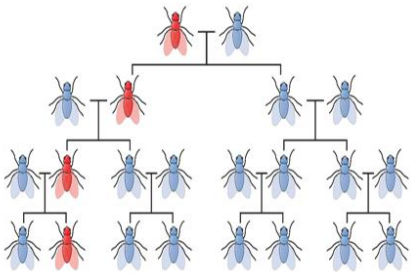
WHY A GLOBAL MORATORIUM ON THE RELEASE OF GENE DRIVE ORGANISMS IS NECESSARY

Gene drive technology, enabled by the new genetic engineering tool CRISPR/Cas9, is designed to genetically modify, replace or eradicate wild populations or entire species.
So far the technology has been demonstrated to work in mosquitos, mice, flies, yeast and nematodes. But in principle it could be used to genetically modify any sexually reproducing organism. Gene drive organisms (GDOs) are meant to mate with their wild conspecifics and spread their engineered genes to 100% of their offspring. This forced inheritance pattern circumvents natures 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.[1] First field trials in nature are being foreseen in the near future.

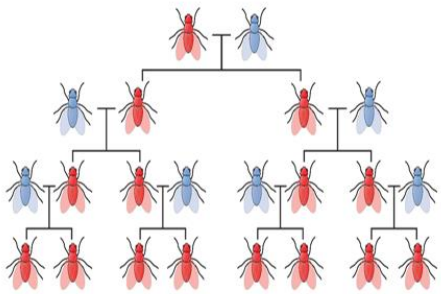
Proposed applications:

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)



Inheritance with gene drive (100%)



State of Regulation

This new technology lacks specific, binding national, EU and international regulation as existing GMO regulations are insufficient for GDOs.[2]

The UN Convention on Biological Diversity (CBD) with its Cartagena Protocol is the appropriate forum to develop and agree on globally binding rules.
COP 15 of the Convention of Biological Diversity in Kunming, China could be the last moment to enforce precaution and secure a global moratorium on the release of gene drive organisms into nature before first environmental releases could be undertaken in the near future.

WHY A GLOBAL MORATORIUM ON THE RELEASE OF GENE DRIVE ORGANISMS IS NECESSARY

Although Gene Drive Organisms have so far only been tested in the laboratory and to our knowledge, there has been no release into nature to date, there are numerous risks and open questions that speak in favor of establishing a global moratorium on the release of Gene Drive Organisms into nature. Such a moratorium would be justified until globally binding rules and solutions to the following problems, risks and open questions are found:

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.[3]

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[4].

Genetic engineering tools 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.[5]

Modelling of ecological effects is complicated if not impossible[6]: 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.

Lack of date 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.[7] The discussion on the need for developing guidelines for the risk assessment of gene drive organisms under the Cartagena Protocol and within the EU (EFSA) is only just beginning.

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.[8]

WHY A GLOBAL MORATORIUM ON THE RELEASE OF GENE DRIVE ORGANISMS IS NECESSARY

Dual use potential for military purposes: The US military research institute DARPA is one of the main sponsors of Gene Drive research[9], mainly to counteract the possible use of Gene Drives for military or hostile purposes.[10] 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.[11]

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.[12]

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.[13]

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 social debate.

Incompatibility with the precautionary principle: In view of these open questions, risks and lack of 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.

Contact:

Save Our Seeds / Zukunftsstiftung Landwirtschaft

Policy advisor on gene drive technology

Mareike Imken: imken@saveourseeds.org

References

1) Esvelt, K., et al. (2014). Concerning RNA-guided gene drives for the alteration of wild populations. Elife 17(3). // Rode, N., et al. (2019). Population management using gene drive: molecular design, models of spread dynamics and assessment of ecological risks. Conservation Genetics 20: 671-690. // National Academies of Sciences Engineering and Medicine (2016). Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty and Aligning Research with Public Values. Washington DC, The National Academies Press
2) Lim, L. C. / Lim, L. L. (2019): Gene Drives. Legal and Regulatory Issues. Third World Network. Online: https://twn.my/title2/books/pdf/Gene-drives.pdf
3) Benedict, M. Q. et al (2018). Recommendations for Laboratory Containment and Management of Gene Drive Systems in Arthropods. Vector borne and zoontic diseases. 18 (1). / Akbari O. S. et al. (2015). Biosafety. Safeguarding gene drive experiments in the laboratory. Science 349: 927–929
4) Noble, C. et al. (2018). Current CRISPR Gene Drive Systems Are Likely to Be Highly Invasive in Wild Populations. ELife 7. https://doi.org/10.7554/eLife.33423 / Esvelt, Kevin M. / Neil J. Gemmell. 2017. “Conservation Demands Safe Gene Drive.” PLOS Biology 15 (11): e2003850. https://doi.org/10.1371/journal.pbio.2003850
5) Kawall K. / Cotter J. / Then, C, (2020) Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. (accepted) 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
6) 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. Online: https://www.cbd.int/doc/c/a763/e248/4fa326e03e3c126b9615e95d/cp-ra-ahteg-2020-01-05-en.pdf
7) Ibid. / Samson, S. / Otto, M. / Engelhard, M. (2018). Synthetic Gene Drive: Between Continuity and Novelty. EMBO Reports 19 (5). https://doi.org/10.15252/embr.201845760
8) CSS, ENSSER, VDW (2019). Gene Drives. A report on their science, applications, social aspects, ethics and regulations. Online: https://genedrives.ch/wp-content/uploads/2019/10/Gene-Drives-Book-WEB.pdf
9) Gene Drive Files, Online: http://genedrivefiles.synbiowatch.org/
10) Defense Advanced Research Projects Agency (2019). Safe Genes Tool Kit Takes Shape. Online: https://www.darpa.mil/news-events/2019-10-15
11) Meeting of Experts on Review of Developments in the Field of Science and Technology Related to the Convention: Reflections and proposals for possible outcomes. (2018). BWC/MSP/2018/CRP.3 Online: https://www.unog.ch/80256EDD006B8954/(httpAssets)/327ACB8D34AFD3C8C12583930032B711/$file/CRP_3.pdf
12) 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. Online: https://link.springer.com/book/10.1007/978-3-030-38934-5 / Dolezel, M. / Simon, S. / Otto, M. / Engelhard, M. / Züghart, W. (2020): Gene Drive Organisms. Implications for the Environment and Nature Conservation. Online: https://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0705.pdf / Samson, S. / Otto, M. / Engelhard, M. (2018). Synthetic Gene Drive: Between Continuity and Novelty. EMBO Reports 19 (5). https://doi.org/10.15252/embr.201845760
13) Lim, L. C. / Lim, L. L. (2019): Gene Drives. Legal and Regulatory Issues. Third World Network. Online: https://twn.my/title2/books/pdf/Gene-drives.pdf