

EXECUTIVE SUMMARY

Biotechnology is facing profound transitions due to technological advances that augment the speed, quality and depth of genetic engineering intervention. This ever continued pace of development is posing challenges to the ability of understanding the possible impacts on biodiversity, human and animal health, environment and nature conservation. One example of a rapidly evolving scientific field in this context are genetically modified organisms (GMOs) with synthetic gene drives, also referred to as gene drive organisms (GDOs). Gene drive organisms are designed to spread genetically engineered traits into wild populations. As gene drives have been proposed to control pathogens, pests and invasive species, GDOs gain much attention in the scientific literature, the administration and the public.

GDOs represent a general shift in both, the strategy on how agricultural and environmental issues are being addressed, and how GMOs will interact with the environment. In contrast to classical GMOs, GDOs are intended to spread in the environment and will be applied to modify wildlife instead of crops. Being a powerful tool, gene drives have also been suggested to be applied in nature conservation. Because of the far-reaching consequences for the environment and nature conservation, gene drives are discussed in the EPA/ENCA Interest Group on Risk Assessment and Monitoring of GMOs.

The present document provides an overview over the technical realization of gene drives and their proposed applications, including nature conservation. The main focus of the report is on four aspects:

- i) The environmental implications of GDOs
- ii) The challenges that applications pose for the environmental risk assessment, monitoring and risk management
- iii) Critical uncertainties associated with the approach
- iv) Conceptual and legal challenges of GDO applications in nature conservation

While gene drive applications might have the potential to address environmental or human health issues, they also bear the potential for significant and irreversible environmental harm.

In order to assess gene drive applications, methods for risk assessment, environmental monitoring and risk management need to be developed and operational before any release of GDOs into the environment takes place. Due to the complexity of GDOs and its interaction with the environment, it remains unclear if and how risk assessment could result in sufficiently reliable conclusions. In parallel, societal and ethical issues need to be fully addressed when considering a GDO release.