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Gene drive is a genetic phenomenon that occurs in nature and causes a selected trait to spread rapidly through a species via sexual reproduction over several generations. The use of gene drive approaches is currently being investigated in different fields such as public health and conservation biology. While the potential of use of gene drive is interesting, research is at a relatively early stage, and the risks and benefits of these potential applications still need to be thoroughly investigated.

WHAT'S A RISK ASSESSMENT?

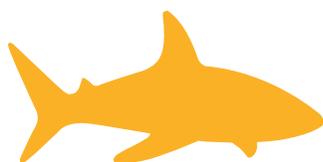
Risk assessment is a process that involves the collection and critical review of available data for identifying and quantifying, when possible, the risks resulting from any activity that may pose threats to the ecosystem, animals, and people.

Three concepts are frequently used during a risk assessment:

- **Hazard:** which is anything that could cause potential damage, harm or adverse effects on something or someone
- **Exposure:** the extent to which someone is subjected to hazard
- **Risk:** which is the chance - high or low – that someone or something will be harmed by a hazard.

Risk assessments are an important element of the staged approach to gene drive research. They are not carried out just for the purpose of the final regulatory evaluation of a gene drive technology before its deployment, but instead take place at key stages of the research, for example before starting small-scale outdoor evaluations.

The process of risk assessment needs engagement with stakeholders, communities, and other publics to help define the values and preferences about gene drive technologies that can be then used to inform the endpoints of the risk assessment by researchers and risk assessors.



HAZARD



EXPOSURE



RISK

OUTREACH NETWORK FOR GENE DRIVE RESEARCH

Why do assessments need to take place on a case-by-case basis?

Gene drive is an approach, but not all the tools deployed using this approach will be the same. It is not possible to have one general assessment of the risk of gene drive technologies. The risks and benefits associated to each gene drive technology will primarily depend on the type of modification made, the species it is applied to, and the ecosystem and geography where the organism with the drive system will be used, rather than on the gene drive approach itself. Therefore, any assessment of gene drive applications should be carried out on a case-by-case basis.



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GENE DRIVE APPLICATIONS AND RISK ASSESSMENT

While appropriate risk assessments are ongoing for the current gene drive research, no detailed risk assessments for field applications of these potential tools has been completed yet because there have been no applications for regulatory review. However, there are already guidelines that can help guide future risk assessments of gene drive technologies. For example, because gene drive technologies would involve creating Living Modified Organisms (LMOs), the principles and methodologies used for the risk assessment of LMOs under the Cartagena Protocol on Biosafety provide a useful framework to assess the potential risk of gene drive applications.

Several expert bodies, such as the Australian Academy of Science and European Academies Science Advisory Council have also started to consider whether gene drive technologies raise new or different questions from previous genetically modified organisms, and what might need to be added to current guidance¹.

The US National Academy of Sciences, Engineering and Medicine (NASEM) has also recommended that ecological risk assessments could be used as a framework for risk assessment of gene drive applications. It notes that there are distinguishing features of gene-drive modified organisms that could increase the overall complexity of the assessment, and so more research, both in the laboratory and in confined field trials, may also be needed.

Similarly, the Australian Academy of Science recommends taking decisions on any potential release of synthetic gene drive on a case-by-case basis following a comprehensive environmental risk assessment which includes ecological and evolutionary modelling and considering the wider implications of synthetic gene drives (e.g. trade implications).

General principles for risk assessment of LMOs

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) resulting from modern biotechnology.

The Protocol defines LMOs as any living organism that possesses a novel combination of genetic material obtained using modern biotechnology.

According to the Protocol, the risk assessment of LMOs includes, the following principles:

- ⚠ Risk assessment should be carried out in a scientifically sound and transparent manner;
- ⚠ Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a level of risk, an absence of risk, or an acceptable risk;
- ⚠ Risks should be considered in the context of risks posed by the non-modified recipients or parental organisms;
- ⚠ Risks should be assessed on a case-by-case basis.

¹Among these expert bodies see for example Australian Academy of Science: "Synthetic Gene Drives in Australia: Implications of Emerging Technologies" (May 2017) and European Academies Science Advisory Council: "Genome editing: scientific opportunities, public interests and policy options in the European Union" (March 2017)

WHAT IS THE PROCESS FOR A RISK ASSESSMENT?

Every risk assessment has different steps. First, risk assessors identify the perceived or assumed hazards and then validate which of these presumed hazards actually exist. Then, they look at what are the pathways through which hazards may present risks and determine their significance for each step of the pathways. Finally if risks are significant, they decide whether and what measures can be taken to manage or minimize the risk to an acceptable level.

