene Drive Organisms

CRISPR Gene drives are a particular application of the new genetic engineering tool CRISPR/Cas9 and are designed to genetically modify, replace or eradicate wild populations or entire species. So far they work in mosquitos, mice, flies, yeast and nematodes. But in principle this technology could be used to genetically modify any sexually reproducing organism. Gene drive organisms (GDOs) are meant to mate with their wild relatives and spread their engineered genes to ALL of their offspring. This forced inheritance pattern circumvents nature's normal rules of inheritance. It triggers a genetic chain reaction in which the genetic engineering tool CRISPR/Cas9 and sometimes an additional new gene are passed on from generation to generation. Genetic changes induced by a gene drive can lead to sterility or the change of sex ratio of their descendants, leading to a crash in their population. **First field trials in nature are foreseen for the near future.**

Proposed applications: Eradication of invasive species -- Eradication of agricultural pests

Eradication or modification of disease transmitting insects or animals -- dual use as bioweapons for military purposes.

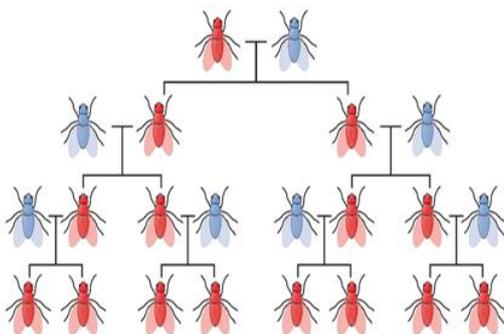
Normal inheritance (50:50)



Risks

- **Invasiveness & uncontrollable, transboundary spread:** GDOs will spread in any ecosystems they can survive in, likely beyond national borders – which could give rise to conflict.
- **Persistence over generations:** GDOs will persist and spread in the environment over generations
- **Irreversibility:** GDOs cannot be recalled and will spread into the environment irreversibly; eventually causing changes to ecosystems. The genetic makeup of the natural population may not be restored.
- **Unintended genetic effects:** The active genetic engineering tool CRISPR/Cas9 built into the organisms, can create and spread unintended new effects and mutations.
- **Transfer to non-target species:** Gene drives could be transferred to and further spread in related species.
- **Unpredictable effects:** effects of GDOs in their population dynamics and ecosystems are highly unpredictable due to the complexity of nature and unlimited spread and persistence in nature over many generations.
- **Disruption of food webs and ecosystems:** Suppressing or eradicating wild populations or species will have negative effects on food webs and could even lead to ecosystem collapse.
- **Negative effects for organic farming, peasants and food security.**

Inheritance with gene drive (100%)



State of regulation:

The UN Convention on Biological Diversity (CBD) with its Cartagena Protocol is the appropriate forum to develop and agree on globally binding rules. But up to now this new technology lacks specific, binding national, EU and international regulation. Existing international regulations are insufficient for GDOs. Methodologies for risk assessment have yet to be developed. Few countries have specific safety standards for gene drive research in the lab. There is no international oversight on gene drive research and no internationally agreed process for detection and monitoring of released GDOs. There are no means to control, recall or reverse the effects of GDOs in nature. There is no legally enforceable specific agreement on liability and redress for damaged caused by this technology.

Policy Recommendations

- A global moratorium on the release of Gene Drive Organisms into nature, including field trials
- Development of a global standard for decision-making on the release of GDOs
- Development of methods and guidelines for the identification and assessment of environmental and health risks
- Inclusive technology assessment, including ethical, cultural and socio-economic questions
- Establishment of globally uniform safety standards and a global notification scheme for research on GDOs
- Agreement on global, legally enforceable rules for liability and redress
- Prohibition of the development of GDOs with potential for military use

Gene Drives at the Convention on Biological Diversity

Gene Drive Organisms (GDO's) have been discussed within the CBD since 2015 as part of the convention's work addressing synthetic biology and as part of the discussions around risk assessment of living modified organisms (LMO) under the Cartagena Protocol on Biosafety.

At COP 14 in Egypt the CBD agreed decisions regarding gene drive organisms that

- reiterated previous commitments to a precautionary approach
- direct the CBD to develop guidance on risk assessment which must exist prior to any releases of gene drive organisms into nature, including field trials
- emphasized the importance of obtaining the free prior and informed consent of potentially affected indigenous peoples and local communities before any release of GDO's, including field trials

Experimentation and lobbying:

The UK-based research consortium Target Malaria, which develops and promotes gene drive mosquitoes has obtained permission from the government of Burkina Faso, to proceed with preparations for first field trials with the tentative aim of releasing gene drive mosquitos in 2027 Documents obtained under the US freedom of information provisions (the „Gene Drive Files“) have shown that Target Malaria finances an agribusiness public affairs firm called Emerging AG who sought to covertly skew an expert process under the CBD in order to lobby against the regulation of GDOs. Target Malaria's backers have also poured funds into shaping African biosafety processes to secure African Union support for the controversial technique. Consequently African delegates reversed their previous precautionary stance towards gene drive organisms at the last COP 14 in Egypt.

COP 15 of the Convention of Biological Diversity in Kunming, China is a decisive moment to enforce precaution and secure a global moratorium on the release of gene drive organisms into nature before Target Malaria begins with field trials.

Standing for Precaution, Assessment and Consent:

Therefore the EU and EU Member States should take a clear position on gene drive organisms and other related emerging technologies at the comming CBD COP 15 taking place in China, in order to uphold EU law and to fully support the objectives of the Convention. This can be acheived by calling for:

- **Establishing a global moratorium** on releases of gene drive organisms into nature, including field trials, in order to uphold the precautionary principle as a core element of the CBD.
- Agreeing the means to undertake **horizon scanning, technology assessment, and monitoring** of new technological developments emerging from synthetic biology.
- Enshrining the **precautionary principle, horizon scanning, technology assessment, and monitoring** and a **human rights-based approach** as key pillars of the Post 2020 Global Biodiversity Framework particularly with regard to the adoption of new technologies
- Ensuring that **free, prior and informed consent** is sought and optained to assess those applications which may impact the traditional knowledge, innovation, practices, livelihoods and use of land, resources and water of indigenous peoples and local communities. This mustbe done in a participatory manner involving all potentially affected communities, prior to any deployment.