

## Reflections on risk and impact assessment for engineered gene drives

Camilla Beech

Cambea Consulting Ltd, Reading , UK

e.mail: [cambeaconsults@gmail.com](mailto:cambeaconsults@gmail.com)

### Abstract

Genetically engineered organisms with synthetic gene drives are being developed for a variety of uses including public health, agriculture and the eradication of invasive species. To date gene drive organisms are still at the laboratory stage. However there is much debate by scientists, academics, policy makers and others in both international and national contexts as to the regulatory frameworks and assessments that are likely to be required for field release, particularly as some gene drives are designed for extended persistence and spread in the environment.

The environmental risk assessment (ERA) assists with the identification of potential harms in a systematic way. It is used widely for GMO evaluation and decision making and familiar to developers and decision makers. It is also a framework of value for the assessment of gene drives. A case study example of the use of systematic ERA for a population suppression gene drive in *Anopheles* mosquitoes for field release in West Africa will be presented based on a recent publication by Connolly et al (2021)\*

However there are other aspects of gene drive organisms that may provide challenges for current guidance and regulatory frameworks to address. The commonalities and adequacy of existing governance and regulatory frameworks for the assessment of gene drive organisms will be explored including identification of specific gaps where further guidance may be required or other parameters need to be considered. These could include societal values, socio-economic and health assessments. These dimensions may require developers, regulators and policy makers to look beyond the current statutes of risk based ERA and incorporate other types of assessment tools and methodologies for the evaluation of gene drive organisms. These could include probabilistic analysis and modelling scenarios (as recommended by the National Academics of Science Engineering and Medicine 2016 report "Gene Drives on the Horizon". These methods have utility in areas of uncertainty, or broader impact assessments that are more inclusive of stakeholder engagement and consider both positive and negative impacts. In the future, prior to field release of gene drive organisms it is likely that a combination of evaluation tools will be required to provide the case by case risk-benefit assessment needed.

**Keywords:** gene drive, risk assessment, impact assessment, vector control

\* Connolly, J.B., Mumford, J.D., Fuchs, S. *et al.* Systematic identification of plausible pathways to potential harm via problem formulation for investigational releases of a population suppression gene drive to control the human malaria vector *Anopheles gambiae* in West Africa. *Malar J* **20**, 170 (2021). <https://doi.org/10.1186/s12936-021-03674-6>