

Gene Drive Scientific Resources

A good general overview on relevant aspects of risks that Gene Drive governance should consider is summarized in this Science article written by Gene Drive developers:

- [Oye, K. A. , Esvelt, K et al \(2014\): Regulating gene drives. Regulatory gaps must be filled before gene drives could be used in the wild.](#) Science, Vol. 345, issue 6197, pp. 626-628

This is a short summary of risks, that are detailed below, including further references:

- **Risky research**
- **Genetic engineering tools like CRISPR/Cas9 are prone to error**
- **Non-recoverable, uncontrollable cross-border spread**
- **Modelling of ecological effects is complicated if not impossible**
- **Lack of data and inadequacy of existing risk assessment methodologies and guidance**
- **Serious damage to biodiversity is possible**
- **Existing genetic engineering regulations lack specification**
- **Dual use potential for military purposes**
- **Lack of a comprehensive prior technology assessment**
- **Lack of a global decision making body**

In light of these knowledge & regulatory gaps as well as the yet unassessed risks, Save Our Seeds, as part of its campaign that aims to promote a political and public debate around this technology from a precautionary stance, has formulated the following science based policy recommendations that you can find here:

<https://www.stop-genedrives.eu/en/policy-recommendations/>

Please feel free to contact me if you would like to receive further information on this topic.

Yours sincerely

Mareike Imken

Policy advisor on Gene Drive technology

Save our Seeds / Zukunftsstiftung Landwirtschaft

Marienstr. 19-20

D-10117 Berlin

E-Mail: imken@saveourseeds.org

phone: +49 (0) 30 28482326

mobile: +49 (0) 151 53112969

web: <https://www.saveourseeds.org/> www.stop-genedrives.eu

Risky research: Research on Gene Drive Organisms can be very risky, since already a few organisms are sufficient to trigger the genetic chain reaction of an unstoppable outcrossing and potentially global spread of the organisms. Even Gene Drive developers warn of this in view of the lack of globally binding safety standards for the development of Gene Drive Organisms in closed systems.

- [Akbari O. S. et al. \(2015\). Biosafety. Safeguarding gene drive experiments in the laboratory. Science 349: 927–929](#)
- [Benedict, M. Q. et al \(2018\). Recommendations for Laboratory Containment and Management of Gene Drive Systems in Arthropods. Vector borne and zoonotic diseases. 18 \(1\)](#)

Genetic engineering tools like CRISPR/Cas9 are prone to error: The genetic engineering tools used - and those active in the released organisms, such as CRISPR/Cas9 - do not function without error. Unforeseen effects at the genetic level are therefore likely.

- [Kawall K. / Cotter J. / Then, C, \(2020\) Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. Environmental Science Europe](#)
- [Kosicki M, Tomberg K, Bradley A \(2018\). Repair of double-strand breaks induced by CRISPR-Cas9 leads to large deletions and complex rearrangements. Nat Biotechnol 36:765](#)

Non-recoverable, uncontrollable cross-border spread: According to the current state of knowledge and research, the release of a Gene Drive Organism cannot be controlled or reversed. It could lead to a cross-border, possibly global spread of the organisms.

- [Noble, C. et al. \(2018\). Current CRISPR Gene Drive Systems Are Likely to Be Highly Invasive in Wild Populations. ELife 7.](#)
- [Esvelt, Kevin M. / Neil J. Gemmell. 2017. "Conservation Demands Safe Gene Drive." PLOS Biology 15 \(11\): e2003850.](#)

Modelling of ecological effects is complicated if not impossible: Gene Drives are designed to spread within natural populations over generations. Predicting their effects in natural populations (including next generation effects) and their interactions in their food webs and ecosystems is practically impossible, given the complexity and diversity of ecosystems in which GDOs can spread over time.

- [TWN Biosafety Briefing, *Sirinathsinghji, Eva* \(2020\): Risk Assessment Challenges of Synthetic Gene Drive Organisms](#)
- [Then, C. \(2020\): Limits of Knowledge and Tipping Points in the Risk Assessment of Gene Drive Organisms. In: von Gleich, A. / Schröder, W. \(2020\): Gene Drives at Tipping Points. Precautionary Technology Assessment and Governance of New Approaches to Genetically Modify Animal and Plant Populations. Springer Link.](#)
- [Convention on Biological Diversity. Ad Hoc Technical Expert Group on Risk Assessment \(2020\). Report of the Ad Hoc Technical Expert Group on risk assessment. CBD/CP/RA/AHTEG/2020/1/5.](#)

Lack of data and inadequacy of existing risk assessment methodologies and guidance: At the same time, these risks to humans and the environment are largely unexplored due to the lack of data and inadequacy of existing risk assessment methodologies and guidance for assessing GDOs. The discussion on the need for developing specific guidance materials for the risk assessment of Gene Drive Organisms under the Cartagena Protocol and within the EU (EFSA) is only just beginning.

- [Otto, M. / Engelhard, M. \(2018\). Synthetic Gene Drive: Between Continuity and Novelty. Crucial differences between gene drive and genetically modified organisms require an adapted risk assessment for their use. EMBO Reports 19 \(5\).](#)

- [Dolezel, M. / Simon, S. / Otto, M. / Engelhard, M. / Züghart, W. \(2020\): Gene Drive Organisms. Implications for the Environment and Nature Conservation.](#)
- [Convention on Biological Diversity. Ad Hoc Technical Expert Group on Risk Assessment \(2020\). Report of the Ad Hoc Technical Expert Group on risk assessment. CBD/CP/RA/AHTEG/2020/1/5.](#)

Serious damage to biodiversity is possible: For the reasons mentioned above and others, a release of GDOs could, in the worst case scenario, cause serious damage to biodiversity and the web of life.

- [CSS, ENSSER, VDW \(2019\). Gene Drives. A report on their science, applications, social aspects, ethics and regulations.](#)

Dual use potential for military purposes: The US military research institute DARPA is one of the main sponsors of Gene Drive research, mainly to counteract the possible use of Gene Drives for military or hostile purposes. The UN Bioweapons Convention has also been discussing the potential threat posed by the use of Gene Drive Organisms as biological weapons for several years.

- [Meeting of Experts on Review of Developments in the Field of Science and Technology Related to the Bioweapons Convention: Reflections and proposals for possible outcomes. \(2018\). BWC/MSP/2018/CRP.3](#)
- [Gene Drive Files Expose Leading Role of US Military in Gene Drive Development](#)
- [Defense Advanced Research Projects Agency \(2019\). Safe Genes Tool Kit Takes Shape.](#)

Lack of a comprehensive prior technology assessment: The power and scope of the technology and the large number of open technical, ecological, ethical, cultural, social and regulatory issues surrounding the application of the technology in open systems suggest the necessity of a comprehensive prior technology assessment before any application in nature, including field trials.

- [von Gleich, A. / Schröder, W. \(2020\): Gene Drives at Tipping Points. Precautionary Technology Assessment and Governance of New Approaches to Genetically Modify Animal and Plant Populations.](#)
- [Dolezel, M. / Simon, S. / Otto, M. / Engelhard, M. / Züghart, W. \(2020\): Gene Drive Organisms. Implications for the Environment and Nature Conservation.](#)

Existing genetic engineering regulations lack specification: Regarding Gene Drive technology, previous regulations on genetically modified organisms are reaching their limits and need to be adapted. For example, the globally binding processes for the import of genetically modified organisms across national borders, which are regulated by the Cartagena Protocol, do not apply to self-propagating GDOs. Liability and redress regulations regarding the use of the technology are also not sufficiently clarified worldwide.

- [Lim, L. C. / Lim, L. L. \(2019\): Gene Drives. Legal and Regulatory Issues. Third World Network.](#)

Lack of a global decision making body: If Gene Drive Organisms can and should spread worldwide, the question must be clarified as to who can ultimately decide on the release of Gene Drive Organisms and who should be involved at what level. The establishment of such a body and decision-making mechanism at global level is necessary and requires a broad societal debate.

- ➔ **Incompatibility with the precautionary principle:** In view of these open questions, risks and lack of specific regulatory procedures referred to here, as well as the devastating situation of dramatically declining global biodiversity, it

would currently be incompatible with the precautionary principle to release Gene Drive Organisms into the environment even for research purposes.