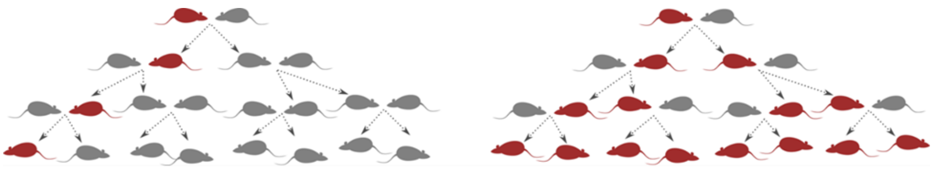
Impacts of Gene Drive Organisms on the Environment and Nature Conservation

An Opinion Paper of the Joint EPA / ENCA Interest Group on Genetically Modified Organisms



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This position paper has been prepared as output from an expert Working Group mandated by EPA network and ENCA network. The following agencies support this opinion paper:

Schweizerische Eidgenossenschaft
Confédération suisse
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Swiss Confederation

Bundesamt für Umwelt BAFU
Office fédéral de l'environnement OFEV
Ufficio federale dell'ambiente UFAM
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Federal Office for the Environment FOEN

SYKE
Finnish Environment Institute

LAMMC
LITHUANIAN RESEARCH CENTRE FOR AGRICULTURE AND FORESTRY

BfN
Bundesamt für Naturschutz

ERA
Environment & Resources Authority

Ministry of Climate and Environment

ISPRA
Istituto Superiore per la Protezione e la Ricerca Ambientale

Sistema Nazionale per la Protezione dell'Ambiente

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About the Joint EPA / ENCA Interest Group on Genetically Modified Organisms:

The Joint EPA ENCA Interest Group on Genetically Modified Organisms (IG GMO) promotes the exchange of information and experience on environmental risk assessment and monitoring of genetically modified organisms (GMO) between the Network EPA[1] and ENCA[2]. The overall aim of the IG GMO mandate is to develop joint and consolidated views and positions of the EPA and ENCA networks in order to add additional emphasis to environmental aspects in the course of GMO approval procedures, environmental risk assessment (ERA) and environmental monitoring programmes. The IG GMO is composed of members from environmental protection agencies and nature conservation agencies or institutions with competence and expertise in ERA and monitoring in different regulatory fields. The author institutions support current efforts to further develop and improve environmental risk assessment and monitoring of GMOs in Europe, particularly considering new techniques for genetic modification, while stressing the need for a stronger emphasis on the environment and nature conservation in the approval processes and during monitoring of GMOs.

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This position paper is the result of the work of the EPA and ENCA Network's Interest Group on Genetically Modified Organisms (IG GMO). While it reflects the inputs of participants on the Interest Group, it is only endorsed in this form [including policy recommendations] by those Agencies mentioned on the front page.

[1] Network of the Heads of Environmental Protection Agencies. The EPA Network is an informal grouping of the directors of national environmental protection agencies and similar bodies across Europe.
[2] The European Network of Heads of Nature Conservation Agencies. ENCA is an informal network, which fosters exchange of information and collaboration amongst its partners, identifies future challenges and offers information and advice to decision-makers in the field of nature conservation and landscape protection. ENCA brings together scientific evidence and knowledge of practical application together with experiences in administration and policy advice in the context of biodiversity and ecosystem goods and services. .

Background (reasons for opinion)

Novel techniques of genetic modification enable the preferential inheritance of specific alleles or traits within a population, a phenomenon called `gene drive´ (Figure 1). This `greater-than-Mendelian´ transmission of a specific genetic element exists in nature, too (natural gene drive). Although most of the applications using synthetic gene drives are still conceptual and not ready for release yet, there is empirical evidence that their application allows to shift the genetic modification process from the laboratory to the field, resulting in self-sustaining genetically modified wild populations. Two main types of application have been proposed. While *modification drives* are intended to result in genetically modified populations or species, *suppression drives* are intended to result in the reduction or elimination of populations or species.

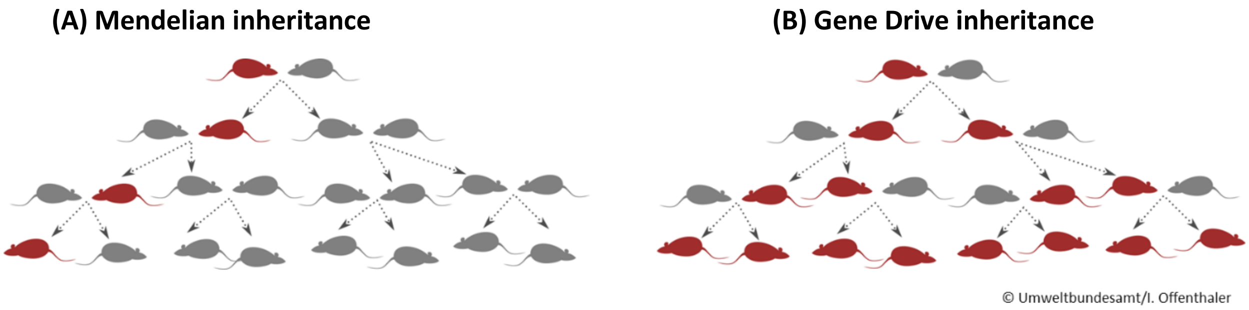

Figure 1: Gene drives can be designed to introduce and spread an intended genetic modification into wild populations. In theory, according to Mendelian inheritance (A) typically only 50 % of the offspring receive a specific trait, while according to Gene Drive inheritance (B) 100 % of the offspring receive this trait.

Approaches based on genetically modified organisms (GMOs) with synthetic gene drives, also referred to as gene drive organisms (GDOs)[3], have been suggested as problem-solving tools in areas, where GMOs have been used previously, i.e. public health (e.g. control or eradication of human-pathogen vectors) or agriculture (e.g. suppression of agricultural pests, restoration of herbicide sensitivity). Because of their novel features, GDOs have also been suggested as a tool to address environmental and nature conservation challenges (e.g. to enable the adaptation of natural populations to climate change or to restore highly valued ecosystems by elimination of invasive alien species).

The application of GDOs in the environment and in nature conservation programmes or actions raises unprecedented biosafety, ethical and socio-economic concerns and may have the potential for significant and irreversible environmental harm (Table 1).

[3] This term is identical in meaning to "*engineered gene drive organisms*" (e.g. Convention on Biological Diversity) and "*gene drive modified organisms*" (e.g. European Food Safety Authority).

Table 1: Gene drive strategies and examples of their potential impacts on the environment

Gene Drive Strategy	**Example**	**Potential Impact on the Environment** (Examples)
Suppression drive	Gene Drive mosquitoes: reduction or elimination of malaria-transmitting mosquito populations in sub-Saharan Africa (Figure 2)	Loss of whole populations may adversely impact important prey and food sources of higher trophic levels, whole food chains and ecosystems, their biodiversity as well as ecosystem functions
	Gene Drive mice: control or eradication of invasive alien species on islands (Figure 3)	Due to their potential for uncontrolled transboundary spread, applications using GDOs may affect other countries' biodiversity. Escape of GDOs to geographic regions where the modified species is native may cause harm to food webs, ecosystems and biodiversity
Modification drive	Gene drive plants: confer or restore herbicide sensitivity to weeds (Figure 4)	Restoration of sensitivity in weeds that have become resistant and sensitizing naturally tolerant weed species adds to the widespread herbicide use in agriculture, affecting biodiversity in agricultural areas.

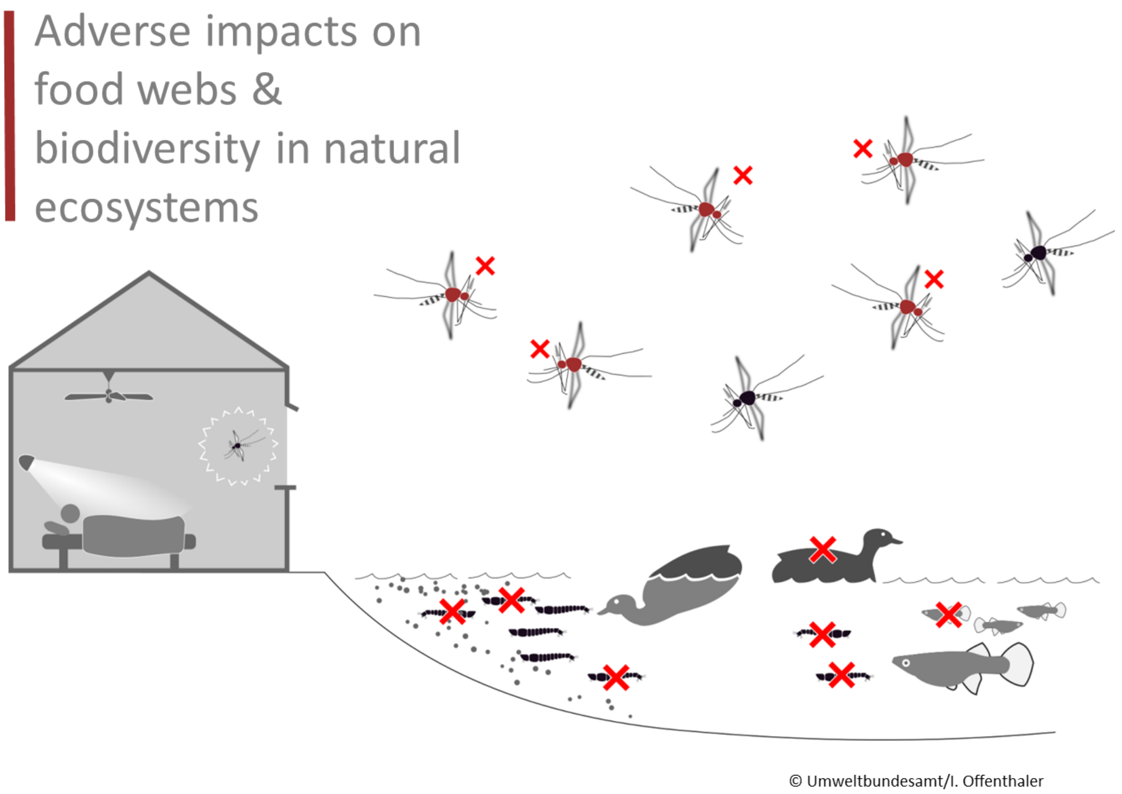

Figure 2: Reduce or eliminate pathogen-transmitting mosquitoes (suppression drive)

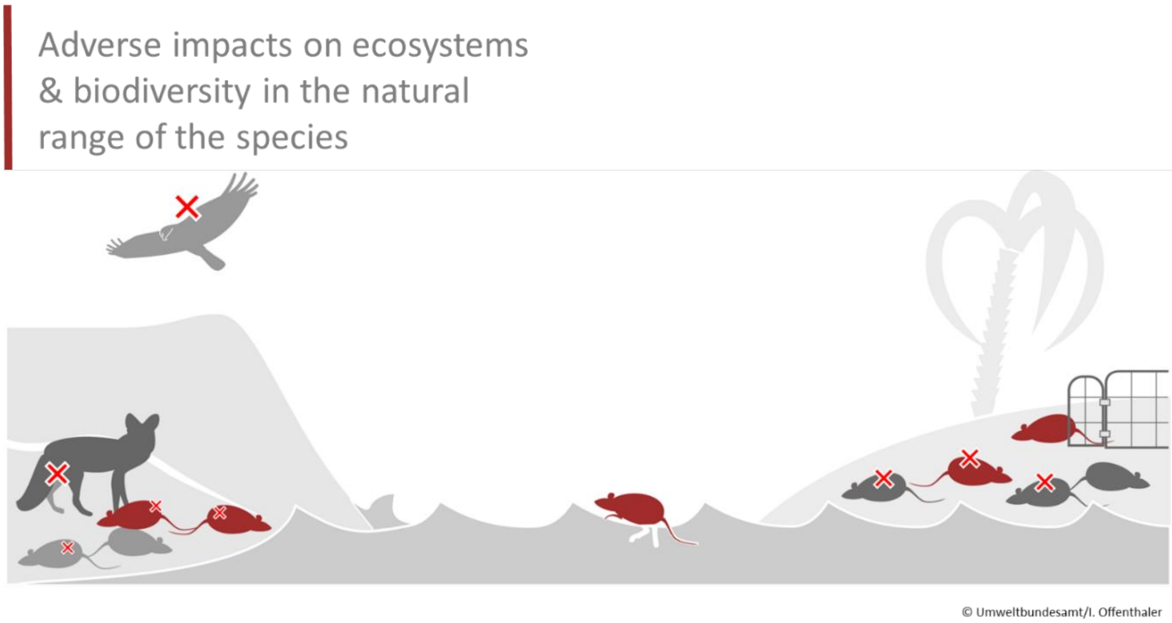

Figure 3: Control or eradicate invasive alien species on islands (suppression drive)

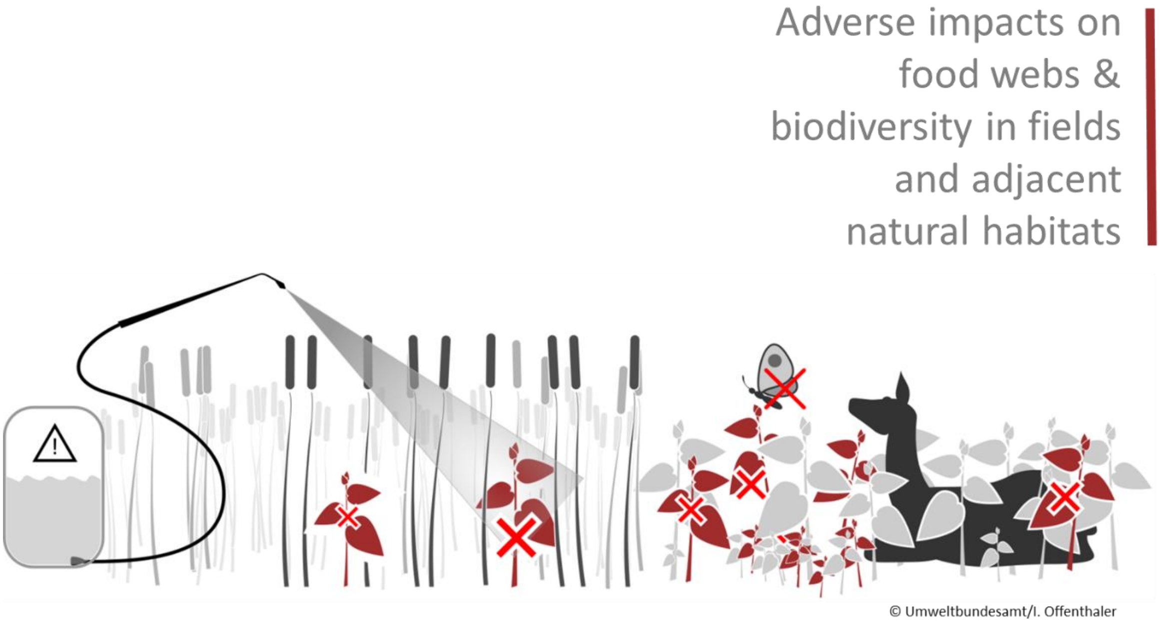

Figure 4: Confer or restore herbicide sensitivity of weeds in agricultural areas (modification drive)

Key messages

Gene drive applications are likely to entail considerable ethical and ecological implications. Apart from societal issues, they pose challenges for environmental risk assessment (ERA), monitoring and risk management:

- GDOs differ fundamentally from classical GMOs. Notably, GDOs are aimed at the modification, suppression or eradication of wild populations and have the potential to irreversibly spread novel traits in natural ecosystems. GDOs circumvent Mendelian inheritance and therefore evolutionary consequences are presently poorly understood.
- Currently, applications with GDOs are still at experimental stage. Critical scientific uncertainties and knowledge gaps regarding their functionality, their containment, their environmental implications and the availability of reversal methods are evident.
- Due to their persistence and autonomous propagation, environmental implications of GDOs include large-scale spread and potentially irreversible changes of ecosystems, in particular if suppression of populations or even species is the goal of a specific application with GDOs.
- For many risk-related questions, the necessary knowledge and data to support ERA are not yet available. The current ERA tools and methods, together with monitoring provisions in the EU (and elsewhere), do not sufficiently address the specific risks GDOs pose for the environment and nature conservation. ERA tools and methods need to include a broader technology assessment.
- The detection and identification of GDOs in the environment is a mandatory requirement for monitoring and traceability of harmful environmental effects.

Recommendations of the Joint EPA / ENCA Interest Group on Risk Assessment and Monitoring of GMOs

- Current ERA, risk management and monitoring methods need to be adapted to the unique features and potential effects of GDOs in order to be fit for purpose before releases into the environment take place. Robust approaches need to be developed to characterize the specific risks related to GDOs, including the identification of potential new pathways to harm.
- Biosafety research is needed to fill existing knowledge gaps and address scientific uncertainties related to effects on biodiversity in the long and short term – this is of critical importance to the ERA of GDOs, to the development of suitable risk management measures (e.g. containment, reversal methods) and monitoring programmes.
- Because of these knowledge gaps and the high potential risks of GDOs, the precautionary approach[4] and the stepwise principle[5] need to be strictly applied.
- Due to their potential for uncontrolled transboundary spread, applications using GDOs may affect other countries' biodiversity. A framework for international cooperation, information exchange and the control of research and releases of GDOs is necessary as well as internationally coordinated monitoring activities.
- Currently, too many knowledge gaps related to the spread, confinement and ecological consequences of GDOs exist. Testing potential applications with GDOs in the environment requires sufficient and robust data for the ERA as well as adequate risk management and environmental monitoring strategies.
- The consequences of applications with GDOs for the environment and nature conservation must not only be considered from a pure risk perspective. An assessment needs to include also legal, ethical and socio-economic considerations. Addressing these aspects will require novel tools in order to facilitate a broader technology assessment.
- Considering all relevant aspects, decisions for the release of GDOs need a broad interdisciplinary stakeholder involvement.

For more details, please read the IG GMO Technical Report (2020): Gene Drive Organisms – Implications for the Environment and Nature Conservation

[4] As defined by Principle 15 of the Rio Declaration on Environment and Development and used by the Cartagena Protocol on Biosafety

[5] According to Directive 2001/18/EC; also referred to as "stepwise approach" by EFSA